K123215

FEB 0 5 2013

Section 5: 510(k) Summary

This summary of the Traditional 510(k) substantial equivalence information is being submitted in accordance with the requirements of 21 CFR 807.92.

I. Applicant's Name and Address

Ultradent Products, Inc.
505 West 10200 South
South Jordan, UT 84095

Contact Person:	Karen Kakunes, RN
Title:	Sr. Regulatory Affairs Associate
Telephone:	800-552-5512 x4420, 801-553-4366
FAX:	801-553-4609
Date Summary Prepared:	26 Sep 2012

II. Name of the Device

Trade Name:	ViscoStat® Clear
Common Name:	Cord, Retraction
Device Classification:	Unclassified
Classification Product Code:	MVL
Regulation No.	None

III. Legally Marketed Predicate Devices to Which Equivalence is Claimed

ViscoStat® Clear is substantially equivalent to Racegel™ (K093711), manufactured by Septodont, which is cleared under dental device product code MVL (cord, retraction). ViscoStat Clear is substantially similar to the predicate device in Indications for Use, chemical composition, mechanical and physical properties and method of application and removal.

IV. Device Description:

ViscoStat Clear is a 25% Aluminum Chloride gel in a viscous, aqueous vehicle which leaves no residue or stain and makes it ideal for use in the esthetic zone. The product is contained within a 30mL or 1.2mL plastic syringe. The 30mL syringe is a bulk container and, prior to application, will be dispensed into provided, empty 1.2mL plastic syringe

for delivery to the patient. Dento-Infusor application tips are included and are used to apply the product to the prepared area.

V. Statement of intended use:

ViscoStat Clear is intended for sulcus retraction prior to impression making and to control bleeding and gingival oozing in restorative and operative dentistry used with gingival retraction cord and/or the Dento Infusor. The gel facilitates the insertion of the cord into the sulcus.

VI. Comparison of technological characteristics

Table 5-1: Substantial equivalence comparison

Characteristic	Comparison Product (Racegel™ K093711)	ViscoStat Clear
Intended Use	Racegel is a gel containing aluminum chloride which is intended for sulcus retraction prior to impression taking; control of bleeding and gingival oozing, particularly in restorative dentistry; and, if using a gingival retraction cord, the gel facilitates the insertion of the cord into the sulcus	ViscoStat Clear is intended for sulcus retraction prior to impression making and to control bleeding and gingival oozing in restorative and operative dentistry used with gingival retraction cord and/or the Dento Infusor. The gel facilitates the insertion of the cord into the sulcus.
Intended user	Dental professional	Dental professional
Chemical Characteristics	Aluminum chloride gel	Aluminum chloride gel
Recommended contact time	2 minutes	1-3 minutes
Delivery system	Pre-filled syringe with applicator tip	1.2ml pre-filled syringe with applicator tip, 30ml Indispense syringe with 1.2ml empty syringe and applicator tip
Physical properties	Orange, odorless gel	Clear gel

ULTRADENT PRODUCTS, INC.
505 West 10200 South
South Jordan, Utah 84095, USA
www.ultradent.com
800.552.5512

	24 month shelf life	42 month shelf life
Biocompatibility	Acute oral toxicity Sensitization Oral Mucosa Irritation Cytotoxicity	Cytotoxicity
Functional Testing	Unknown	Aluminum Chloride content Effect on Shear Bond Strength Blood coagulation

ViscoStat Clear is a similar material used in the same way by the same types of users as the identified predicate device Racegel, introducing no new safety or efficacy questions. Biocompatibility testing shows that the product is safe when used as instructed by a dental professional. In-house comparison testing has been performed on ViscoStat Clear and the predicate device, Racegel. The data supports the functionality of ViscoStat Clear. In summary, this submission demonstrates that ViscoStat Clear is safe and effective and performs equivalently to the identified predicates for its intended use.

ULTRADENT PRODUCTS, INC.
505 West 10200 South
South Jordan, Utah 84095, USA
www.ultradent.com
800.552.5512

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 5, 2013

Ms. Karen Kakunes, RN
Senior Regulatory Affairs Associate
Ultradent Products, Incorporated
505 West 10200 South
SOUTH JORDAN UT 84095

Re: K123215
Trade/Device Name: ViscoStat® Clear
Regulation Number: Unclassified
Regulation Name: Cord, Retraction
Regulatory Class: Unclassified
Product Code: MVL
Dated: September 26, 2012
Received: November 7, 2012

Dear Ms. Kakunes:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

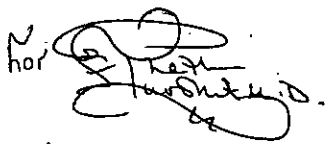
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4: Statement of Indications for Use

510(k) Number (if known): K123215

Device Name: ViscoStat Clear

Indications for Use: ViscoStat Clear is intended for sulcus retraction prior to impression making and to control bleeding and gingival oozing in restorative and operative dentistry used with gingival retraction cord and/or the Dento Infusor. The gel facilitates the insertion of the cord into the sulcus.

Prescription Use _X_ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner DDS, MA 2013.01.30 11:55:56 -05'00'

Page 1 of 1

(Posted November 13, 2003)

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K123215

K123215

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 5, 2013

Ms. Karen Kakunes, RN
Senior Regulatory Affairs Associate
Ultradent Products, Incorporated
505 West 10200 South
SOUTH JORDAN UT 84095

Re: K123215
Trade/Device Name: ViscoStat® Clear
Regulation Number: Unclassified
Regulation Name: Cord, Retraction
Regulatory Class: Unclassified
Product Code: MVL
Dated: September 26, 2012
Received: November 7, 2012

Dear Ms. Kakunes:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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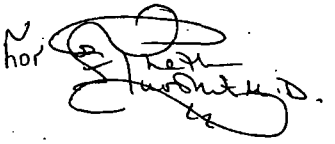

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
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Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Concurrence & Template History Page
[THIS PAGE IS INCLUDED IN IMAGE COPY ONLY]

Full Submission Number: K123215

For Office of Compliance Contact Information:

http://insideportlets.fda.gov:9010/portal/page?_pageid=197,415881&_dad=portal&_schema=PORTAL&org=318

For Office of Surveillance and Biometrics Contact Information:

http://insideportlets.fda.gov:9010/portal/page?_pageid=197,415881&_dad=portal&_schema=PORTAL&org=423

Digital Signature Concurrence Table	
Reviewer Sign-Off	Myra E. Browne Digitally signed by Myra E. Browne DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Myra E. Browne, 0.9.2342.19200300.100.1.1=1300013790 Date: 2013.02.05 12:23:05 -05'00'
Branch Chief Sign-Off AIS for MSR	Andrew I. Steen 2013.02.05 12:25:15 -05'00'
Division Sign-Off	Tejashri Purohit-Sheth, M.D. Clinical Deputy Director, DAGRID 2013.01.31 07:22:28 -05'00'

Template Name: K1(A) – SE after 1996

Template History:

Date of Update	By	Description of Update
7/27/09	Brandi Stuart	Added Updates to Boiler Table
8/7/09	Brandi Stuart	Updated HFZ Table
1/11/10	Diane Garcia	Liability/Warranty sentence added at bottom of 1st page
10/4/11	M. McCabe Janicki	Removed IFU sheet and placed in Forms
9/25/12	Edwena Jones	Added digital signature format
12/12/12	M. McCabe Janicki	Added an extra line between letter signature block and the word "Enclosure". Also, added a missing digit in 4-digit extension on letterhead zip code: "002" should be "0002".

Section 4: Statement of Indications for Use

510(k) Number (if known): K123215

Device Name: ViscoStat Clear

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner DDS, MA 2013.01.30 11:55:56 -05'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K123215

(b) (6)

[redacted]

REASON FOR ERROR
E-1) HANG UP OR LINE FAIL
E-2) BUSY
E-3) NO ANSWER
E-4) NO FACSIMILE CONNECTION

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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10903 New Hampshire Avenue
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February 5, 2013

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Senior Regulatory Affairs Associate
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505 West 10200 South
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Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

From: Reviewer Name Myra Browne

Subject: 510(k) Number K123215

To: The Record

Please list CTS decision code SE

☐ Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)

☐ Hold (Additional Information or Telephone Hold).

☑ Final Decision (SE, SE with Limitations, NSE (select code below), Withdrawn, etc.).

Not Substantially Equivalent (NSE) Codes

☐	NO	NSE for lack of predicate
☐	NI	NSE for new intended use
☐	NQ	NSE for new technology that raises new questions of safety and effectiveness
☐	NU	NSE for new intended use AND new technology raising new questions of safety and effectiveness
☐	NP	NSE for lack of performance data
☐	NS	NSE no response
☐	NL	NSE for lack of performance data AND no response
☐	NM	NSE pre-amendment device call for PMAs (515i)
☐	NC	NSE post-amendment device requires PMAs
☐	NH	NSE for new molecular entity requires PMA
☐	TR	NSE for transitional device

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	*Attach IFU*	✓	
510(k) Summary /510(k) Statement	*Attach Summary*	✓	
Truthful and Accurate Statement.	*Must be present for a Final Decision*	✓	
Is the device Class III?			✓
If yes, does firm include Class III Summary?	*Must be present for a Final Decision*		
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)		✓	
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC			✓
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			✓
Is this device intended for pediatric use only?			
Is this a prescription device? (If both prescription & OTC, check both boxes.)		✓	
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?			✓
Is clinical data necessary to support the review of this 510(k)?			✓
For United States-based clinical studies **only**: Did the application include a completed FORM FDA 3674, *Certification with Requirements of ClinicalTrials.gov Data Bank*? (If study was			✓

conducted in the United States, and FORM FDA 3674 was not included or incomplete, then applicant must be contacted to obtain completed form.) ✓

Does this device include an Animal Tissue Source? ✓

All Pediatric Patients age<=21 ✓

Neonate/Newborn (Birth to 28 days) ✓

Infant (29 days -< 2 years old) ✓

Child (2 years -< 12 years old) ✓

Adolescent (12 years -< 18 years old) ✓

Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.) ✓

Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old) ✓

Nanotechnology ✓

Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html) *Contact OC.* ✓

Regulation Number	Class*	Product Code
	Unclassified	76 MVL

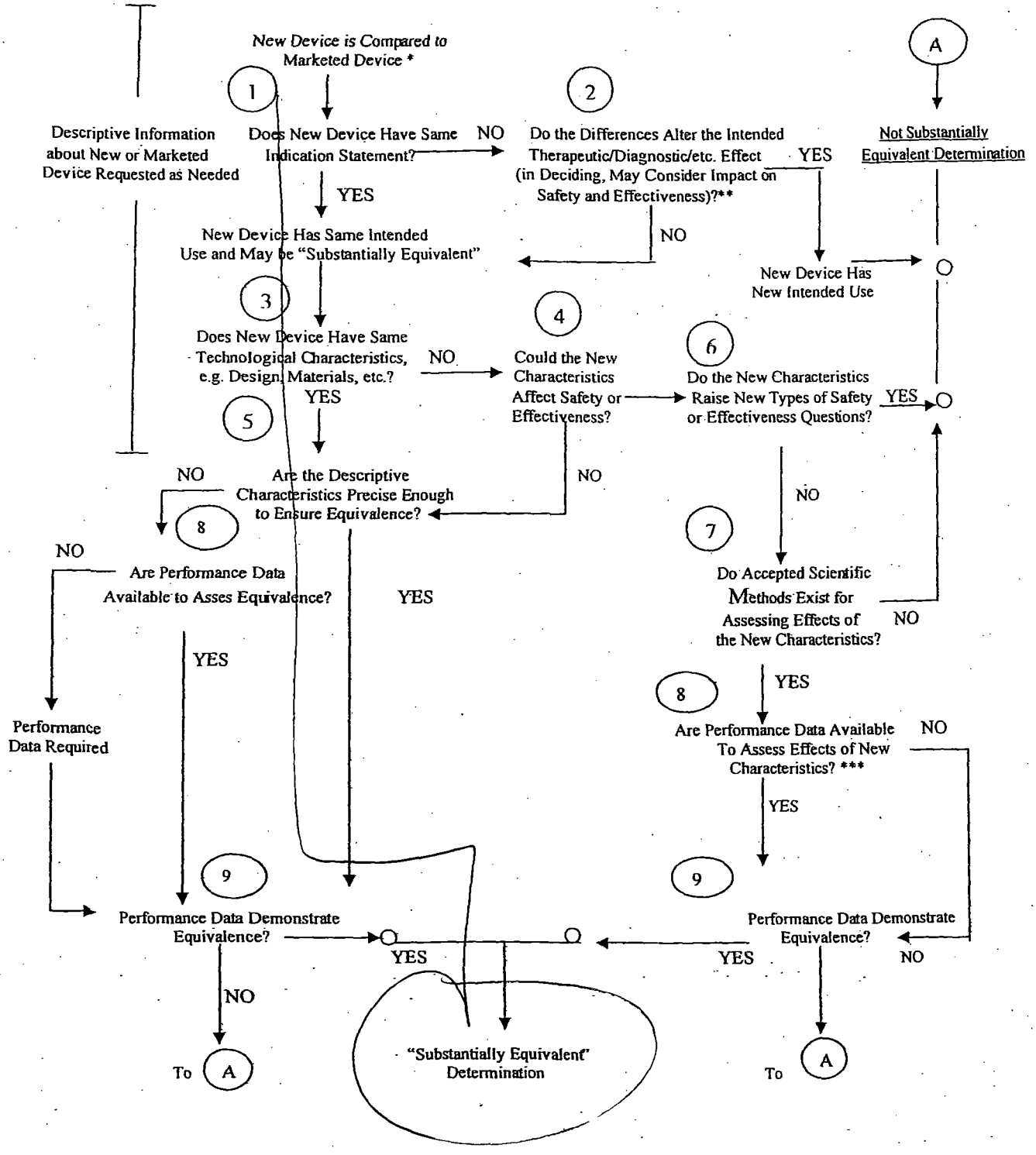
(*If unclassified, see 510(k) Staff)

Additional Product Codes:

Review: _____ DEDB 1/30/13
(Branch Chief) (Branch Code) (Date)

Final Review: _____ DAGRD 2/05/13
(Division Director) (Date)

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



* 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

*** Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.

(b) (4)

[redacted]

(b) (4)

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[redacted]

(b) (4)

[redacted]

(b) (4)

(b) (4)

[redacted]

DEPARTMENT OF HEALTH & HUMAN SERVICES **Public Health Service**

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

November 08, 2012

ULTRADENT PRODUCTS, INC.
505 WEST 10200 SOUTH
SOUTH JORDAN, UTAH 84095
ATTN: KAREN KAKUNES

510k Number: K123215

Received: 11/7/2012

Product: VISCOSTAT CLEAR

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), has received the Premarket Notification, (510(k)), you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act(Act) for the above referenced product and for the above referenced 510(k) submitter. Please note, if the 510(k) submitter is incorrect, please notify the 510(k) Staff immediately. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in all future correspondence that relates to this submission. We will notify you when the processing of your 510(k) has been completed or if any additional information is required. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (DMC) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official 510(k) submission.

On September 27, 2007, the President signed an act reauthorizing medical device user fees for fiscal years 2008 - 2012. The legislation - the Medical Device User Fee Amendments of 2007 is part of a larger bill, the Food and Drug Amendments Act of 2007. Please visit our website at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/default.htm
for more information regarding fees and FDA review goals. In addition, effective January 2, 2008, any firm that chooses to use a standard in the review of ANY new 510(k) needs to fill out the new standards form (Form 3654) and submit it with their 510(k). The form may be found at http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm.

We remind you that Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA) amended the PHS Act by adding new section 402(j) (42 U.S.C. § 282(j)), which expanded the current database known as ClinicalTrials.gov to include mandatory registration and reporting of results for applicable clinical trials of human drugs (including biological products) and devices. Section 402(j) requires that a certification form http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm accompany 510(k)/HDE/PMA submissions. The agency has issued a draft guidance titled: "Certifications To Accompany Drug, Biological

Product, and Device Applications/Submissions: Compliance with Section 402(j) of The Public Health Service Act, Added By Title VIII of The Food and Drug Administration Amendments Act of 2007" http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm134034.htm. According to the draft guidance, 510(k) submissions that do not contain clinical data do not need the certification form.

Please note the following documents as they relate to 510(k) review: 1) Guidance for Industry and FDA Staff entitled, "Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs and BLA Supplements". This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm. Please refer to this guidance for information on a formalized interactive review process. 2) Guidance for Industry and FDA Staff entitled, "Format for Traditional and Abbreviated 510(k)s". This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

In all future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA resources and may help reviewers navigate through longer documents more easily. Under CDRH's e-Copy Program, you may replace one paper copy of any premarket submission (e.g., 510(k), IDE, PMA, HDE) with an electronic copy. For more information about the program, including the formatting requirements, please visit our web site at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm134508.html. In addition, the 510(k) Program Video is now available for viewing on line at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm070201.htm .

Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.

Lastly, you should be familiar with the regulatory requirements for medical devices available at Device Advice http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm. If you have questions on the status of your submission, please contact DSMICA at (301)796-7100 or the toll-free number (800)638-2041 , or at their internet address http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm. If you have procedural questions, please contact the 510(k) Staff at (301)796-5640.

Sincerely,

510(k) Staff

(b) (4)

[redacted]

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

User Fee Hold Letter

October 16, 2012

Karen Kakunes, Sr. Regulatory Affairs Associate
Ultradent Products, Inc.
505 West 10200 South
South Jordan, UT 84095
United States

Dear Karen Kakunes:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) acknowledges receipt of your submission. This submission has been assigned the following unique document control number. Failure to reference this assigned number in future correspondence may result in processing delays.

510(k) Number: K123215
Device: Viscostat Clear
Dated: 26-SEP-2012
Received: 15-OCT-2012

The Federal Food, Drug, and Cosmetic Act (the Act), as amended by the Medical Device User Fee and Modernization Act of 2002 (MDUFMA), the FDA Amendments Act of 2007 (FDAAA) (Public Law 110-85), and the Medical Device User Fee Amendments of 2012 (MDUFA III), authorizes FDA to collect user fees for certain types of submissions. This submission cannot be accepted for review until the user fee is paid in full.

You have received this letter because we have not received your payment in full. Additional information on user fees, including how and where to submit your user fee payment and how to generate a User Fee Cover Sheet, may be found on our webpage entitled,"Premarket Notification [510(k)] Review Fees" at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketApprovalPMA/ucm048161.htm

In addition, please fax a completed copy of the User Fee Cover Sheet that includes the specific submission number above and the Payment Identification Number for this submission to our CDRH Document Control Center at (301) 847-8113.

You now have the option to pay online by credit card. We recommend this form of payment. Credit card payments are directly linked to your user fee cover sheet and are processed the next business day. You may also pay by check. If you choose to pay by check, make the check out to the Food and Drug Administration and reference the payment identification number, include a copy of the User Fee Cover sheet with the check, and mail them to one of the addresses listed below:

By Regular Mail

Food and Drug Administration
P.O. Box 956733
St. Louis, MO 63195-6733

By Private Courier (e.g., Fed Ex, UPS)

U.S. Bank
Attn: Government Lockbox 956733
1005 Convention Plaza
St. Louis, MO 63101
(314) 418-4821

When we have been notified that your user fee payment has been received, review of the submission will resume as of that date. Alternatively, you may request withdrawal of your submission.

If payment has not been received within 30 days, your 510(k) will be deleted from the system. If you have any questions concerning this letter, please contact Ms. Edwena Jones at (301) 796-6308 or by email at edwena.jones@fda.hhs.gov.

Sincerely yours,

Marjorie Shulman
Director, 510(k) Program
Program Operations Staff
Office of Device Evaluation
Center for Devices and Radiological Health

(b) (4)

[redacted]

TRADITIONAL 510(k) Premarket Notification

ViscoStat® Clear

Ultradent Products, Inc.
505 West 10200 South
South Jordan, UT 84095

Establishment Registration Number 1718912

Table of Contents

Section 1: Medical Device User Fee Cover Sheet (Form FDA 3601)

Form Approved. OMB No. 0910-51[illegible] (b) (4) [redacted]

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
MEDICAL DEVICE USER FEE COVER SHEET

PAYMENT IDENTIFICATION NUMBER:
Write the Payment Identification number on

A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/mdufma/coversheet.html

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)	2. CONTACT NAME
ULTRADENT PRODUCTS INC 505 West 10200 South South Jordan UT 84095 US	Diane Rogers 2.1 E-MAIL ADDRESS diane.rogers@ultradent.com 2.2 TELEPHONE NUMBER (include Area code) 801-553-4491
1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) *****6957	2.3 FACSIMILE (FAX) NUMBER (Include Area code) 801-553-4609

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/oc/mdufma

Select an application type:	3.1 Select a center
[X] Premarket notification(510(k)); except for third party	[X] CDRH
[ ] 513(g) Request for Information	[ ] CBER
[ ] Biologics License Application (BLA)	3.2 Select one of the types below
[ ] Premarket Approval Application (PMA)	[X] Original Application
[ ] Modular PMA	Supplement Types:
[ ] Product Development Protocol (PDP)	[ ] Efficacy (BLA)
[ ] Premarket Report (PMR)	[ ] Panel Track (PMA, PMR, PDP)
[ ] Annual Fee for Periodic Reporting (APR)	[ ] Real-Time (PMA, PMR, PDP)
[ ] 30-Day Notice	[ ] 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)

[ ] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA

[X] NO, I am not a small business

4.1 If Yes, please enter your Small Business Decision Number:

5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA?

[X] YES (*All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within* 30 days of FDA's approval/clearance of this device.)

[ ] NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see http://www.fda.gov/cdrh/mdufma for additional information)

6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.

[ ] This application is the first PMA submitted by a qualified small business, including any affiliates

[ ] The sole purpose of the application is to support conditions of use for a pediatric population

[ ] This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only

[ ] The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).

[ ] YES [X] NO

PAPERWORK REDUCTION ACT STATEMENT

Public reporting burden for this collection of information is estimated to average 18 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the address below.

Department of Health and Human Services, Food and Drug Administration, Office of Chief Information Officer, 1350 Piccard Drive, 4th Floor Rockville, MD 20850
[Please do NOT return this form to the above address, except as it pertains to comments on the burden estimate.]

(b) (4) [redacted]

YMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION

22-Aug-2012

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 0910-0120
Expiration Date: December 31, 2013
See OMB Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number *(if known)*
09/26/2012	(b) (4)	

SECTION A TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Meeting
☐ Original Submission	☐ Regular (180 day)	☐ Original PDP	☒ Original Submission:	☐ Pre-510(K) Meeting
☐ Premarket Report	☐ Special	☐ Notice of Completion	☒ Traditional	☐ Pre-IDE Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☐ Special	☐ Pre-PMA Meeting
☐ Amendment	☐ 30-day Supplement		☐ Abbreviated (Complete section I, Page 5)	☐ Pre-PDP Meeting
☐ Report	☐ 30-day Notice		☐ Additional Information	☐ Day 100 Meeting
☐ Report Amendment	☐ 135-day Supplement		☐ Third Party	☐ Agreement Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Determination Meeting
	☐ Amendment to PMA & HDE Supplement			☐ Other *(specify)*:
	☐ Other			

IDE	Humanitarian Device Exemption (HDE)	Class II Exemption Petition	Evaluation of Automatic Class III Designation (De Novo)	Other Submission
☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ 513(g)
☐ Amendment	☐ Amendment	☐ Additional Information	☐ Additional Information	☐ Other *(describe submission)*:
☐ Supplement	☐ Supplement			
	☐ Report			
	☐ Report Amendment			

Have you used or cited Standards in your submission? ☐ Yes ☐ No *(If Yes, please complete Section I, Page 5)*

SECTION B SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name	Establishment Registration Number *(if known)*
Ultradent Products, Inc.	1718912
Division Name *(if applicable)*	**Phone Number *(including area code)***
	801-553-4366
Street Address	**FAX Number *(including area code)***
505 West 10200 South	801-553-4609

City	State / Province	ZIP/Postal Code	Country
South Jordan	UT	84095	USA

Contact Name	
Karen Kakunes	
Contact Title	**Contact E-mail Address**
Sr. Regulatory Affairs Associate	karen.kakunes@ultradent.com

SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

Company / Institution Name	
Division Name *(if applicable)*	**Phone Number *(including area code)***
Street Address	**FAX Number *(including area code)***

City	State / Province	ZIP Code	Country

Contact Name	
Contact Title	**Contact E-mail Address**

FORM FDA 3514 (12/10) Page 1 of 5 Pages

PSC Publishing Services (301) 443-6740 EF

SECTION D1 REASON FOR APPLICATION - PMA, PDP, OR HDE

- ☐ New Device
- ☐ Withdrawal
- ☐ Additional or Expanded Indications
- ☐ Request for Extension
- ☐ Post-approval Study Protocol
- ☐ Request for Applicant Hold
- ☐ Request for Removal of Applicant Hold
- ☐ Request to Remove or Add Manufacturing Site

- ☐ Change in design, component, or specification:
  - ☐ Software/Hardware
  - ☐ Color Additive
  - ☐ Material
  - ☐ Specifications
  - ☐ Other *(specify below)*

- ☐ Location change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager

- ☐ Process change:
  - ☐ Manufacturing ☐ Packaging
  - ☐ Sterilization
  - ☐ Other *(specify below)*

- ☐ Labeling change:
  - ☐ Indications
  - ☐ Instructions
  - ☐ Performance Characteristics
  - ☐ Shelf Life
  - ☐ Trade Name
  - ☐ Other *(specify below)*

- ☐ Report Submission:
  - ☐ Annual or Periodic
  - ☐ Post-approval Study
  - ☐ Adverse Reaction
  - ☐ Device Defect
  - ☐ Amendment

- ☐ Response to FDA correspondence:

- ☐ Change in Ownership
- ☐ Change in Correspondent
- ☐ Change of Applicant Address

- ☐ Other Reason *(specify)*:

SECTION D2 REASON FOR APPLICATION - IDE

- ☐ New Device
- ☐ New Indication
- ☐ Addition of Institution
- ☐ Expansion / Extension of Study
- ☐ IRB Certification
- ☐ Termination of Study
- ☐ Withdrawal of Application
- ☐ Unanticipated Adverse Effect
- ☐ Notification of Emergency Use
- ☐ Compassionate Use Request
- ☐ Treatment IDE
- ☐ Continued Access

- ☐ Change in:
  - ☐ Correspondent / Applicant
  - ☐ Design / Device
  - ☐ Informed Consent
  - ☐ Manufacturer
  - ☐ Manufacturing Process
  - ☐ Protocol - Feasibility
  - ☐ Protocol - Other
  - ☐ Sponsor

- ☐ Report submission:
  - ☐ Current Investigator
  - ☐ Annual Progress Report
  - ☐ Site Waiver Report
  - ☐ Final

- ☐ Response to FDA Letter Concerning:
  - ☐ Conditional Approval
  - ☐ Deemed Approved
  - ☐ Deficient Final Report
  - ☐ Deficient Progress Report
  - ☐ Deficient Investigator Report
  - ☐ Disapproval
  - ☐ Request Extension of Time to Respond to FDA
  - ☐ Request Meeting
  - ☐ Request Hearing

- ☐ Other Reason *(specify)*:

SECTION D3 REASON FOR SUBMISSION - 510(k)

- ☒ New Device
- ☐ Additional or Expanded Indications
- ☐ Change in Technology

- ☐ Other Reason *(specify)*:

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	MVL	2		3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

- [x] 510 (k) summary attached
- [ ] 510 (k) statement

Information on devices to which substantial equivalence is claimed *(if known)*

	510(k) Number	*Trade or Proprietary or Model Name*	*Manufacturer*
1	K093711	Racegel	Septodont
2			
3			
4			
5			
6			

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification name

Cord, Retraction

	Trade or Proprietary or Model Name for This Device	Model Number
1	ViscoStat Clear	6407, 6408, 6409, 6410,
2		
3		
4		
5		

FDA document numbers of all prior related submissions *(regardless of outcome)*

1	K052835	2		3		4		5		6	
7		8		9		10		11		12	

Data Included in Submission

- [x] Laboratory Testing
- [ ] Animal Trials
- [ ] Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code	C.F.R. Section *(if applicable)*	Device Class
MVL	N/A	☐ Class I ☐ Class II ☐ Class III ☒ Unclassified

Classification Panel

Dental

Indications *(from labeling)*

ViscoStat Clear is intended for sulcus retraction prior to impression making and to control bleeding and gingival oozing in restorative and operative dentistry used with gingival retraction cord and/or the Dento Infusor. The gel facilitates the insertion of the cord into the sulcus.

Note: Submission of the information entered in Section H does not affect the need to submit device establishment registration.

FDA Document Number *(if known)*:

SECTION H — MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

☒ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number: 1718912
☒ Manufacturer ☐ Contract Manufacturer ☐ Contract Sterilizer ☐ Repackager / Relabeler	
Company / Institution Name: Ultradent Products, Inc.	Establishment Registration Number: 171892
Division Name *(if applicable)*:	Phone Number *(including area code)*: 888-230-1420
Street Address: 505 West 10200 South	FAX Number *(including area code)*: 801-553-4609
City: South Jordan	State / Province: UT; ZIP Code: 84095; Country: USA
Contact Name: Karen Kakunes	Contact Title: Sr. Regulatory Affairs Associate; Contact E-mail Address: karen.kakunes@ultradent.com

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number:
☐ Manufacturer ☐ Contract Manufacturer ☐ Contract Sterilizer ☐ Repackager / Relabeler	
Company / Institution Name:	Establishment Registration Number:
Division Name *(if applicable)*:	Phone Number *(including area code)*:
Street Address:	FAX Number *(including area code)*:
City:	State / Province: ; ZIP Code: ; Country:
Contact Name:	Contact Title: ; Contact E-mail Address:

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number:
☐ Manufacturer ☐ Contract Manufacturer ☐ Contract Sterilizer ☐ Repackager / Relabeler	
Company / Institution Name:	Establishment Registration Number:
Division Name *(if applicable)*:	Phone Number *(including area code)*:
Street Address:	FAX Number *(including area code)*:
City:	State / Province: ; ZIP Code: ; Country:
Contact Name:	Contact Title: ; Contact E-mail Address:

SECTION I	UTILIZATION OF STANDARDS				
Note: Complete this section if your application or submission cites standards or includes a *"Declaration of Conformity to a Recognized Standard"* statement.					
	Standards No.	Standards Organization	Standards Title	Version	Date
1	ISO 10993-1	ISO	Biological Evaluation of Medical Devices	Fourth Ed.	10/05/2009
2					
3					
4					
5					
6					
7					

Please include any additional standards to be cited on a separate page.

Public reporting burden for this collection of information is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, Room 400
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Form Approved: OMB No. 0910-0120; Expiration Date: 12/31/13

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO 10993 Biological Evaluation of Medical Devices

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#2-156	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☒	☐
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

FORM FDA 3654 (6/11) Page 1 PSC Publishing Services (301) 443-6740 EF

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
ISO 10993 Biological Evaluation of Medical Devices

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
Entire standard used		☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

♦ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, Room 400
Rockville, MD 20850

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FORM FDA 3654 (6/11) Page 2

Form Approved: OMB No. 0910-0120; Expiration Date: 12/31/13

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO 7405: Dentistry - Evaluation of Biocompatibility of Medical Devices used in Dentistry

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☐	☒
FDA Recognition number [3]	# _____	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☒	☐
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

FORM FDA 3654 (6/11) Page 1 PSC Publishing Services (301) 443-6740 EF

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
ISO 7405: Dentistry - Evaluation of Biocompatibility of Medical Devices used in Dentistry

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
Entire standard used		☒ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ♦		
DESCRIPTION		
JUSTIFICATION		

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ♦		
DESCRIPTION		
JUSTIFICATION		

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ♦		
DESCRIPTION		
JUSTIFICATION		

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

♦ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, Room 400
Rockville, MD 20850

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FORM FDA 3654 (6/11) Page 2

Section 3: 510(k) Submission Cover Letter (Traditional 510(k))

26 Sep 2012

K69

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (W066-G609)
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Subject: Traditional 510(k) Notification for ViscoStat® Clear

Dear Sir or Madam,

In compliance with the Code of Federal Regulations, the enclosed 510(k) Notification (21 CFR 807.90 (e)) by Ultradent Products, Inc., hereby notifies the FDA of its intent to market ViscoStat Clear.

ViscoStat Clear is a device which has been submitted previously for 510k review in 2005 (K052835). It was determined at that time that the product was regulated as a drug as defined in 201(g) of the Federal Food, Drug, and Cosmetic Act rather than a device as defined in section 201(h) of the same Act. However, since the original submission, CDRH has cleared a similar product, which has been reviewed and granted 510(k) approval under product code MVL (cord, retraction). This 510k is being submitted for review and approval as a medical device. ViscoStat Clear will be manufactured and marketed by Ultradent Products, Inc., 505 West 10200 South, South Jordan, UT 84095, Establishment Registration Number 1718912. It is substantially equivalent to Racegel (K093711), manufactured by Septodont, in formulation, technology, and intended use.

This traditional 510(k) submission is considered proprietary and falls within the confidentiality of information as stipulated in 21 CFR 807.95. The contents in this 510(k) follow the FDA guidance document, "Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s", issued August 12, 2005.

ULTRADENT PRODUCTS, INC.
505 West 10200 South
South Jordan, Utah 84095, USA
www.ultradent.com
800.552.5512

The new product is classified as follows:

Device:	Cord, Retraction
Trade/Device Name:	ViscoStat® Clear
Review Panel:	Dental
Regulation Number:	None
Device Class:	Unclassified
Product Code:	MVL

Design and Use of the Device (from "Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s"):

Table 3-1: Design and Use

Question	Yes	No
Is the device intended for prescription use (21 CFR 801 Subpart D)?	X	
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?		X
Does the device contain components derived from a tissue or other biologic source?		X
Is the device provided sterile?		X
Is the device intended for single use?		X
Is the device a reprocessed single use device?		X
If yes, does this device type require reprocessed validation data?		
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?		X
Does the submission include clinical information?		X
Is the device implanted?		X

The enclosed information is true and correct to the best of my knowledge and no material facts have been omitted. (b) (4) [redacted]

Please do not hesitate to contact me if you require any clarification or information.

Sincerely,

Karen Kakunes, RN
Sr. Regulatory Affairs Associate
Ultradent Products, Inc.
505 West 10200 South
South Jordan, UT 84095 USA
TEL: 800-552-5512 x4366, 801-553-4366
Cell: 801-673-1072
FAX: 801-553-4609
Email: karen.kakunes@ultradent.com

Table 3-2: Screening Checklist for Traditional/Abbreviated Premarket Notification [510(k)] Submissions

based on
Guidance for Industry and FDA Staff
Format for Traditional and Abbreviated 510(k)s

Title	Related Information	Present	Inadequate	N/A
MDUFMA Cover Sheet	Medical Device User Fee Cover Sheet	X		
CDRH Premarket Review Submission Cover Sheet	CDRH Premarket Review Submission Cover Sheet	X		
510(k) Cover Letter	Appendix A of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005	X		
Indications for Use Statement	Device Advice "Content of a 510(k)" Section D	X		
510(k) Summary or 510(k) Statement	Device Advice "Content of a 510(k)" Section E	X		
Truthful and Accuracy Statement	Device Advice "Content of a 510(k)" Section G	X		
Class III Summary and Certification	Class III Summary and Certification Form			X
Financial Certification or Disclosure Statement	FORM FDA 3454, Certification: Financial Interests and Arrangements of Clinical Investigators FORM FDA 3455, Disclosure: Financial Interests and Arrangements of Clinical Investigators Financial Disclosure by Clinical Investigators	X		
Declarations of Conformity and Summary Reports (Abbreviated 510(k)s)	Use of Standards in Substantial Equivalence Determinations FDA Standards program Declaration of conformity Required Elements for Declaration of Conformity to Recognized Standard			X
Executive Summary	See section 10 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005	X		
Device Description	See section 11 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005	X		
Substantial Equivalence Discussion	Guidance on the CDRH Premarket Notification Review Program 6/30/86 (K86-3)	X		

Title	Related Information	Present	Inadequate	N/A
Proposed Labeling	Device Advice " Content of a 510(k)" Section H	X		
Sterilization/Shelf Life	Updated 510(k) Sterility Review Guidance (K90-1) For reuse of single use devices, see Guidance for Industry and FDA Staff – Medical Device User Fee and Modernization Act of 2002 Validation Data in Premarket Notification Submissions (510(k)s) for Reprocessed Single-Use Medical Devices	X		
Biocompatibility	FDA Blue Book Memo, G95-1, Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing"	X		
Software	Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices			X
Electromagnetic Compatibility/Electrical Safety	CDRH Medical Device Electromagnetic Compatibility Program See also IEC 60601-1- 2 Medical Electrical Equipment -- Part 1: General Requirements for Safety; Electromagnetic Compatibility -- Requirements and Tests (Second Edition, 2001)			X
Performance Testing – Bench	See section 18 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005	X		
Performance Testing – Animal	See section 19 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005			X
Performance Testing – Clinical	See section 20 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005 FORM FDA 3454, Certification: Financial Interests and Arrangements of Clinical Investigators FORM FDA 3455, Disclosure: Financial Interests and Arrangements of Clinical Investigators			X
Kit Certification	Device Advice: Special Considerations			X

Section 4: Statement of Indications for Use

510(k) Number (if known): K123215

Device Name: ViscoStat Clear

Indications for Use: ViscoStat Clear is intended for sulcus retraction prior to impression making and to control bleeding and gingival oozing in restorative and operative dentistry used with gingival retraction cord and/or the Dento Infusor. The gel facilitates the insertion of the cord into the sulcus.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of 1

(Posted November 13, 2003)

K123215

Section 5: 510(k) Summary

This summary of the Traditional 510(k) substantial equivalence information is being submitted in accordance with the requirements of 21 CFR 807.92.

I. Applicant's Name and Address

Ultradent Products, Inc.
505 West 10200 South
South Jordan, UT 84095

Contact Person:	Karen Kakunes, RN
Title:	Sr. Regulatory Affairs Associate
Telephone:	800-552-5512 x4420, 801-553-4366
FAX:	801-553-4609
Date Summary Prepared:	26 Sep 2012

II. Name of the Device

Trade Name:	ViscoStat® Clear
Common Name:	Cord, Retraction
Device Classification:	Unclassified
Classification Product Code:	MVL
Regulation No.	None

III. Legally Marketed Predicate Devices to Which Equivalence is Claimed

ViscoStat® Clear is substantially equivalent to Racegel™ (K093711), manufactured by Septodont, which is cleared under dental device product code MVL (cord, retraction). ViscoStat Clear is substantially similar to the predicate device in Indications for Use, chemical composition, mechanical and physical properties and method of application and removal.

IV. Device Description:

ViscoStat Clear is a 25% Aluminum Chloride gel in a viscous, aqueous vehicle which leaves no residue or stain and makes it ideal for use in the esthetic zone. The product is contained within a 30mL or 1.2mL plastic syringe. The 30mL syringe is a bulk container and, prior to application, will be dispensed into provided, empty 1.2mL plastic syringe

for delivery to the patient. Dento-Infusor application tips are included and are used to apply the product to the prepared area.

V. Statement of intended use:

ViscoStat Clear is intended for sulcus retraction prior to impression making and to control bleeding and gingival oozing in restorative and operative dentistry used with gingival retraction cord and/or the Dento Infusor. The gel facilitates the insertion of the cord into the sulcus.

VI. Comparison of technological characteristics

Table 5-1: Substantial equivalence comparison

Characteristic	Comparison Product (Racegel™ K093711)	ViscoStat Clear
Intended Use	Racegel is a gel containing aluminum chloride which is intended for sulcus retraction prior to impression taking; control of bleeding and gingival oozing, particularly in restorative dentistry; and, if using a gingival retraction cord, the gel facilitates the insertion of the cord into the sulcus	ViscoStat Clear is intended for sulcus retraction prior to impression making and to control bleeding and gingival oozing in restorative and operative dentistry used with gingival retraction cord and/or the Dento Infusor. The gel facilitates the insertion of the cord into the sulcus.
Intended user	Dental professional	Dental professional
Chemical Characteristics	Aluminum chloride gel	Aluminum chloride gel
Recommended contact time	2 minutes	1-3 minutes
Delivery system	Pre-filled syringe with applicator tip	1.2ml pre-filled syringe with applicator tip, 30ml Indispense syringe with 1.2ml empty syringe and applicator tip
Physical properties	Orange, odorless gel	Clear gel

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800.552.5512

	24 month shelf life	42 month shelf life
Biocompatibility	Acute oral toxicity Sensitization Oral Mucosa Irritation Cytotoxicity	Cytotoxicity
Functional Testing	Unknown	Aluminum Chloride content Effect on Shear Bond Strength Blood coagulation

ViscoStat Clear is a similar material used in the same way by the same types of users as the identified predicate device Racegel, introducing no new safety or efficacy questions. Biocompatibility testing shows that the product is safe when used as instructed by a dental professional. In-house comparison testing has been performed on ViscoStat Clear and the predicate device, Racegel. The data supports the functionality of ViscoStat Clear. In summary, this submission demonstrates that ViscoStat Clear is safe and effective and performs equivalently to the identified predicates for its intended use.

ULTRADENT PRODUCTS, INC.
505 West 10200 South
South Jordan, Utah 84095, USA
www.ultradent.com
800.552.5512

Section 6: Truthful and Accurate Statement

I certify in my capacity as a Senior Regulatory Affairs Associate of Ultradent Products, Inc., I believe, to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

Karen Kakunes, RN
Sr. Regulatory Affairs Associate

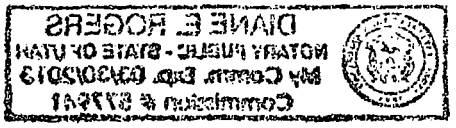
26 Sep 2012
Date

Premarket Notification 510(k) Number

State of Utah, County of Salt Lake
Subscribed and sworn to before me
this 26 day of Sept 2012

Diane E. Rogers
Diane Rogers, Notary Public

DIANE E. ROGERS
NOTARY PUBLIC - STATE OF UTAH
My Comm. Exp. 03/30/2013
Commission # 577941



Section 7: Class III Summary and Certification

ViscoStat Clear is not a Class III device; therefore, this section does not apply to this 510(k).

Section 8: Financial Certification or Disclosure Statement

This section does not apply to this 510(k) as no clinical studies were conducted for this product. A completed Form 3674 follows on the next page.

See OMB Statement on Reverse. Form Approved: OMB No. 0910-0616, Expiration Date: 2-28-2015

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Certification of Compliance, under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))

(For submission with an application/submission, including amendments, supplements, and resubmissions, under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.)

SPONSOR / APPLICANT / SUBMITTER INFORMATION

1. NAME OF SPONSOR/APPLICANT/SUBMITTER
Ultradent Products, Inc./Karen Kakunes

2. DATE OF THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES
Sep 26, 2012

3. ADDRESS *(Number, Street, State, and ZIP Code)*
505 West 10200 South
South Jordan, UT 84095 USA

4. TELEPHONE AND FAX NUMBERS *(Include Area Code)*
(Tel.) 801-553-4366
(Fax) 801-553-4609

PRODUCT INFORMATION

5. **FOR DRUGS/BIOLOGICS:** Include Any/All Available Established, Proprietary and/or Chemical/Biochemical/Blood/Cellular/Gene Therapy Product Name(s)
FOR DEVICES: Include Any/All Common or Usual Name(s), Classification, Trade or Proprietary or Model Name(s) and/or Model Number(s)
(Attach extra pages as necessary)

APPLICATION / SUBMISSION INFORMATION

6. TYPE OF APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES
☐ IND ☐ NDA ☐ ANDA ☐ BLA ☐ PMA ☐ HDE ☒ 510(k) ☐ PDP ☐ Other

7. INCLUDE IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/OTHER NUMBER *(If number previously assigned)*

8. SERIAL NUMBER ASSIGNED TO APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES

CERTIFICATION STATEMENT / INFORMATION

9. CHECK ONLY ONE OF THE FOLLOWING BOXES *(See instructions for additional information and explanation)*

☒ A. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply because the application/submission which this certification accompanies does not reference any clinical trial.

☐ B. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply to any clinical trial referenced in the application/submission which this certification accompanies.

☐ C. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, apply to one or more of the clinical trials referenced in the application/submission which this certification accompanies and that those requirements have been met.

10. IF YOU CHECKED BOX C, IN NUMBER 9, PROVIDE THE NATIONAL CLINICAL TRIAL (NCT) NUMBER(S) FOR ANY "APPLICABLE CLINICAL TRIAL(S)," UNDER 42 U.S.C. § 282(j)(1)(A)(i), SECTION 402(j)(1)(A)(i) OF THE PUBLIC HEALTH SERVICE ACT, REFERENCED IN THE APPLICATION/ SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES *(Attach extra pages as necessary)*

NCT Number(s):

The undersigned declares, to the best of her/his knowledge, that this is an accurate, true, and complete submission of information. I understand that the failure to submit the certification required by 42 U.S.C. § 282(j)(5)(B), section 402(j)(5)(B) of the Public Health Service Act, and the knowing submission of a false certification under such section are prohibited acts under 21 U.S.C. § 331, section 301 of the Federal Food, Drug, and Cosmetic Act.
Warning: A willfully and knowingly false statement is a criminal offense, U.S. Code, title 18, section 1001.

11. SIGNATURE OF SPONSOR/APPLICANT/SUBMITTER OR AN AUTHORIZED REPRESENTATIVE (Sign)
Karen Kakunes

12. NAME AND TITLE OF THE PERSON WHO SIGNED IN NO. 11
(Name) Karen Kakunes
(Title) Sr. Regulatory Affairs Associate

13. ADDRESS *(Number, Street, State, and ZIP Code) (of person identified in Nos. 11 and 12)*
Ultradent Products, Inc.
505 West 10200 South
South Jordan, UT 84095 USA

14. TELEPHONE AND FAX NUMBERS *(Include Area Code)*
(Tel.) 801-553-4420
(Fax) 801-553-4609

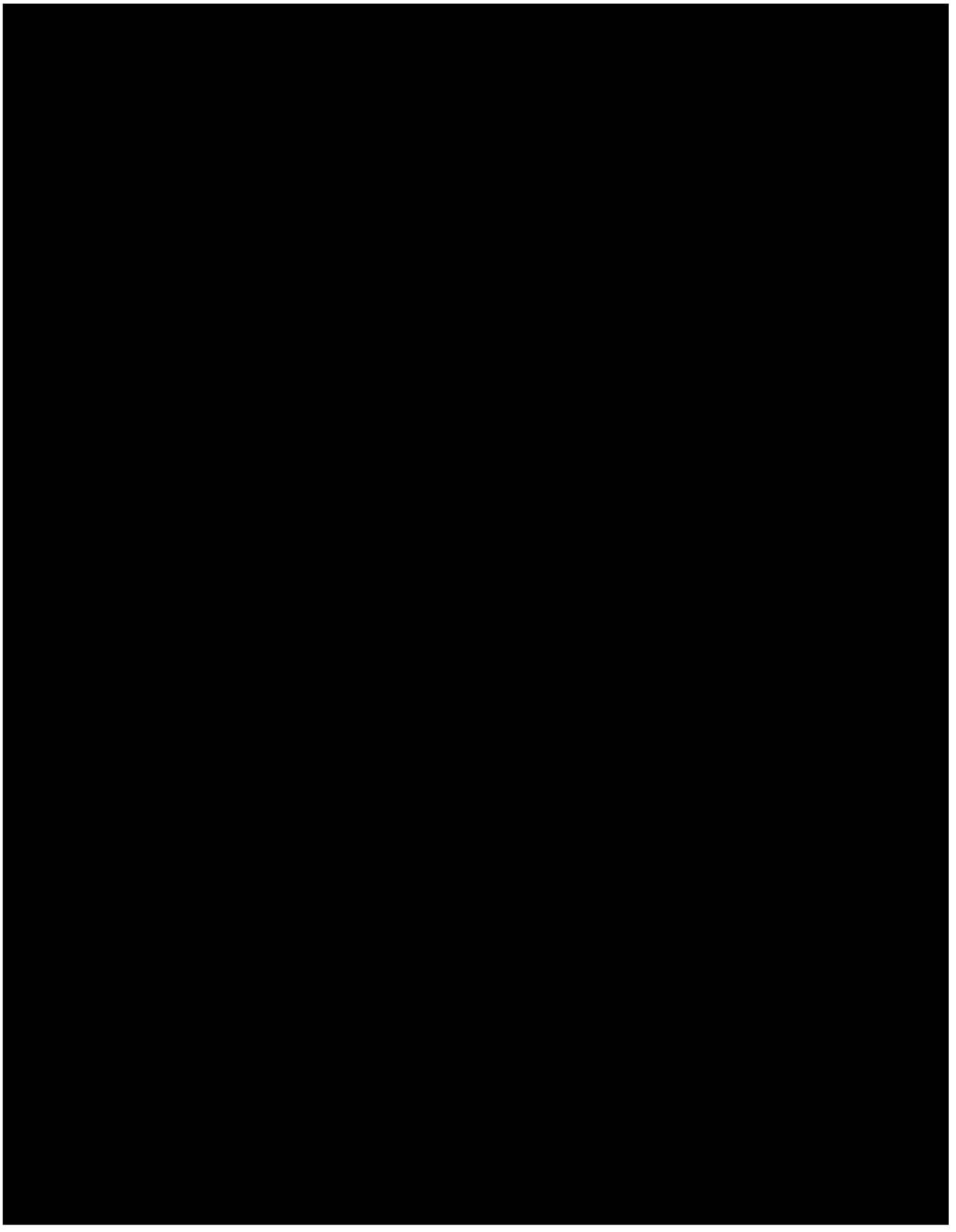
15. DATE OF CERTIFICATION
Sep 26, 2012

Form FDA 3674 (3/12) (FRONT)

PSC Publishing Services (301) 443-6740 EF

Section 9: Declarations of Conformity and Summary Reports

This is a traditional 510(k) submission, not an abbreviated 510(k); therefore, this section is not applicable.



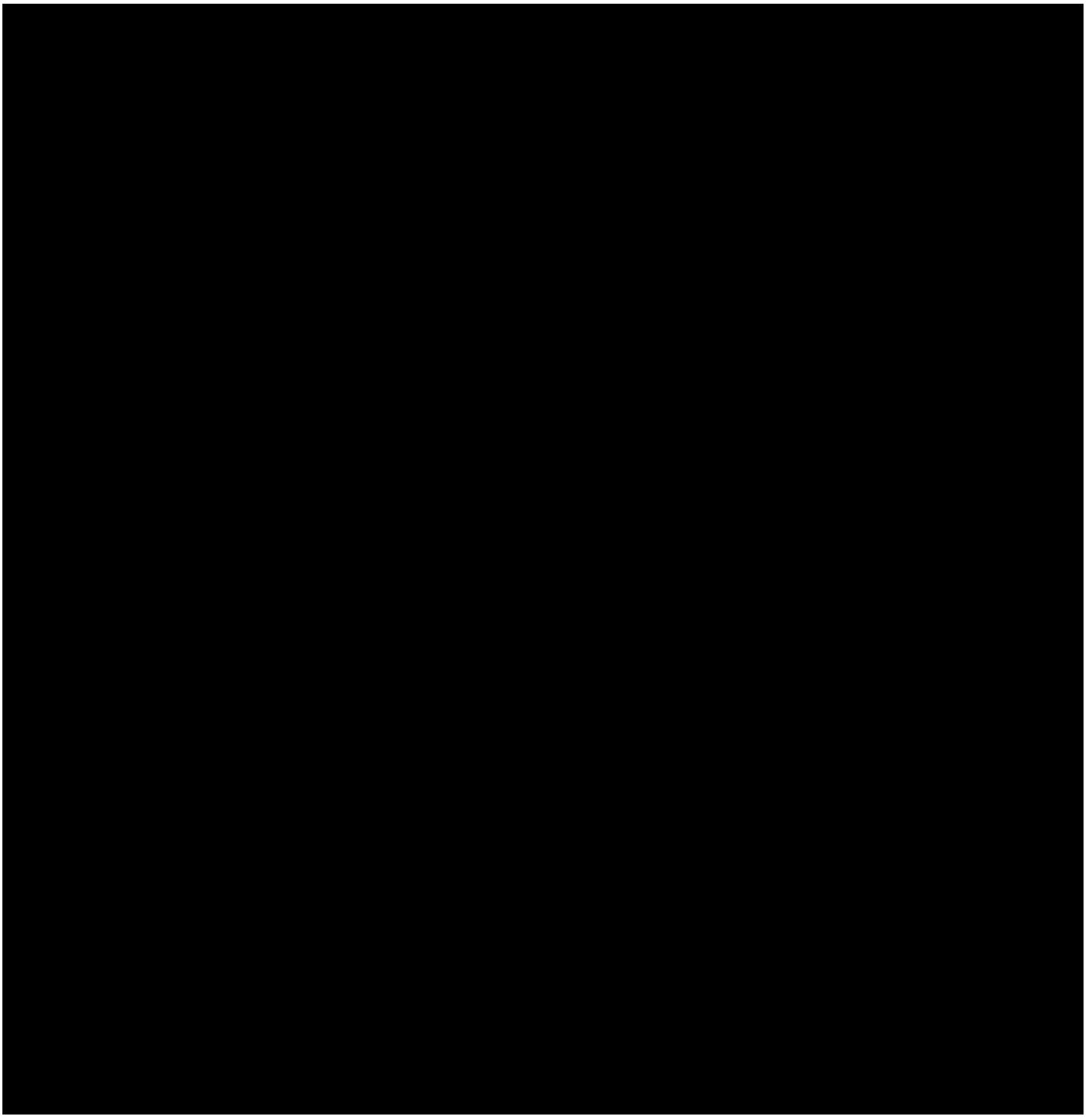
Intended user	Dental professional	Dental professional
Chemical characterisitics	Aluminum chloride gel	Aluminum chloride gel
Recommended contact time	2 minutes	1-3 minutes
Delivery system	Pre-filled syringe with applicator tip	1.2ml pre-filled syringe with applicator tip, 30ml Indispense syringe with 1.2ml empty syringe and applicator tip
Physical properties	Orange, odorless gel 24 month shelf life	Clear gel 42 month shelf life
Biocompatibility	Acute oral toxicity Sensitization Oral Mucosa Irritation Cytotoxicity	Cytotoxicity

ViscoStat Clear is intended to a tissue management option for dental practitioners performing restoration procedures. ViscoStat Clear is a similar material used in the same way by the same types of users, licensed dental practitioners, as the identified predicate device, introducing no new safety or efficacy questions.

(See Section 5: 510(k) Summary and Section 12: Substantial Equivalence Discussion)

ViscoStat Clear has been tested against the predicate listed above for aluminum chloride content, effect on shear bond strength, and blood coagulation. Since there is no federal or FDA guidance document for such devices, there was no standard available to use as a testing guidance. Biocompatibility testing shows that the product is safe when used as instructed by a dental professional. (Ref. Section 15: Biocompatibility)

In summary, this submission demonstrates that ViscoStat Clear is substantially equivalent in intended use, technology, performance, and biocompatibility to the identified predicate.



Kit Configurations (4):

REF/UP 6409: ViscoStat Clear Dento-Infusor Kit
4 – 1.2ml Syringes ViscoStat Clear
20 – Metal Dentor-Infusor Tips

REF/UP 6407: ViscoStat Clear Dento-Infusor IndiSpense Kit
1 – 30ml Indispense syringe ViscoStat Clear
20 – Metal Dento-Infusor tips
20 – 1.2ml empty syringes

REF/UP 6410: ViscoStat Clear Econo Refill
20 – 1.2ml syringes ViscoStatClear

REF/UP 6408: ViscoStat Clear IndiSpense Syringe
1 – 30ml syringe ViscoStat Clear

(b) (4)

(b) (4)

[redacted]

Section 12: Substantial Equivalence Discussion

Device Description ViscoStat Clear is a 25% Aluminum Chloride gel in a viscous, aqueous vehicle which leaves no residue or stain and makes it ideal for use in the esthetic zone.

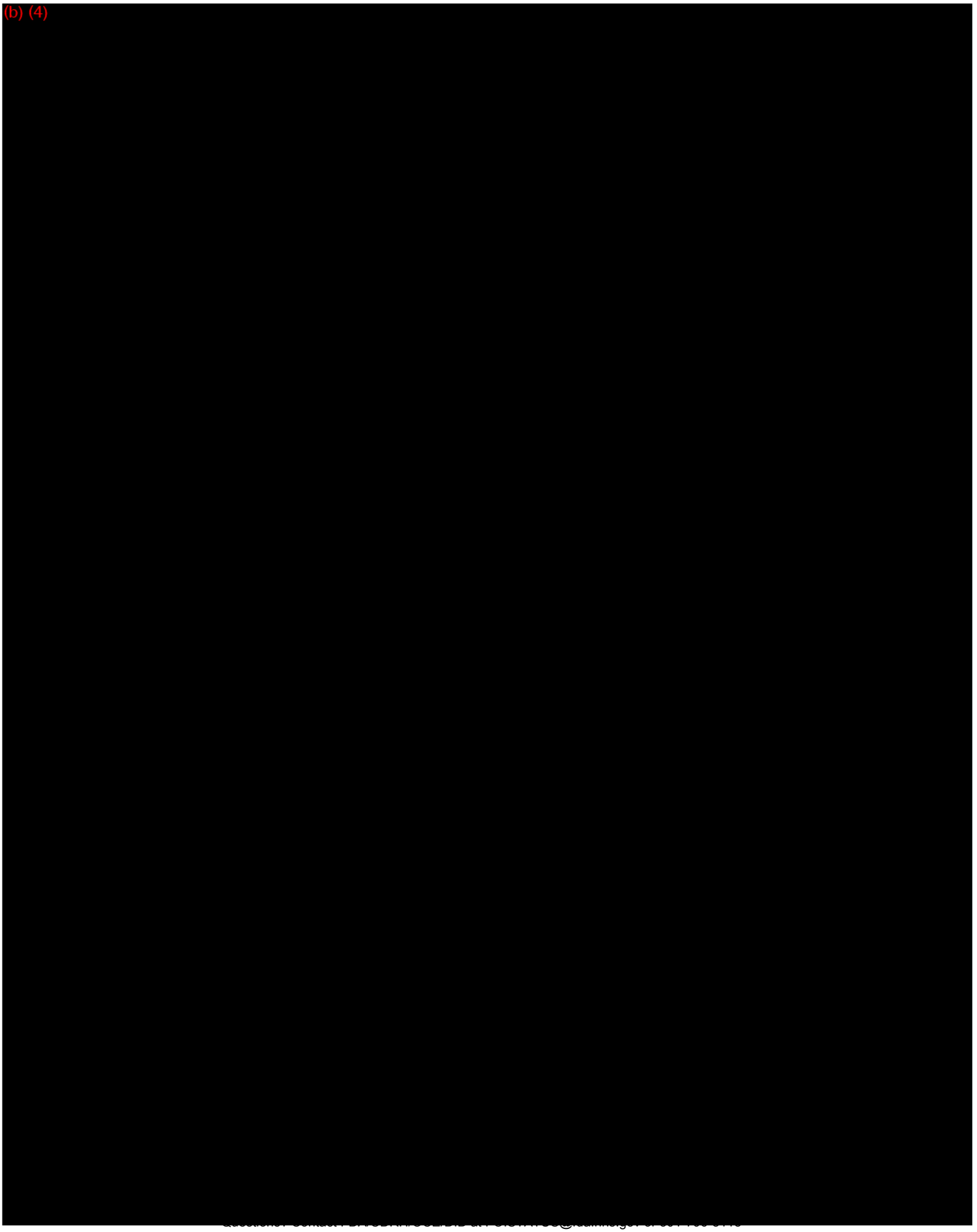
Statement of intended use: ViscoStat Clear is intended for sulcus retraction prior to impression making and to control bleeding and gingival oozing in restorative and operative dentistry used with gingival retraction cord and/or the Dento Infusor. The gel facilitates the insertion of the cord into the sulcus.

Legally Marketed Predicate Devices to Which Equivalence is Claimed: The predicate device is Racegel (K093711), manufactured by Septodont 1050 Connecticut Ave., Nw, Washington, DC 20036.

Both ViscoStat Clear and the predicate, Racegel, are aluminum chloride based gels with similar characteristics and intended use, as indicated in Table 12-1. The shelf life of ViscoStat Clear is significantly longer; however, stability testing has been performed and data gathered to support the 42 month shelf life.

Table 12-1: Substantial equivalence comparison

Characteristic	Comparison Product (Racegel™ K093711)	ViscoStat Clear
Intended Use	Racegel is a gel containing aluminum chloride which is intended for sulcus retraction prior to impression taking; control of bleeding and gingival oozing, particularly in restorative dentistry; and, if using a gingival retraction cord, the gel facilitates the insertion of the cord into the sulcus	ViscoStat Clear is intended for sulcus retraction prior to impression making and to control bleeding and gingival oozing in restorative and operative dentistry used with gingival retraction cord and/or the Dento Infusor. The gel facilitates the insertion of the cord into the sulcus.
Intended user	Dental professional	Dental professional
Chemical Characteristics	Aluminum chloride gel	Aluminum chloride gel
Recommended contact time	2 minutes	1-3 minutes
Delivery system	Pre-filled syringe with applicator tip	1.2ml pre-filled syringe with applicator tip, 30ml Indispense syringe with 1.2ml empty syringe and applicator tip
Physical properties	Orange, odorless gel 24 month shelf life	Clear gel 42 month shelf life
Biocompatibility	Acute oral toxicity Sensitization Oral Mucosa Irritation Cytotoxicity	Cytotoxicity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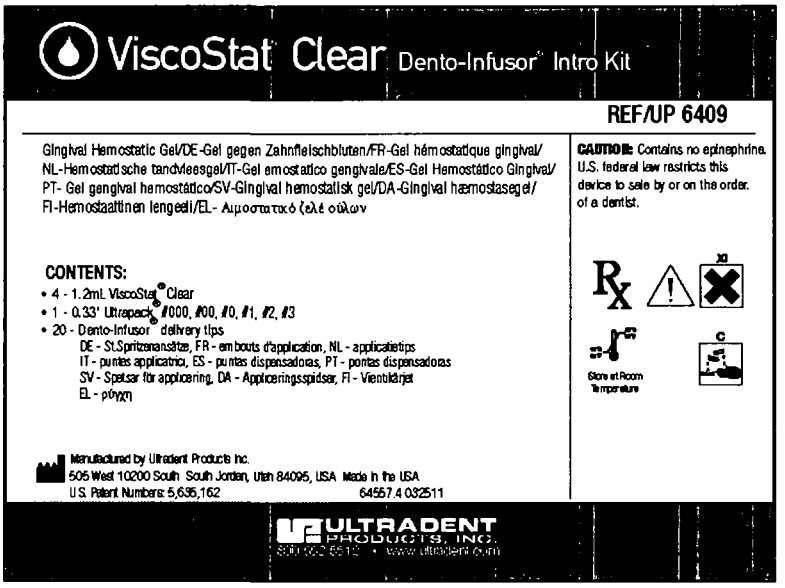
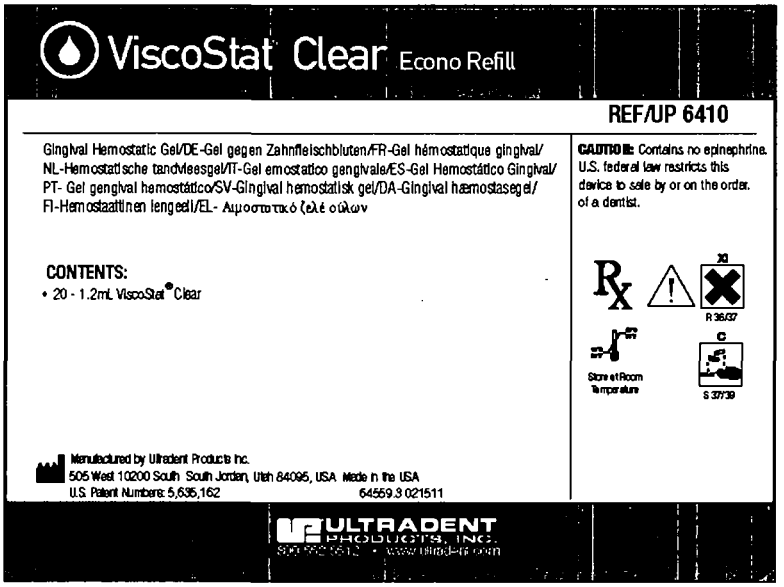
(b) (4)

Section 13: Labeling

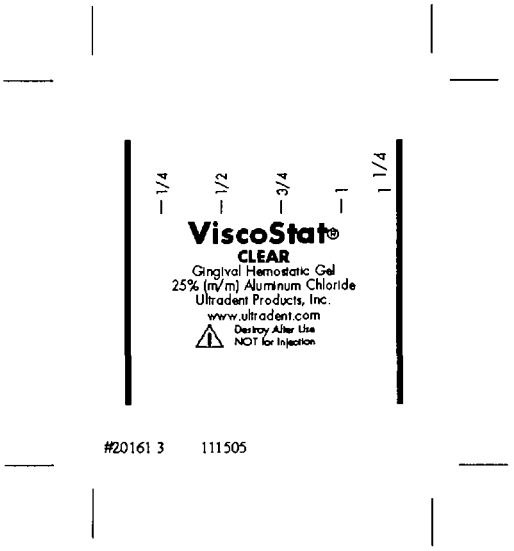
#6409 Dento-Infusor Kit Label:



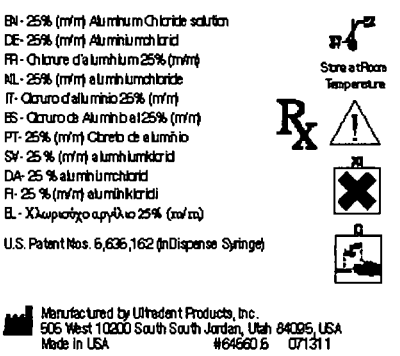
#6410 Econo Refill Label:



1.2mL Syringe labeling:



30mL Syringe labeling:



Instructions for Use:

ViscoStat Clear
25% Aluminum Chloride

Description

ViscoStat Clear is a 25% Aluminum Chloride gel in a viscous, aqueous vehicle which leaves no residue or stain and makes it ideal for use in the esthetic zone.

Indications

ViscoStat Clear is intended for sulcus retraction prior to impression making and to control bleeding and gingival oozing in restorative and operative dentistry used with gingival retraction cord and/or the Dento Infusor. The gel facilitates the insertion of the cord into the sulcus.

Directions for Use - General

1. For 1.2ml syringe
   a. Remove Luer cap.
   b. Securely attached working tip of choice (Metal Dento-Infusor or Blue Mini Dento-Infusor tip).
   c. Verify flow prior to applying intraorally.
2. For IndiSpense Syringe
   a. Remove Luer cap from Indispense syringe.
   b. Attach a 1.2ml syringe to the male threads of the IndiSpense syringe.
   c. Depress IndiSpense plunger while guiding 1.2ml syringe plunger to desired fill.
   d. Separate syringes and re-cap IndiSpense syringe.
   e. Securely attach working tip of choice (Metal Dento-Infusor or Blue Mini Dento-Infusor tip).
   f. Verify flow prior to applying intraorally.
3. Using a palm grasp, slowly express solution while rubbing against bleeding tissue. (Fig. X)

NOTE: To avoid cross contamination, use new syringes and tips for additional volumes.

NOTE: Recommended contact time for ViscoStat Clear is 1-3 minutes.

Directions for Use - Impressions

1. Follow "General" steps above.
2. Rub around the full circumference of the preparation expressing the solution into bleeding tissue surface to control bleeding.
3. When hemostasis is obtained, use a firm air/water spray to clean preparation. Check for hemostasis. If bleeding occurs, repeat step 2 above to bleeding area. Re-check with air/water spray until bleeding has stopped.
4. Displace tissue by packing size appropriate Ultrapak or displacement cord into sulcus. For optimum displacement and hemostasis, place a small amount of ViscoStat Clear in a dappen dish and soak cord prior to packing.
5. Wait 1-3 minutes before removing cord.
6. Remove cord, rinse with a firm air/water spray, check for hemostasis, and make impression.

Directions for Use – Direct and Indirect Bonded Restorations

1. Follow "General" steps above.
2. Lightly rub around the full circumference of the preparation expressing the solution into bleeding tissue surface to control bleeding.
3. When hemostasis is obtained, use a firm air/water spray to clean preparation. Check for hemostasis. If bleeding occurs, repeat step 2 above to bleeding area. Re-check with air/water spray until bleeding has stopped.
4. Soak Ultrapak or cord in ViscoStat Clear solution.
5. Gently pack size appropriate cord into sulcus.
6. Thoroughly rinse preparation and surrounding tissue using a firm air/water spray to clean and check for hemostasis and sulcular fluid control.
7. Scrub preparation surface with pumice or Ultradent's Consepsis Scrub.
8. Wait 1-3 minutes and remove cord. If using an unsoaked cord for tissue displacement, cord may be left in place during restorative procedure to protect soft tissue or may be removed.
9. Rinse again with a firm air/water spray and dry.
10. Apply bonding agent and restorative as per manufacturer's instructions.

CLEANSING NOTE: The tooth and surrounding tissue should be thoroughly cleaned and all residual hemostatic agent and coagulum removed to avoid contamination of the dentin and/or enamel substrate. Failure to do so may jeopardize the bond and seal causing microleakage. Temporary cements may also contaminate the surface causing microleakage and bonding failure.

Precautions and warnings:

1. For professional use only.
2. Carefully read and understand all instructions, precautions and warnings before use.
3. Do not use on patients with known allergies to aluminum chloride or chemical sensitivities.
4. ViscoStat Clear, temporary cements, mucins, and blood will prevent quality adhesion and polymerization/set of resins and will lead to microleakage under any restoration. Preparations must be thoroughly cleaned using a firm air/water spray and/or pumice or Consepsis scrub.
5. ViscoStat Clear must be thoroughly washed from the preparation site with a firm air/water spray to avoid reaction with polyether materials and thereby compromising the surface set of the impression.
6. When using self-etch bonding agents, the tooth/preparation surface must be scoured with pumice or Consepsis Scrub and thoroughly washed before application. This is not necessary when using a phosphoric etch bonding system or when using conventional glass ionomer, zinc phosphate, or similar cements.
7. Do not combine with other hemostatic agents or chemistries without first thoroughly cleansing tooth and surrounding tissue.
8. ViscoStat Clear is designed for intraoral use.
9. Verify flow of all syringes prior to applying intraorally. If resistance is met, replace tip and re-check.
10. Use only recommended tips.
11. Dispose of used tips and empty syringes properly.
12. To avoid cross contamination, do not re-use tips.
13. Do not use after expiration date noted on containers.
14. All syringe tips and empty syringes are disposable product and for single use only to avoid cross-contamination. Fill a new empty syringe with the amount of material needed for the individual patient. Dispose of syringe after use.
15. Prefilled syringes can be used several times, when protected during each use by syringe covers. Please note the instructions for use of the Syringe Covers. Re-cap syringe with the Luer Lock cap and disinfect syringe with an intermediate level disinfectant.

16. Do not allow product to be ingested.
17. Keep products out of direct heat/sunlight.
18. Use protective clothing and eye shield when loading and handling ViscoStat Clear.
19. Keep out of reach of children.

NOTE: For MSDS and additional information about using ViscoStat Clear or related products, please go to www.ultradent.com

(b) (4)

(b) (4)

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Section 14: Sterilization and Shelf Life

Sterilization: ViscoStat Clear is not a sterile or sterilizable product. Therefore, the sterilization section does not apply to this 510(k).

(b) (4)

[redacted]

Section 15: Biocompatibility

(b)(4) Testing

[redacted]

References:

- ISO 10993-1: Biological Evaluation of Medical Devices – Part 1: Guidance on Selection of Tests
- ISO 7405: Dentistry – Evaluation of Biocompatibility of Medical Devices used in Dentistry

Section 16: Software

ViscoStat Clear, used for tissue management in dental procedures, contains no software, electrical components or any power source; therefore, this section is not applicable.

Section 17: Electromagnetic Compatibility/ Electrical Safety

ViscoStat Clear, used for tissue management in dental procedures, contains no software, electrical components or any power source; therefore, this section is not applicable.

Section 18: Performance Testing - Bench

(b)(4) Testing

[redacted]

(b) (4)

(b) (4)

(b) (4), (b)(4) Testing

(b) (4), (b)(4) Testing

(b) (4)

Section 19: Performance Testing – Animal

No animal testing was conducted using ViscoStat Clear; therefore, this section is not applicable.

Section 20: Performance Testing – Clinical

ViscoStat Clear was tested against the identified predicate in comparison testing (reported in Section 18). No clinical testing was conducted for this 510(k) submission; therefore, this section is not applicable.

Appendix A : Clinical Literature

CLINICAL SUMMARY

Viscostat Clear

I. Introduction:

The following summary provides a documented review of clinical data collected with respect to the involved device as part of the conformity assessment procedure required by the Medical Device Directive (93/42/EEC), using the 'literature route.' The following clinical literature evaluation demonstrates safety and efficacy of the device, and provides a basis for clinical evaluation and assessment of the risk to benefit for the intended use and claims as required.

A. **General details:** Viscostat Clear is a 25% aluminum chloride material manufactured by Ultradent Products Inc.

B. **Description of the device and its intended application:** Viscostat Clear is a 25% Aluminum Chloride gel in a viscous, aqueous vehicle which leaves no residue or stain and makes it ideal for use in the esthetic zone. The product is contained within a 30mL or 1.2mL plastic syringe. The 30mL syringe is a bulk container and prior to application, will be dispensed into a provided, empty 1.2mL plastic syringe. Dento-Infusor application tips are used to apply the product to the prepared area.

C. **Intended use and/or diagnostic indications and claims:** Viscostat Clear is intended for sulcus retraction prior to impression making and to control bleeding and gingival oozing in restorative and operative dentistry used with gingival retraction cord and/or the Dento Infusor. The gel facilitates the insertion of the cord into the sulcus.

II. Evaluation Background:

The control of sulcular fluids and minor bleeding is often a problem for the clinician during dental procedures and endodontic surgery. Since the 1970's, aluminum chloride has been an accepted soft tissue management agent used to control both sulcular fluids and minor bleeding in the dental practice. Additionally, aluminum chloride is commonly used in gingival retraction because of its ability to cause contraction and shrinkage of tissue. It has been used in the dental industry for many years with successful results.

Tissue management and gingival retraction are integral elements in successful dental restorations. One of the keys to fabricating well-fitting crowns is the quality of the impression. Without a clean treatment field, the restoration may be unsuccessful or fail and cause the need for re-treatment. Agents, such as ViscoStat Clear, aid in the success of the restoration.

A documented review of clinical data has been collected, with respect to the involved device, as part of the conformity assessment procedure required by the Medical Device Directive (93/42/EEC). ViscoStat Clear contains no special design features that pose special performance or safety concerns, as documented in the Risk Analysis of this technical file. ViscoStat Clear does not incorporate new technology or new clinical applications. The clinical data used to support the safety and efficacy of the product is based off of similar devices with nearly identical or similar clinical applications and indications for use. The predicate for Viscosat Clear, Racegel, as manufactured by Septodont, was researched via PubMed and Google search engine. Due to the minimum amount of literature available, 25% aluminum chloride in dental applications was used as a general search. Current articles that also used Expa-syl, an aluminum chloride paste currently approved and released on the market, were also used because of the relevance to the safety and efficacy of its active ingredient and not necessarily the mode of application. Each of the articles relevant has been chosen because of the use of aluminum chloride as its active ingredient.

Table Viscostat Clear: Substantial equivalence comparison among similar devices on market:

This table is an illustration of similarities of the competitive product found in the literature search to Viscostat Clear. This will show that the articles found do represent Viscostat Clear and its safety and efficacy in patient use.

Characteristic	Comparison Product (Racegel™ K093711)	Comparison Product (Expa-syl K050180)	Viscostat Clear
Intended Use	Racegel is a gel containing aluminum chloride which is intended for sulcus retraction prior to impression taking; control of bleeding and gingival oozing, particularly in restorative dentistry; and, if using a gingival retraction cord, the gel facilitates the insertion of the cord into the sulcus	Expa-syl is a paste containing aluminum chloride which is intended to be used for the temporary retraction and hemostasis of the gingival margin during dental procedures such as, but not limited to, dental impressions, seating of temporary and permanent restorations, restorations of cavities and placement of rubber dam.	Viscostat Clear is intended for sulcus retraction prior to impression making and to control bleeding and gingival oozing in restorative and operative dentistry used with gingival retraction cord and/or the Dento Infusor. The gel facilitates the insertion of the cord into the sulcus.
Intended user	Dental professional	Dental professional	Dental professional

Chemical characteristics	Aluminum chloride gel	Aluminum chloride paste	Aluminum chloride gel
Recommended contact time	2 minutes	1-2 minutes	1-3 minutes
Delivery system	Pre-filled syringe with applicator tip	Pre-filled plastic cartridge with applicator	1.2ml pre-filled syringe with applicator tip, 30ml Indispense syringe with 1.2ml empty syringe and applicator tip
Physical properties	Orange, odorless gel 24 month shelf life	Blue paste	Clear gel 42 month shelf life
Biocompatibility	Acute oral toxicity Sensitization Oral Mucosa Irritation Cytotoxicity	Unknown	Cytotoxicity

III. Summary of Clinical Literature Evaluation:

Eight keyword searches were performed on PubMed or via Google to obtain articles relevant to Viscostat Clear and the safety and efficacy of aluminum chloride when used in dental applications. However, due to the lack of published material in regards to Viscostat Clear, the search was expanded to include similar product that contain aluminum chloride and aluminum chloride dental applications so that relevant safety and efficacy issues are addressed as appropriate:

"Retraction cord with Aluminum Chloride 25%" via Google Sep 2012:

Two articles were chosen from the search results for credit to the use of retraction cords with 25% Aluminum Chloride. One of the articles was excluded because it was retrieved in a previous search and included in the summary.

"Aluminum Chloride" AND "In-Vitro" AND "Dental" via PubMed Aug 2012:

This search returned six articles, of which one was found not to be relevant as it discusses the concern of bond strengths. The remaining five articles were omitted because they did not discuss the safety and efficacy of aluminum chloride or there was a different system of mechanism for aluminum chloride.

"Aluminum Chloride" AND "Hemostasis" via PubMed Aug 2012:

This search returned three articles, of which one was considered to be relevant to the safety and effectiveness of Viscostat Clear. The remaining two articles were

excluded because they did not pertain to the use of aluminum chloride in a dental application and instead focused on other medical procedures.

"Aluminum Chloride" AND "Efficacy" AND "Bleeding" via PubMed Aug 2012:

This search returned two articles, of which one was considered to be relevant. This article; however, was a duplicate to a previous search. The other article was not within the scope of use for aluminum chloride and was excluded.

"25% Aluminum Chloride" AND "Dental" via PubMed Aug 2012:

Two articles were returned with this search. Both articles were considered relevant and included in the summary.

"Folia Biologica" AND "Nowakowska" via PubMed Single Citation Search Aug 2012.

Two articles were retrieved and one was considered relevant. The other article was excluded because the study did not include Aluminum Chloride in the materials being studied.

"Aluminum Chloride" AND "Dental" and "Efficacy" via Google Aug 2012:

Five articles were chosen from the search results that were considered to be relevant to the safety and efficacy of Viscostat Clear.

"Hemostatics" and "ADA" via Google Aug 2012:

One publication was desired and retrieved in this search. The target was to access the ADA guidelines for Dental Hemostatics and all other articles were excluded.

"(Hemostatics" [Mesh] OR "Hemostatics [Pharmacological Action] OR "Hemostatic Techniques [Mesh])" AND "Dental" AND "Impression" via PubMed Sep. 2010:

This search returned thirty-eight articles. Seven articles were selected to be relevant. Articles excluded were omitted because they were over 10 years old. One article that was published in 1998 was chosen because of its relevance to Ultradent Products, Inc. The remaining articles were excluded because they did not pertain to hemostatics, the safety and efficacy of hemostatic, or they were not available in English.

"Aluminum Chloride" AND "Dental" AND "Hemostat" via PubMed Sep. 2010:

This search returned eight articles, of which three were considered to be relevant to the safety and effectiveness of the product. Articles excluded were omitted for the

following reasons: duplicate articles retrieved from the previous search, no reference to Aluminum Chloride, or no relevance to the safety or efficacy of aluminum chloride solution.

III. Safety Literature:

A. *In Vivo* Studies

1. KQ Al Hamad, et al. A clinical study on the effects of cordless and conventional retraction techniques on the gingival and periodontal health. J Clin Periodontal 2008; 35:1053-1058.
AIM: To investigate the influence of two cordless techniques on the periodontium in comparison with conventional cords. MATERIALS and METHODS: Dental students (n=60 with healthy gingival conditions were recruited – an expanding poly vinyl siloxane material (Magic Foam Cord®), a paste-like material (Expasyl®), and a conventional retraction cord (Ultrapak®) were applied on the buccal aspects of three premolars of each subject. Probing depth, clinical attachment level, gingival index, mobility, bleeding, and sensitivity were assessed at baseline, and at 1 and 7 days after application. Data were analyzed using Kruskal-Wallis and Mann-Whittney tests ($\alpha = 0.05$). RESULTS: The periodontal parameters were not statistically significant among the groups at all time intervals except for the GI, which was increased for all groups after 1 day. The highest was Expasyl ($p=0.011$). After 7 days, the GI returned to a non-significant level compared with baseline except for Expasyl, which was still significant ($p=0.044$). Expasyl induced sensitivity in four subjects. Bleeding was only induced by Ultrapak in 28.3% and 26.7% during and after retraction, respectively. CONCLUSIONS: All techniques caused a temporary gingival inflammation; the greatest was in Expasyl, which also showed slower recovery. Cordless techniques did not induce bleeding during or after retraction.

2. Arx T von, et al. Hemostatic agents used in periradicular surgery: an experimental study of their efficacy and tissue reactions. International Endodontic Journal 2006;39:800-808.

AIM: To evaluate the hemostatic efficacy and the histologic tissue responses after the application of different hemostatic agents used in periradicular surgery. METHODOLOGY: The study was conducted in the calvarium of six rabbits. Standardized bone defects (diameter 4 mm) were tephined, and different hemostatic agents were applied and compared with control defects: bone wax (left for 10 min), Stasis® (ferric sulphate, left for 5 s), Expasyl™ (aluminum chloride, left for 2 min and left permanently *in situ*), and a combination of Expasyl™ and Stasis® (5s). The sites were photographed before the application and after the removal of the hemostatic agents. Three independent examiners judged the initial and final bleeding (on the photographs) using a bleeding score for each site and treatment. The results were compared using Wilcoxon's signed rank test. For the histologic analysis, three animals were killed after 3 weeks and three animals after 12 weeks. Transverse, nondecalcified sections were stained with combined basic fuchsin and toluidine blue for descriptive histology.

RESULTS: The most efficient hemorrhage control was by Expasyl™ alone, whereas bone wax had the weakest bleeding reduction effect. The histologic analysis after 3 weeks demonstrated an inflammatory and foreign body tissue response towards all hemostatic agents. At 12 weeks, this tissue response was less pronounced but still present in sites treated with bone wax or Expasyl™. In general, the inflammatory tissue reactions were limited to the bone defects, and never extended into the surrounding tissues. CONCLUSIONS: Expasyl™ alone or in combination with Stasis® appeared to be the most efficient of tested agents to control the bleeding within the bony defects created in rabbit calvarium model.

3. Kopac I, et al. Gingival Inflammatory Response Induced by Chemical Retraction Agents in Beagle Dogs. Int J Prosthodont 2002;15:14-19.

PURPOSE: The aim of this in vivo study on dogs was to investigate and compare the inflammatory potential of four different retraction agents on the gingival connective tissue. MATERIALS and METHODS: All procedures on eight beagle dogs were performed under general anesthesia; taking oral hygiene measures, placing retraction cords medicated with four chemical agents into the gingival sulci, and taking tissue biopsies. The specimens were evaluated after a 10-minute exposure to chemical agents. The inflammatory response of the connective tissue underlying the sulcular and junctional epithelium triggered by retraction agents was assessed quantitatively. Microscopic images of tissue specimens were morphometrically analyzed using a computer-assisted morphometric method. RESULTS: The most intense inflammatory response in the connective tissue underlying the sulcular epithelium was triggered by astringent retraction agents – Racestyptine in specimens taken after 1 day and 1 week and rastringent after 1 day (P<.05). Tetrahydrozoline-sympathomimetic vasoconstrictor (Visine) was found to have the lowest inflammatory potential. Retraction chemicals produced no significant effects on the connective tissue subjacent to the junctional epithelium. The ratio of the connective tissue area to that of the inflammatory infiltrate showed that 25% aluminum chloride (Racestyptine) was the most aggressive and tetrahydrozoline the least aggressive retraction agent used. CONCLUSION: All the retraction chemicals tested increased the infiltration with inflammatory cells in the gingival connective tissue.

B. *In Vitro* Studies

4. Kopac I, et al. Electron microscopic analysis of the effects of chemical retraction agents in cultured rat keratinocytes. J Prosthet Dent 2002;87:51-6.

Chemical retraction agents used in fixed prosthodontics for temporary displacement of free gingival tissue before impression making can cause injury to the gingival tissue cells. PURPOSE: This study evaluated changes in cultured rat keratinocytes treated with 2 chemical agents used for gingival retraction. Treated cultures were compared with untreated cultures. MATERIAL and METHODS: Keratinocytes of rat gingiva were grown

in a specific medium for 10 days. After treating 1 group of specimens with 0.05% tetrahydozoline and another group with 25% aluminum chloride, both for 10 minutes, the cultured cells were examined with scanning and transmission electron microscopy and compared with control specimens. RESULTS: Twenty-five percent aluminum chloride produced a significantly greater extent of cellular damage than 0.05% tetrahydrozoline, which caused only mild changes in the cultured cells. CONCLUSION: On the basis of the morphologic and ultrastructural changes in primary cell cultures of rat keratinocytes observed in this study, it was concluded that 25% aluminum chloride was significantly more aggressive than 0.05% tetrahydrozoline.

5. Nowakowska E, et al. Dynamic Oxidoreductive Potential of Astringent Retraction Agents. Folia Biologica. 2010;56(6):263-8.

   ABSTRACT: The aim of this study was to evaluate the dynamics of the cytotoxicity of gingival margin retraction astringents based on aluminum chloride, aluminum sulphate, and ferric sulphate (solutions and gels) in human fibroblasts isolated from the gingiva. The cytocompatibility of ten astringent-based chemical retraction agents: Gingiva Liquid, Alustin, Racestypine, Orbat sensitive, Astringedent®, Alustat, Hemostat, Racecord, Gelcord and Viscostat®, in dilutions of 1:10 and 1:20, with human gingival fibroblasts was investigated. The MTT assay was performed to determine oxidoreductive mitochondrial function after 3, 5, 10 min and 24 h of incubation. Cell viability was determined according to the chemical group, concentration, exposure time, and the clinical form of the gingival retraction agents. Ferric sulphate-based agents were the most cytotoxic, followed by aluminum chloride and aluminum sulphate. The form of the astringents influenced cell viability. The evaluated astringents may have cytotoxic potential for gingival margin tissues under clinical conditions.

C. Review Articles

6. Donovan T, et al. Current concepts in gingival displacement. Dent Clin N Am 2004;48:434-444.

   SUMMARY: Gingival displacements an important procedure with fabricating indirect restorations. Gingival displacement is relatively simple and effective when dealing with healthy gingival tissues and when margins are properly placed a short distance into the sulcus.
   The most common technique used with gingival displacement is use of gingival retraction cords with hemostatic medicament. Retraction cords of sufficient diameter should be used to provide adequate lateral displacement to create a mean sulcular width of 0.2mm. Epinephrine containing retraction cords should be avoided.
   Several techniques have proven to be relatively predictable, safe, and efficacious. No scientific evidence has established the superiority of one technique over the others, so the choice of technique depends on the presenting clinical situation and operator preference.

V. **Efficacy Literature:**

A. *In Vivo* Studies

7. Elledge, D. Effective Hemostasis and Tissue Management. Dent Today. 2010;29(10):150,152-3.

INTRODUCTION: A common clinical challenge dentists face with restorative procedures is blood contamination. There are a variety of reasons that the gingiva can bleed, including from plaque, trauma, and/or an encroached biologic width. Plaque causes gingivitis, caries, and periodontitis. Trauma that happens during the restorative procedure can cause bleeding. Wedges can press laterally and aggressively against the gingival papilla, and metal or plastic matrix bands' sharp edges can cut healthy/inflamed tissue during the isolation of the cavity. Burs are used to excise the caries, excise inflammatory tissue, and widen the gingival sulcus. Cords are packed to deflect or retract the gingiva in attempt to expose the cavity margin. Any of these events can result in blood contaminating the restorative field, thus negatively affecting impressions, cavity preparation, restorative materials, and cementation.
There is an association between restorative care and periodontal health. An encroachment of the biologic width happens when the restorative margins are placed too deep within the sulcus. Inadequate restorations can have ledges or areas that are not cleansable, which can contribute to plaque accumulation. Adolescents and geriatrics alike can have poor oral hygiene. New restorations are often needed because plaque control has been compromised. In addition, a high-carbohydrate (sugary, carbonated beverages) and nutrient-poor (refined foods) diet is a primary contributing factor in the patient examples presented in this article.
With case examples, this article will demonstrate how one can improve the quality of one's indirect restorative work by changing his or her technique protocol (system) to effectively control bleeding and manage the soft tissues.

8. Phatale S, et al. Effect of retraction materials on gingival health: A histopathological study. J Indian Soc Periodontal. 2010; 14(10):35-39. As taken from www.ncbi.hlm.nih.gov on August 21, 2012.
http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2933527/

BACKGROUND: Gingival retraction methods are used in dentistry for impressions of subgingival crown margins, such as, mechanical, chemical, chemicomechanical, and surgical. These methods may injure the gingival sulcular epithelium. Hence, the present study is carried out to evaluate the effect of different retraction materials, such as Expasyl, Magic Foam Cord, and impregnated retraction cord on the gingival sulcular

epithelium. MATERIALS and METHODS: This study included 30 cases of bilateral premolar extraction patients with Loe and Silness gingival index zero. Retraction materials were kept in the dry, isolated labial gingival sulcus for the required time. The retraction materials were removed by rinsing with water. Retracted gingiva of 2 – 3 mm from the gingival margin along with the tooth was extracted and the decalcified sections were microscopically studied. Data analysis: Data were analyzed by applying the chi-square test. RESULTS: This study showed better results with retraction paste as compared to the retraction cord, and there was a significant association between retraction materials and the relative degree of injury to the sulcular epithelium. CONCLUSION: There is a significant association between retraction materials and gingival sulcular epithelium. It can be stated that impregnated retraction cord, may be used commonly but it need proper tissue manipulation and is technique sensitive. Newly advanced material in the form of retraction paste like Expasyl or Magic Foam Cord was found to be better than cord as assessed histologically, it respects periodontium.

B. *In Vitro* Studies

9. Harnirattisai C, et al. Bond Strengths of Resin Cements to Astringent-contaminated Dentin. Operative Dentistry, 2009, 34-4, 415-422.

   SUMMARY: The current study evaluated the micro-shear bond strength of two resin cements to astringent-contaminated dentin. Twelve occlusal dentin discs were prepared from extracted caries-free human molars and divided into two groups subjected to two types of resin cements, Panavia F (PF) and Variolink II (VL). Each disc was ground 600 grit SiC paper and sectioned into two semi-discs, one for the normal dentin surface and the other for the contaminated dentin surface. For contaminated dentin, an astringent containing aluminum chloride was applied for two minutes and rinsed before the bonding procedures. A micro tygon tube was placed on the dentin surface following the bonding application and then filled with a resin cement. After the resin was polymerized, the specimen was kept in water for 24 hours before the micro-shear bond strengths evaluation. The micro morphology of the treated surfaces and resin-dentin interfaces were observed under a scanning electron microscope (SEM). Aluminum content under different dentin conditions was also examined. No significant differences were found between the dentin bond strengths to normal dentin and contaminated dentin surfaces in both the PF and VL groups ($p>0.05$). PF showed similar bond strengths to VL on normal and contaminated dentin ($p>0.05$). SEM observations of the VL groups revealed no differences in the treated dentin surfaces and the resin-dentin interfaces between normal and contaminated dentin. However, for the PF group, an inconsistent etching pattern of the self-etching primer and gap formation at the interface of resin cement to contaminated dentin were observed.

10. Kuphasuk W, et al. Bond Strengths of Two Adhesive Systems to Dentin Contaminated with a Hemostatic Agent. Operative Dentistry, 2007, 32-4, 399-405.

RP019.1

SUMMARY: This study evaluated the bond strength of a total-etch and a self-etch adhesive to dentin contaminated with a hemostatic agent containing aluminum chloride ($AlCl_3$). Eighteen occlusal dentin discs were prepared from human molars. Each disc was ground and sectioned into two halves, one for normal dentin and the other for contaminated dentin. The specimens of both normal and contaminated dentin were randomly divided into three groups and treated with the following materials: 1) Excite (EX); 2) Clearfil SE Bond with 20-second primer application time (DB-20) and 3) Clearfil Se Bond with 40-second primer application time (CB 40). The microshear bond strength specimens were prepared using the resin composite Clearfil APX. The bond strengths were evaluated on a universal testing machine. Statistical analysis was performed at α=0.05. The surface micromorphology and aluminum content of the different dentin conditions were also examined. In EX, no significant difference was found between the bond strengths of normal dentin and contaminated dentin. The bond strength of CB20 to contaminated dentin was significantly lower than that to normal dentin. The extension of primer application time from 20 to 40 seconds significantly increased the bond strength of CB to contaminated dentin.

11. O'Mahony A, et al. Effect of 3 medicaments on the dimensional accuracy and surface detail reproduction of polyvinyl siloxane impressions. Quintessence Int 2000;31:201-206.
OBJECTIVE: The purpose of this study was to determine the effect of retraction cord medicaments (aluminum chloride, ferric sulfate, and ferric subsulfate/sulfate) on the dimensional accuracy and surface detail reproduction of polyvinyl siloxane impressions. METHOD and MATERIALS: Polyvinyl siloxane impressions were made of standardized metal dies (American Dental Associate [ADA] specification No. 19) treated with 1 of the 3 retraction cord medicaments. Dimensional accuracy was evaluated by comparing the average length of a line in the impressions to the standard die. Surface detail reproduction was evaluated by viewing the impressions under low-angle illumination at x10 magnification. Reproduction was considered satisfactory if 2 of 3 horizontal lines were reproduced continuously. The dies were also evaluated under the microscope before the impression was made. RESULTS: The medicaments did not significantly effect the dimensional accuracy; mean shrinkage was within ADA guidelines in the treatment groups. All of the medicaments had an adverse effect on surface detail reproduction. These effects were statistically significant compared to the untreated control. CONCLUSION: Although the changes in dimensional accuracy were within ADA guidelines, the surface detail reproduction was modified such that the impression would be considered clinically unacceptable. For optimal results, care must be taken to remove all traces of these retraction cord medicaments prior to recording polyvinyl siloxane impression.

12. Land M, et al. Smear layer instability caused by hemostatic agents. J Prosthoet Dent. 1996 Nov;76(5):477-82.

The effect of hemostatic agents, other than a 15.5% $Fe_2(SO_4)_3$ solution, on prepared tooth structure is unknown. The purpose of this study was to (1) compare the effect of six commonly used hemostatic solution and two nondental astringents on the dentinal smear layer and (2) determine whether different responses caused by product and/or time could be established. Standardized dentinal smear layers were exposed to eight astringent solutions for 30, 120, and 300 seconds (n=6). A total of 144 SEM photographs at x2400 magnification were ranked according to predetermined criteria for five categories of smear layer removal and etching of underlying tooth structure. There were significant differences ($p<0.001$) caused by the solution, exposure time, and their interaction. Greatest smear layer removal was observed with 21.3% $AlCl_3$-6 hydrate, 8% racemic epinephrine HCl, and 15.5% $Fe_2(SO_4)_3$ solutions at longer exposures. These caused significantly more removal than did almost pH neutral tetrahydrozoline or oxymetazoline ($p<0.05$).

C. Review Studies

13. Mohan M, et al. Pharmacological Agents in Dentistry: A Review. British Journal of Pharmaceutical Research. 2011;1(3):66-87. As taken on August 14, 2012 from http://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=11&ved=0CGIQFjAAOAo&url=http%3A%2F%2Fwww.sciencedomain.org%2Fdownload.php%3Ff%3D1307275882-Published_Parolia_2011BJPR272.pdf&ei=Y74qUNKHLom9igKIuYGAAg&usg=AFQjCNFJ0j1VaTkw-sfW4HCTXB1zm4TJew&sig2=uoKKw41oEv5dyy2fZRIRfg.

    ABSTRACT: All clinicians should be fully aware of the recent trends in their specialty to enable them to provide effective and successful treatment to their patients. One vital aspect of the treatment is that the clinician should constantly update his knowledge on the drugs being administered during the course of treatment and their interactions. The purpose of this article is to review the current pharmacological agents being used in Prosthodontics along with their interactions and indications. This paper mainly focuses on Therapeutic drugs and drugs that aid in prosthodontics treatment. Therapeutic drugs include local anesthetics, antiseptics, steroids, analgesics, antimicrobials, antifungals, antianxiety drugs, centrally acting muscle relaxants. Drugs that aid in prosthodontics treatment include astringents, vasoconstrictors, hemostatic agents, sialogogues, anti-sialogogues, denture cleansers, gum paints, denture adhesives, ORAL protective agents and demulcents. An ondontologist should have sound knowledge of the benefits and drawbacks of all these agents. This will enable the clinician to provide a safe and predictable treatment to the patients.

14. Radz G. Soft-Tissue Management. The key to the perfect impression. Compend Contin Educ Dent. 2010 Jul-Aug;31(6):463-5.

    In the ideal world, excellent soft-tissue health would be a pre-requisite for predictable impressions. Inflamed tissues will bleed more readily and exhibit increased crevicular

fluid flow, rendering moisture control more difficult. Despite having less than ideal conditions, the capture of an excellent impression is still possible. The use of a retraction cord is the first line of defense to control fluid flow. When placed in the gingival sulcus, the retraction cord will physically block crevicular fluids from the preparation margin. Most commonly, bleeding is managed chemically. Ferric sulfate, aluminum chloride, and epinephrine are the most common options. These materials will cause constriction of peripheral blood vessels, resulting in a transient shrinkage of the surrounding tissues. Aluminum chloride, while not quite as effective as ferric sulfate, is a popular option for controlling localized bleeding. Its benefit is that no dark residue remains on the restoration. This makes aluminum chloride the chemical of choice when the final restoration is made of an all-ceramic or indirect composite material.

15. Strassler H. Tissue Management, Gingival Retraction and Hemostasis. Benco Dental ADA/CERP. 2009-2013. As taken on August 14, 2012 from http://d3e9u3gw8odyw8.cloudfront.net/ie2_ce_tissue_management.pdf.

    CONCLUSION: There are a variety of techniques and materials that allow the clinician to manage the gingival tissues during restoration and when making an impression. These include gingival retractions cords, chemical reagents, electrosurgery, laser tissue sculpting, copper tube impressions, hydraulic impressions and non-invasive, atraumatic displacement/hemostatic materials. In most cases, gingival retraction cord is the most effective method for retracting tissue to the depth of the sulcus. The other methods have their advantages and indications. In any case, the control of the soft tissue for exposing the margins of the tooth preparation for restoration and impressioning is critical. It would be worthwhile for the clinician to understand all the choices available.

16. Boghosian A. Clinical and Material Factors in Achieving the Ideal Impression. PennWell ADA/CERP. 2008. As taken on August 14, 2012 from http://www.ineedce.com/courses/1424/PDF/ClinicalandMaterialFactors.pdf.

    ABSTRACT: Clinicians report that the impression-taking process is the most stressful restorative procedure. Key factors involved in producing clinically acceptable impressions include managing soft tissue, appropriately selecting tray and impression material, and enabling impression material to flow predictably. Managing soft tissue is the most critical step in obtaining a perfect impression. Tray selection also plays a significant role with tray choice depending on the clinical situation and on the impression material and technique used. The most commonly used elastomeric impression materials are polyether (PE) and vinyl polysiloxane (VPS) chemistries. Appropriate use of either will produce a clinically accurate impression. The material must have an adequate working time and flowability, and have sufficient tear strength to prevent tearing at thin areas at the margin. Using a hydrophilic impression material and a surface modifier will permit enhanced flow and result in a more accurate and detailed impression. In addition, the impression must be dimensionally stable for a

reasonable time until it is cast. Achieving clinically acceptable impressions requires clinical expertise and appropriate materials, trays, and techniques.

17. Poss, S. Minimally Invasive tissue Management for Restorative Procedures. PennWell ADA/CERP. www ineedce.com. 2007. As taken from on August 14, 2012. http://www.kerrdental.com/index/cms-filesystem-action?file=KerrDental-Products-Articles/poss-minimallyinvasive-ce.pdf

ABSTRACT: The clinical success and longevity of restorations depend on a number of factors, including the initial accuracy of the restoration. Factors attributed to restoration accuracy have included the degree of clinical expertise; properties of impressions, stone and die, and restorative materials; and the conditions under which impressions are taken and restorations completed. When restorations are placed with sub-gingival margins, it is essential that the operative site is clear of debris, dry and that the margins are accessible. This requires gingival retraction, which can be carried out using a number of methods, including retraction cord, copper bands, rubber dams, electrosurgery, and lasers, as well as polymers and pastes. Selection of the appropriate method depends on clinical demands and preferences, the individual patient, and consideration of the potential advantages and disadvantages. Ideally, gingival retraction should be quick, user-friendly, patient friendly, painless, and inexpensive. The use of modern techniques and materials has made possible minimally-invasive and tissue-friendly gingival retraction that preserves periodontal health while enabling clear, dry access to sub-gingival margins.

18. Belozerskaya GG, et al. Local Hemostatics (A Review). Pharmaceutical Chemistry Journal 2006;40(7):353-359.

This review is intended to generalize data concerning the use of drugs with various structures and mechanisms of action, as well as their combinations for the arrest of local bleeding. Local hemostatics can be, albeit quite conditionally, classified into the following groups: (1) Agents producing vasoconstrictive and proaggregant effects; (2) Compounds inducing the transition of blood proteins into solid state and reducing vessel permeability by means of protein denaturation; (3) Compounds stimulating the aggregation and adhesion of formed elements and accelerating fibrin formation; (4) Plasma coagulation factors; (5) Fibrinolysis inhibitors; (6) Combined preparations. The international pharmaceutical market offers a number of mineral hemostatics, which are widely used in dentistry for the arrest of bleeding, including rasestiptin or septodont (containing aluminum chloride and hydroxyquinoline sulfate), imodent (containing 21.3% aluminum chloride) rastrigent (25% aluminum sulfate solution), and stasis (aqueous iron sulfate solution).

To summarize, there are many single-component and combined preparations possessing hemostatic activity and intended for local application. All such products have certain limitations and are intended for use in various clinical conditions. The

specific pharmacological activity was tested under various conditions (in patients with different experimental models, and in various organs and tissues). We believe that, along with the developmental of new products, it would be expedient to perform comparative evaluation of various local hemostatics under identical experimental model conditions. Such comparative tests would provide useful information concerning the character of action of the existing preparations and indicate the promising directions of further search for effective local hemostatics.

19. Stewardson D. Trends in Indirect Dentistry: 5. Impression Materials and techniques. Dent Update. 2005 Sep;35(7):374-6, 379-80, 382-4 passim.

    ABSTRACT: A fundamental pre-requisite for the construction of satisfactory indirect restorations is the ability to record an accurate and detailed impression of the dental structures. Knowledge of the key properties of the available impression materials and their handling behavior is necessary if they are to be used effectively. A variety of techniques can be employed in different situations, each of which can be highly successful, but only if attention is paid to the detail of their execution and the clinician is aware of their individual limitations and pitfalls. Where imperfections occur, an appreciation of how they have been caused, and the strategies to take to prevent them, will lead to greater success in impression taking.

20. Poss S. An Innovative Tissue-Retraction Material. Compendium. 2002 Jan;23(1):13-17.

    ABSTRACT: One of the most challenging problems of fixed prosthodontics is tissue control. Gingival retraction before a final impression can be very frustrating and time consuming. Many different techniques have been developed over the years to accommodate the clinician's struggle to obtain tissue control and achieve an ideal impression. This article discusses several of those techniques and how the new, innovative product Expa-syl™ can be incorporated into these techniques. Expa-syl™ is an injectable retraction and hemostatic agent that can cause little trauma to the tissue as well as save the dentist time and money. The author elaborates on the multiple uses of Expa-syl™ and the correct techniques for making this material a successful took in any dental office.

21. Ch. 5. Hemostatics, astringents and gingival retraction products. ADA guide to dental therapeutics / American Dental Association. Chicago, Ill. : ADA Pub., c2003

    This publication summarizes different bleeding disorders and different types of hemostatics and astringents used in the dental office to control bleeding. As noted throughout, "An understanding of hemostasis, identification of patients with excessive bleeding tendencies, and interventions to stop abnormal bleeding is essential to the provision of safe and appropriate dental care. For slow blood flow and oozing, a combination of hemostatics can be used. The three kinds of hemostatics to be noted here are absorbable hemostatic agents, agents that modify blood coagulation and

vasoconstrictors. Aluminum chloride is an astringent that causes contraction or shrinkage of tissues, making it useful in retracting gingival tissue. It also reduces secretions and minor hemorrhage."

22. Fischer D. Tissue Management Needs for Adhesive Dentistry Now and in the Future. Esthetic Dentistry. 1998;42(4):595-605.

    This article discusses dental impressions, direct restorative dentistry, and the current and future needs for tissue management. Hemostasis and other tissue control are important for proper impression making. A bonding procedure should never be performed in the presence of blood, and with astringent hemostatics such as alum, aluminum chloride and ferric sulfate, there is seldom a need for bonding procedures to be compromised.

23. Strassler H, et al. Tissue Management, Gingival Retraction and Hemostasis. www.oralhealthgroup.com. 2007. Retrieved 26 Sep 2012 from http://www.oralhealthgroup.com/news/tissue-management-gingival-retraction-and-hemostasis/1000519731/.

    One of the most challenging aspects of crown and bridge is management of the gingival tissues when making an impression. Tissue management includes placing the gingival tissues away from the preparation margins so they can be impressed combined with proving for hemostasis when the gingival tissues are susceptible to bleeding. The rationale for tissue management is a critical aspect of impression making whether the impression is made with a conventional impression material or by a digital impression technique so that all tooth preparation margins are captured in the impression to assure an excellent marginal fit of a laboratory fabricated restoration.

24. Thomas M, et al. Nonsurgical Gingival Displacement in Restorative Dentistry. Compendium of Continuing Education in Dentistry. June 2011. As taken from www.cdeworld.com on 26 Sep 2012. http://www.cdeworld.com/courses/4521-nonsurgical-gingival-displacement-in-restorative-dentistry.

    ABSTRACT: Gingival displacement is critical for obtaining accurate impressions for the fabrication of fixed restorations, especially when the finish line is at or just within the gingival sulcus. Displacement of the gingival tissue is also important when dealing with the restoration of cervical lesions due to their proximity to the periodontal tissue. The methods of gingival tissue displacement can be broadly classified as nonsurgical and surgical techniques, with nonsurgical being the more commonly practiced method. Dentists must alter their armamentarium and gingival displacement techniques to meet specific demands and obtain predictable results. Hence, the purpose of this article is to describe the different means by which nonsurgical gingival displacement can be achieved effectively under a variety of clinical situations.

VI. Literature Summary

A. Efficacy:

Aluminum Chloride has been used to control bleeding and sulcular fluids during dental procedures for over twenty-five years. Current, available literature provides evidence of its reliability as an effective material in retracting gingival tissue and reducing secretions and minor bleeding (7,13,16,18,20,21) with multiple articles discussing the use of 20-25% aluminum chloride being the most common and effective (11, 15, 18, 23, 24). ViscoStat Clear, with a 25% total aluminum chloride value, hits this standard of practice and thus proves to be an effective product for dental tissue management procedures. Gingival retraction, using a retraction cord soaked in an astringent or vasoconstrictor, is a common and popular procedure in dentistry (1, 5, 12,15-17) with the cord commonly soaked in an aluminum chloride or ferric sulfate solution prior to placement (11,15). It is noted that retraction cord methods can damage the gingival epithelial tissue (8) because of tissue manipulation, but this can be mitigated with proper technique (8,14). Without proper control of fluids, dental impressions can be negatively affected (7,15-17,22) because of poor margin definition (19,22). A concern lies within the accuracy of the impression when using this technique. One study investigated the effect of retraction cord with aluminum chloride had on the dimensional accuracy of an impression material (11). This study showed that the accuracy was within ADA guidelines. In addition to impression accuracy, there is a concern that the bond strength of the restorative material can be affected when the dentin surface is contaminated with dental hemostatic agents. Both in-house testing, and literature show that bond strength is not negatively affected by Viscostat Clear (in-house testing) or other hemostatic agents containing aluminum chloride (9,10).

The use of retraction cords and aluminum chloride agents such as those currently approved and released on the market (Racegel and Expasyl) and the proposed Viscostat Clear prove to be a benefit to the dental practitioner because of their ability to control sulcular fluids and minor bleeding throughout the restoration process. Each of the articles above presents the efficacy of aluminum chloride in this field. Viscostat Clear utilizes aluminum chloride, an established dental hemostatic, and will provide another option to the licensed dental practitioner.

B. Safety:

The safety of Viscostat Clear has been previously established through biocompatibility testing and clinical research illustrating the long historical use of aluminum chloride in the dental field. There is no new technology introduced in Viscostat Clear and there are multiple, similar devices released and used in the dental arena that utilize aluminum chloride as the active ingredient to control sulcular fluids and control bleeding during dental procedures. Current literature studies reflect this (6). Multiple studies

investigate Expasyl®, a 15% aluminum chloride paste. The first compares Expasyl® to gingival retraction cord (1) and another to Stasis®(2). Although both showed gingival inflammation, the cordless technique did not induce bleeding during or after retraction (1) and the inflammatory reactions were limited to the bone defects in the second study (2). ViscoStat Clear will be used in conjunction with the retraction cord so bleeding will be controlled and all procedures, cordless and corded; will promote some sort of inflammation as tissues are being manipulated outside of their normal function. Other studies on a 25% aluminum chloride device also conclude that the produce induces significant inflammatory response on gingival tissue (3) or in cultured cells (4,5). However, each of these includes a protocol where the product was left in contact for 10 minutes or longer. The study by Nowakowska (5) included a 3 and 5 minute time interval as well which shows 40-70% cell viability after exposure. Viscostat Clear instructions recommends a contact time of 1-3 minutes, which will help reduce the inflammatory response.

In addition to the studies presented for safety, there are numerous studies available which demonstrate the safe use of dental hemostatic agents (6). Significant research has been performed which indicate that aluminum chloride is safe when used as directed by a dental professional.

C. Product Literature and Instructions for Use:

The labeling, literature and instructions for use (IFU) for Viscostat Clear are consistent with the clinical data and predicate devices. All hazards and other clinically relevant information that may impact the use of the device or safety of the patient are included within these.

VII. Conclusions

These studies and reviews, in conjunction with the product risk analysis, supporting biocompatibility test result, and complaint history demonstrate that the safe and effective use of Viscostat Clear when used as directed by licensed dental professionals. The use of ViscoStat Clear, as compared to similar product already approved and released on the market, does not pose any undue risks to patients when used as directed. The risks associated with the use of Viscostat Clear are acceptable when weighed against the benefits to the patient.

VIII. Clinical Literature Evaluator(s)

Refer to attached CVs for each evaluator

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RP019.1

Journal of Clinical Periodontology

J Clin Periodontol 2008; 35: 1053–1058 doi: 10.1111/j.1600-051X.2008.01335.x

Journal of Clinical Periodontology

A clinical study on the effects of cordless and conventional retraction techniques on the gingival and periodontal health

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Al Hamad KQ, Azar WZ, Alwaeli HA, Said KN. A clinical study on the effects of cordless and conventional retraction techniques on the gingival and periodontal health. J Clin Periodontol 2008; 35: 1053–1058. doi: 10.1111/j.1600-051X.2008.01335.x.

Abstract

Aim: To investigate the influence of two cordless techniques on the periodontium in comparison with conventional cords.

Material and Methods: Dental students ($n = 60$) with healthy gingival conditions were recruited – an expanding poly vinyl siloxane material (Magic Foam Cord®), a paste-like material (Expasyl®), and a conventional retraction cord (Ultrapak®) were applied on the buccal aspects of three premolars of each subject. Probing depth, clinical attachment level, gingival index (GI), plaque index, mobility, bleeding, and sensitivity were assessed at baseline, and at 1 and 7 days after application. Data were analysed using Kruskal–Wallis and Mann–Whitney tests ($\alpha = 0.05$).

Results: The periodontal parameters were not statistically significant among the groups at all time intervals except for the GI, which was increased for all groups after 1 day. The highest was in Expasyl ($p = 0.011$). After 7 days, the GI returned to a non-significant level compared with baseline except for Expasyl, which was still significant ($p = 0.044$). Expasyl induced sensitivity in four subjects. Bleeding was only induced by Ultrapak in 28.3% and 26.7% during and after retraction, respectively.

Conclusions: All techniques caused a temporary gingival inflammation; the greatest was in Expasyl, which also showed slower recovery. Cordless techniques did not induce bleeding during or after retraction.

Key words: cordless techniques; gingival displacement; gingival health; retraction cord

Accepted for publication 7 September 2008

Introduction

Management of the gingival tissues is essential for obtaining accurate impressions for the fabrication of fixed restorations, particularly when the finish line is at, or just within, the gingival sulcus (Goldberg et al. 2001, Rosenstiel et al. 2006, Hansen et al. 1999, Perakis et al. 2004, Donovan & Chee 2004). This is also true when dealing with procedures for the restoration of cervical lesions due to their proximity to the periodontal tissue (Meraner 2006).

Gingival displacement is defined as the deflection of the marginal gingiva away from the tooth (Glossary of prosthodontics; The Academy of Prosthodontics, 2005). This is performed to create sufficient lateral and vertical space between the preparation finish line and the gingival tissue to allow the injection of adequate bulk of impression material into the expanded gingival crevice (Nemetz et al. 1984, Weir & Williams 1984, Benson et al. 1986, Cassidy & Gutteridge 1994). It is especially critical when using hydrophobic impression materials that do not displace the gingival tissues (Wassell et al. 2002). Numerous forces act to return the tissues to their original position, such as the elasticity of the gingival cuff around the tooth and the rebound forces of the compressed adjacent attached gingiva during retraction (Livaditis 1998). The critical sulcular width has been reported to be approximately 0.15–0.2 mm at the level of the finish line. Impressions with less sulcular width have higher incidences of voids, tearing of impression materials, and reduction in marginal accuracy

Conflict of interest and source of funding statement

The authors declare that they have no conflict of interests.

No external funding, apart from the support of the authors' institution, was available. Magic Foam Cord® was supplied free of charge by Coltene Whaledent AG, Altstätten, Switzerland.

(Laufer et al. 1996, 1997, Baharav et al. 2004, Donovan & Chee 2004).

Retraction techniques can be classified as mechanical, chemical or surgical, and are often used in combination. The use of retraction cords as a mechanical or chemo-mechanical technique is well established in practice due to their relative predictability, effectiveness, and safety compared with rotary gingival curettage and electrosurgery (Benson et al. 1986, Hansen et al. 1999). However, the use of retraction cord can be laborious, time-consuming, can cause gingival bleeding, uncomfortable for patients in the absence of anaesthesia, and when inappropriately manipulated, can lead to direct injury and gingival recession (Ruel et al. 1980, de Gennaro et al. 1982, Azzi et al. 1983, Feng et al. 2006). Various haemostatic agents with varying degrees of safety and effectiveness are available such as aluminium potassium sulphate (Alum), aluminium chloride, epinephrine, zinc chloride, ferric sulphate and sympathomimetic amines. Recently, cordless techniques have been introduced with several claimed advantages, such as time-savings and enhanced patient comfort while being minimally invasive. Expasyl® (Kerr Corp., Orange, CA, USA) is a paste-like gingival retraction material that depends on the haemostatic properties of aluminium chloride and the hygroscopic expansion of kaolin upon contact with the crevicular fluid, to provide mild displacement of the gingiva in about 2 min. (Lesage 2002). Aluminium chloride has been reported to be irritant in moderate concentrations and caustic in high concentrations. It is sold in a stable acidic buffer, resulting in an etched dentine (Donovan et al. 1985, Felpel 1997, Polat et al. 2007).

Magic Foam Cord® (Coltène Whaledent AG, Altstatten, Switzerland) is an expanding poly vinyl siloxane material designed for easy and fast retraction of the sulcus without the potentially traumatic and time-consuming packing of retraction cord.

Most studies on cordless techniques are demonstrations of their clinical use; their effects on the gingival and periodontal tissues are not well documented (Poss 2002, Shannon 2002, Smelltzer 2003).

Yang et al. (2005) investigated two cordless techniques: Expasyl and Korlex-GR® (Biotech-one, San-Chung, Taiwan) and compared them with Ultrapak® cords (Ultradent Products Inc., South Jordan, Utah). The authors reported no significant difference in achieving gingival deflection, but reported that the use of Ultrapak appeared to be more painful and produced more gingival recession than the cordless technique(s).

This study was conducted to investigate the influence of Expasyl and Magic Foam Cord on the gingival and periodontal tissues in comparison with conventional retraction cord.

Material and Methods

Fourth and fifth year dental students at the Jordan University of Science and Technology were recruited for the study on March 2007, according to the following inclusion criteria: currently enrolled student with no relevant medical history; non-smoker or quit smoking for at least 6 months before the study; with at least three premolars in one of the two arches. The selected premolars were screened for periodontal health and teeth included in the study were those with a gingiva not expressing a highly scalloped margin and at least 2 mm of keratinized tissues, non-fibrotic gingival tissues, no recession, probing depths of $\leq$3 mm, no evidence of significant loss of attachment, no bleeding on probing, and scored 0 or 1 according to the gingival and plaque indices (Löe 1967, Palmer & Floyd 1995).

The study protocol was approved by the health and safety committee for research on humans at Jordan University of Science and Technology, and by the college of dentistry-related committees. The selected participants gave their consent after they were informed about the purpose, procedures, and duration of the study.

The study was performed at the periodontal clinics of the dental health teaching centre, Jordan University of Science and Technology. Probing depth (PD), clinical attachment level (CAL), gingival index (GI), plaque index (PI), and mobility were recorded for the buccal aspects of the selected teeth before gingival retraction was initiated. Subjects were also asked to report the presence or absence of sensitivity (subjective reporting). Cold air test for sensitivity was also performed on the selected teeth through a one second application of cold air from a dental unit syringe (at 20 ± 3°C at 60–65 psi). The same measurements were again recorded on the first and seventh days post-retraction (Löe 1967, Holland et al. 1997). Periodontal probing to the bottom of the sulcus was conducted on the buccal aspect of every selected tooth with Williams probe (Hu-Friedy Manufacturing Inc., Chicago, IL, USA). This probe had a tapered tip with a diameter of 0.5 mm, and markings consisted of milled grooves and were situated at 1, 2, 3, 5, 7, 8, 9, and 10 mm from the tip. The probe was held with a light grasp and pointed towards the apex buccally while being parallel to the long axis of the tooth. Each measurement was rounded to the lowest whole millimetre. Clinical attachment loss measurement was then recorded as the distance from the CEJ to the base of the probable crevice.

The GI was recorded for every selected premolar based on the modification of the method of Löe & Silness (1963). Bleeding also was observed within 15 s after probing, or if there was any tendency to spontaneous bleeding.

For purposes of calibration, a pilot study was conducted during which an experienced periodontist measured the periodontal parameters for selected quadrants on four subjects. The principal investigator randomly repeated the measurements 30 min. later on the same subjects, and subsequently. Duplicate measurements were obtained to measure the reliability of the examination using percent agreement, Kappa test, which revealed more than 95% agreement in parameter assessment.

The following gingival deflection techniques were used on the buccal aspect of the premolars: Ultrapak knitted non-impregnated retraction cord (Ultradent Products Inc., Ref. No. BØ456, LOT UP131), Magic Foam Cord (Coltene Whaledent AG, Art. No. 6735, LOT 0078546), and Expasyl (Kerr Corp., Ref. No. 261030, LOT 3104). Each technique was applied to the buccal gingival sulcus along the distance from the mesial to the distal papilla of the selected premolar.

Three premolars were selected in one arch for each subject to receive the three retraction techniques. Each tooth was assigned a number from 1 to 3 starting from the most distal premolar in the right side of the subject. The middle premolar was assigned number 2 and the last premolar number 3. Each tooth received one retraction technique. Maxillary premolars were chosen in half of the subjects and mandibular premolars were chosen for the other. The sequence of application was chosen taking in consideration the recommended time

Table 1. Subject distribution for periodontal parameters at the three visits for each technique (E, Expasyl®; M, Magic Foam®; R, Ultrapak® Cords)

Parameter	Subjects distribution, $n = 60$								
	before retraction			1 day post-retraction			7 days post-retraction		
	E	M	R	E	M	R	E	M	R
PD (mm)									
1	10	11	9	8	10	9	12	11	13
2	37	30	29	33	31	34	30	32	33
3	13	19	22	19	19	17	18	17	14
4	0	0	0	0	0	0	0	0	0
Mean ± SD	2.05 ± 0.62	2.13 ± 0.70	2.22 ± 0.69	2.2 ± 0.68	2.15 ± 0.68	2.13 ± 0.65	2.1 ± 0.70	2.1 ± 0.68	2.02 ± 0.67
GI									
0	36	34	35	18	25	26	29	36	34
1	24	26	25	18	28	24	20	21	20
2	0	0	0	24	7	10	11	3	6
PI									
0	46	45	47	47	48	48	45	43	45
1	12	15	12	11	10	10	13	16	14
2	2	0	1	2	2	2	2	1	1
Sensitivity									
− ve	60	60	60	56	60	60	56	60	60
+ve	0	0	0	4	0	0	4	0	0
Mobility									
0	60	60	60	60	60	60	60	60	60
CAL (mm)									
0	60	60	60	60	60	60	60	60	60

PD, probing depth; GI, gingival index; PI, plaque index; CAL, clinical attachment level.

of placement for each technique. Ultrapak was applied first as it has the longest possible time of application (10 min.) (Löe & Silness 1963), followed by the Magic Foam Cord (5 min.), and then by Expasyl (2 min.). The sequence of retraction techniques allocation was in the order of teeth number 1, 2, 3. In the next subject the order was changed to 2, 3, 1 and then to 3, 1, 2. The order was changed in the next subject back to 1, 2, 3 and so on. The whole procedure was practised before starting the study.

Tissue displacement was preceded with isolation and drying of the area. Appropriate Ultrapak cord size and length was chosen and wetted with water, and was packed gently in the buccal gingival sulcus with a plastic instrument without anaesthesia and kept in the gingival sulcus no more than 10 min.; during that time, the other two materials were applied on the remaining premolars. A suitable Comprecap size was selected and adjusted proximally to allow its placement and Magic Foam was syringed into the buccal sulcus around the premolar and the Comprecap was placed for 5 min. Expasyl was extruded into the buccal sulcus using the gun at even pressure, the tip was perpendicular to the axis of the tooth, and then it was pressed against the tooth and angled until it contacted the sulcus lining of the gingival margin (Lesage 2002). Expasyl was left in place for 2 min. All materials were removed at the same time; the cord was removed manually, while cordless materials were copiously irrigated with water until no traces of materials were left. The same procedure was repeated in every eligible subject.

The presence or absence of bleeding during and after the procedure was recorded for each technique.

The whole study was carried out by two researchers: one was responsible only for the application of the retraction materials, and the other carried out the rest of the study. The researcher who recorded the periodontal parameters was unaware of the technique applied on the tooth. The data were analysed using Statistical Package for Social Sciences software (version 15.0; SPSS Inc., Chicago, IL, USA). Kruscal–Wallis and Mann–Whitney tests were used to analyse the differences of the periodontal parameters among the three materials and the differences among the three visits within each material applied ($p \leq 0.05$). With regard to sensitivity and evaluation of bleeding within and after the procedure, simple descriptive statistics were computed using the frequency and descriptive procedures of SPSS.

Results

One hundred and eighty premolars in 60 subjects free of clinical signs of gingivitis participated in this study. The sample size was determined in consultation with a statistician. The participants were between 20 and 29 years of age with a mean of (22.32 ± 1.900). Most subjects (93.3%) were between 21 and 26 years, with 56.7% females and 43.3% males. Premolars were equally distributed between the two arches.

Mobility and CAL measurements were not different among the three groups. Sensitivity was only induced by Expasyl in four subjects at the 1 and 7 days period (Table 1). Means of PD for all techniques are presented in Table 1. Mean ranks of PD, GI, and PI are presented in Tables 2–4 for the Expasyl, Magic Foam Cord, and Ultrapak, respectively. Kruskal–Wallis test was used to compare the mean ranks between the three groups at the three times intervals ($p = 0.05$). Mann–Whitney test was used for two-way comparisons and the significant difference is presented in the tables by superscripts. The GI, PD, and PI values at the baseline measurements were homogenous among the three groups. The PD and PI values were not significantly different among the groups at all time intervals.

Table 2. Mean ranks of probing depth (PD), gingival index (GI), and plaque index (PI) for the Expasyl® group (*p*-value using Kruskal–Wallis test)

Parameter	Time	*n*	Mean rank	*p*
PD	Before retraction	60	85.81	0.918
	1 day after retraction	60	95.84	
	7 days after retraction	60	89.85	
GI	Before retraction	60	71.00[a]	0.001
	1 day after retraction	60	112.15[b]	
	7 days after retraction	60	88.35[c]	
PI	Before retraction	60	90.50	0.496
	1 day after retraction	60	89.05	
	7 days after retraction	60	91.95	

Mean ranks with different superscripts are significantly different ($p \leq 0.05$ using Mann–Whitney test).

Table 3. Mean ranks of probing depth (PD), gingival index (GI), and plaque index (PI) for the Magic Foam Cord® group (*p*-value using Kruskal–Wallis test)

Parameter	Time	*n*	Mean rank	*p*-value
PD	Before retraction	60	90.98	0.917
	1 day after retraction	60	92.02	
	7 days after retraction	60	88.51	
GI	Before retraction	60	84.83[a]	0.046
	1 day after retraction	60	102.54[b]	
	7 days after retraction	60	84.13[a]	
PI	Before retraction	60	90.63	0.614
	1 day after retraction	60	86.93	
	7 days after retraction	60	93.94	

Mean ranks with different superscripts are significantly different ($p \leq 0.05$ using Mann–Whitney test).

Table 4. Mean rank of probing depth (PD), gingival index (GI), and plaque index (PI) for the Ultrapak® group (*p*-value using Kruskal–Wallis test)

Parameter	Time	*n*	Mean rank	*p*-value
PD	Before retraction	60	97.29	0.256
	1 day after retraction	60	91.08	
	7 days after retraction	60	83.13	
GI	Before retraction	60	82.67[a]	0.076
	1 day after retraction	60	101.27[b]	
	7 days after retraction	60	87.57[ab]	
PI	Before retraction	60	89.90	0.83
	1 day after retraction	60	88.77	
	7 days after retraction	60	92.83	

Mean ranks with different superscripts are significantly different, while mean ranks with "ab" superscript are at no significant difference with those with "a" or "b" superscripts ($p \leq 0.05$ using Mann–Whitney test).

The use of Ultrapak resulted in a slight decrease in the mean of the PD values after 1 day (2.13 mm) and a further decrease after 7 days (2.02 mm) compared with the baseline (2.22 mm). The mean of the PD for the Magic Foam group almost had the same values (2.13, 2.15 mm, 2.10 at baseline, 1, and 7 days, respectively). The values of the PD for the Expasyl group showed a slight increase from 2.05 mm at baseline to 2.2 and 2.1 mm at 1 and 7 days after retraction.

All techniques resulted in a significant increase in the GI values (Table 1). Mann–Whitney tests demonstrated that the increase in GI means after 1 day by all techniques was significant compared with their baseline measurements (Tables 2–4). The highest increase was induced by Expasyl and was also significantly different from the other groups. After 7 days, the GI for the three retraction techniques decreased to a non-significant level compared with their baseline measurements except the Expasyl group (Table 4).

Bleeding during and after each retraction material was encountered only with the use of Ultrapak. Bleeding during placement happened in 28.3% and after removal in 26.7% of the subjects.

Discussion

A narrow young age range group was studied and teeth were equally distributed between maxilla and mandible, which eliminated age/gender influence and ensured little variation in gingival thicknesses. This allowed using the same size of Ultrapak cord in all subjects (size one) to minimize differences among the groups. Only buccal aspects of premolars with comparable features in terms of periodontal clinical features were selected, also because premolars offered good visibility and accessibility.

The sequence of applications was selected taking in consideration the recommended time of placement for each technique. Ultrapak has the longest possible time of application (10 min.). Retraction cords have been reported to cause necrosis of the crevicular epithelium when placed longer than 10 min. (Löe & Silness 1963). This allowed the application of Magic Foam Cord for 5 min., and then Expasyl for 2 min. as recommended by the respective manufacturers.

This study investigated the effects of different retraction techniques on gingival and periodontal health and did not test the effectiveness of gingival displacement. The use of unprepared teeth was beneficial, because the adverse effects of preparation and provisionlization steps on the gingival tissue were avoided. This provided the study with a homogenous group, as shown by the periodontal baseline measurement (Table 1). On the other hand, because the retraction materials were applied to structurally healthy teeth, in which no crown preparation was performed, one could argue that the results may not be extrapolated to the clinical reality. In order to minimize the possible effects of this on the results, every attempt was made by the expert prosthodontist to apply these materials in the same way as they would be used with prepared teeth. The technique and time of application was strictly followed according to the manufac-

turer's instructions and the relevant literature on conventional retraction cords. The Comprecaps were adjusted proximally to allow a proper placement over the unprepared teeth.

Clinical diagnostic indicators including PD, CAL, GI, PI, mobility, and sensitivity were used to evaluate periodontal health in this study. These indices have been developed to identify the degree of severity of gingival and periodontal disease by analysing the degree of gingival inflammation in gingivitis and the degree of connective tissue destruction in periodontitis. They are easy to perform, cost-effective, and relatively non-invasive. Clinical probing is the most commonly used parameter both to document loss of attachment and to establish a diagnosis of periodontitis. There are, however, some sources of error inherent to this method which contribute to the variability of the measurements. These include the tip of the probe, probing force, placement and angulations of probing, and the crudeness of the measurement scale (Lang & Corbet 1995). In this study, a 0.5 mm probing tip was used in a light force and the placement and angulation was standardized to minimize the variability in measurements. Probing depth is generally assessed to the nearest millimetre (Glavind & Löe 1967). It is evident that even a measurable loss of attachment of 0.5 mm accepts a high incidence of false negative values, which, in turn, means that "true" disease progression may actually occur, but only to a small extent which is not revelled by the crudeness of the measurement scale (Lang & Corbet 1995). Ultrapak use caused PD reduction (about 0.1 mm in 1 day and about 0.2 mm after 7 days). Such reduction is possibly of some clinical importance because it might imply gingival recession. It may have occurred as result of low-grade trauma due to impaction of foreign bodies (retraction cord) on the gingival tissue. Direct injury to the gingiva through mechanical procedures often shows obvious and immediate changes (de Gennaro et al. 1982, Feng et al. 2006). Previous studies reported that gingival retraction with cord caused destruction of the junctional epithelium that took 8 days to heal and caused gingival recession of about 0.2–0.1 mm (Ruel et al. 1980, Wassell et al. 2002). This study did not demonstrate that at a significant level, due probably to the crudeness inherent in the PD measurement. The fact that no anaesthesia was used could have resulted in reduction of the force of impaction. Dentists tend to increase the force of cord placement in the absence of pain. None of the other materials caused any significant changes on PD mean after 1 or 7 days. As mentioned previously, the use of structurally healthy teeth may imply that the retraction techniques could have been used in a different way, causing a different packaging force in the sulcus. Nevertheless, similar results were reported by Yang et al. (2005), who found that the greatest amount of gingival recession was demonstrated by the use of epinephrine-impregnated cord while the recession observed in the cordless techniques was too small and clinically insignificant.

The GI is a valuable tool in assessing gingival condition (Löe & Silness 1963). This index is probably the most widely used index in clinical trials, and provide a more objective assessment of gingivitis than do indices which rely solely on visual criteria (Lang & Corbet 1995).

All techniques caused gingival injury after the first day as shown by the significant increase of GI. This may be explained by the reaction of the inflammatory cells to the mechanical or chemical trauma (de Gennaro et al. 1982). However, when the three groups were compared after the first day, the greatest increase was significantly evident in the Expasyl group, while Ultrapak and Magic Foam groups showed similar increase. Expasyl contains 15% aluminium chloride, which has been reported to result in local tissue damage and transient ischemia in concentrations higher than 10% (Donovan et al. 1985, Felpel 1997, Polat et al. 2007). All groups showed tissue recovery after 7 days. Magic Foam showed the best healing followed by Ultrapak. Expasyl group showed slower healing, and was still significantly different from the baseline measurements. The results for the Ultrapak group in this study were similar to those reported by Feng et al. (2006) who reported that GI was the highest in the first and second day after placement of retraction cord, but it appeared clinically to reverse itself in 2 weeks.

Dentine sensitivity is dependent on exposure and patency of the dentinal tubules (Addy 2002, Banfield & Addy 2004). Expasyl induced sensitivity in four subjects. This might be attributed to its acidity, which may have affected the patency of the dentinal tubules (Baharav et al. 1997). In addition, it was noticed that Expasyl caused a degree of dryness, which although was a desirable characteristics for making successful impressions, it may have resulted in sensitivity.

Bleeding during and after application was only observed with the use of the non- impregnated Ultrapak cord. Retraction cord is usually used in combination with local anaesthesia and a haemostatic agent to provide better control over bleeding. Homeostasis was controlled by the aluminium chloride in the Expasyl group, while the Magic Foam was only applied with little pressure on the gingiva. This was similar to the findings reported by Yang et al. (2005) who found that less bleeding and pain was observed with the cordless techniques compared with the use of traditional retraction cord.

This study did not investigate the efficiency in achieving gingival deflection among the three techniques. This area requires further research to provide the clinicians with valuable clinical information on the efficiency of the cordless techniques.

Each type of retraction appears to possess desirable characteristics. It is imperative to match positive characteristics to a particular challenge presented by each unique patient, clinical condition, and specific abutment.

Conclusions

This study showed that all retraction techniques caused an acute injury after 1 day of retraction, which took 1 week to heal in the Ultrapak and the Magic Foam groups. The Expasyl group had the highest GI compared with others, and showed slower healing. Its use might cause sensitivity in a small number of cases. The use of cordless techniques did not require haemostatic agent to control bleeding during retraction.

Acknowledgements

The authors thank Dr. Dierk Lübber, Coltene Whaledent AG, Altstatten, Switzerland, for providing the Magic Foam Cord® in this study.

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Clinical Relevance

Scientific rationale for the study: The present study is the first to investigate the effects of using cordless techniques on the gingival and periodontal health in comparison with conventional retraction cords.

Principal findings: The data indicated that all retraction techniques caused a temporary inflammation, measured through the gingival index. The recovery at 7 days was slower for Expasyl.

Bleeding during or after retraction was only encountered with the use of conventional retraction cords.

Practical implications: This study showed that none of the techniques tested seems to harm the tissues in the long term; however, clinicians should be aware that Expasyl use is less friendly to the gingival tissues. Cordless techniques do not require haemostatic agents to control bleeding.

In vivo safety & efficacy

(2)

doi:10.1111/j.1365-2591.2006.01152.x

Haemostatic agents used in periradicular surgery: an experimental study of their efficacy and tissue reactions

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Abstract

von Arx T, Jensen SS, Hänni S, Schenk RK. Haemostatic agents used in periradicular surgery: an experimental study of their efficacy and tissue reactions. *International Endodontic Journal*, **39**, 800–808, 2006.

Aim To evaluate the haemostatic efficacy and the histologic tissue responses after the application of different haemostatic agents used in periradicular surgery.

Methodology The study was conducted in the calvarium of six rabbits. Standardized bone defects (diameter 4 mm) were trephined, and different haemostatic agents were applied and compared with control defects: bone wax (left for 10 min), Stasis® (ferric sulphate, left for 5 s), Expasyl™ (aluminium chloride, left for 2 min and left permanently *in situ*), and a combination of Expasyl™ (2 min) and Stasis® (5 s). The sites were photographed before the application and after the removal of the haemostatic agents. Three independent examiners judged the initial and final bleeding (on the photographs) using a bleeding score for each site and treatment. The results were compared using Wilcoxon's signed rank test. For the histologic analysis, three animals were killed after 3 weeks and three animals after 12 weeks. Transverse, nondecalcified sections were stained with combined basic fuchsin and toluidine blue for descriptive histology.

Results The most efficient haemorrhage control was provided by Expasyl™ in combination with Stasis® and by Expasyl™ alone, whereas bone wax had the weakest bleeding reduction effect. The histologic analysis after 3 weeks demonstrated an inflammatory and foreign body tissue response towards all haemostatic agents. At 12 weeks, this tissue response was less pronounced but still present in sites treated with bone wax or Expasyl™. In general, the inflammatory tissue reactions were limited to the bone defects, and never extended into the surrounding tissues.

Conclusions Expasyl™ alone or in combination with Stasis® appeared to be the most efficient of tested agents to control the bleeding within the bony defects created in a rabbit calvarium model.

Keywords: aluminium chloride, bone wax, ferric sulphate, haemorrhage control, periradicular surgery.

Received 23 January 2006; accepted 28 March 2006

Introduction

One of the objectives of periradicular surgery following root-end resection is to hermetically seal the root canal system, thereby enabling healing by forming a barrier between the irritants within the confines of the affected root and the tissues surrounding the root. Haemorrhage control is an essential step in periradicular surgery, allowing adequate intra-operative diagnostic evaluation of the root-end, of the resected surface, and of the root-end preparation (Witherspoon & Gutmann 1996). In addition, it is a prerequisite for placement and setting of most root-end filling materials. Inadequate visibility due to copious bleeding at the surgical

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site can be frustrating and time-consuming to control (Kim & Rethnam 1997).

Various agents and techniques have been promoted for haemorrhage control during periradicular surgery. Locally applied haemostatic agents can be classified by their mechanism of action: mechanical, vasoconstrictive, intrinsic and extrinsic. A number of studies have described the tissue reactions of haemostatic agents (Ibarrola *et al.* 1985, Alberius *et al.* 1987, Haasch *et al.* 1989, Finn *et al.* 1992, Solheim *et al.* 1992, Jeansonne *et al.* 1993, Lemon *et al.* 1993, Allison 1994). Other studies have evaluated the systemic aspects following the use of haemostatic agents or have evaluated the clinical efficacy of haemostasis in periradicular surgery (Vickers *et al.* 2002, Vy *et al.* 2004).

While bone wax is relatively easy to use, and is generally considered as both a haemostatic agent and a debris collector in periradicular surgery, wax residues may produce severe tissue reactions. As an alternative haemostatic agent, the authors have used ferric sulphate. Although the application of this haemostatic solution is very simple, oozing of blood may occur prematurely, and repetitive application results in a creamy substance making working within the bony crypt more difficult than easier. In 2001, the principle author started to use a paste containing aluminium chloride that clinically appeared to be very efficient to control bleeding in periradicular surgery. In certain situations, aluminium chloride and ferric sulphate were combined synergistically to control recurrent bleeding.

The objective of this study was to assess the haemostatic effect and to evaluate the tissue responses after application of these mentioned haemostatic agents in the standardized bone defects in the calvarium of rabbits.

Material and methods

Study design

The study protocol was approved by the authorities of the Canton of Berne (Department of Agriculture, Section Veterinary Service, Experimental Animal Studies, study number 51/03). The experimental study was conducted in six adult Burgundy rabbits, each at least 5 months old and weighing between 4 and 5 kg. Histologic analysis was conducted after healing periods of 3 weeks (three animals) and 12 weeks (three animals).

Medication of animals

All surgery was performed under intravenous general anaesthesia. The animals were premedicated with ketamine, 65 mg kg^{-1} (Narketan®; Vétoquinol, Berne, Switzerland) and xylazine, 4 mg kg^{-1} (Xylapan®; Vétoquinol), mixed and injected intramuscularly into the hind leg. Subsequently, a cannula was placed into the lateral ear vein and general anaesthesia was maintained with an intravenous infusion of ketamine and xylazine (double quantity of premedication dosage) in 100 mL physiologic saline. Each animal was given 100 000 IU benzylpenicilline intramuscularly (Duplocillin LA®; Intervet BV, Boxmeer, the Netherlands). Postoperatively, the animals were given analgesics for 3 days (Novalgin®; Aventis, Zurich, Switzerland; 50 mg kg^{-1}, once a day intramuscularly).

Surgical protocol

The animals were shaved on the top of the head between the eyes and the ears. The skin was disinfected using an iodine-polyvinylpyrrolidone solution (Betadine®; Mundipharma, Basel, Switzerland). After the subcutaneous administration of a local anaesthetic (1 mL Ultracain DS®; Aventis Pharma, Frankfurt a.M., Germany), a midline incision was made and the skin and periosteum were reflected to expose the vault of the skull. Using a bone trephine, circular bone defects (diameter 4 mm, depth 1.5 mm) were drilled into the outer cortex (tabula externa). It was attempted to avoid perforating the inner cortex (tabula interna) and thereby contacting the 'dura mater', but avoiding contact was not always possible. A total of six bony defects were created, three on each side of the sagittal suture. After the removal of the outer cortical bone plate, the six defects received one of the following treatments in a randomized sequence (concealed envelopes) (Fig. 1a):

- Control site: no haemostatic agent was placed.
- Bone wax site: bone wax (Johnson & Johnson AG, Spreitenbach, Switzerland) was placed into the bone defect with a spatula, flush with the adjacent outer cortex; after 10 min the bone wax was removed with a dental curette.
- Expasyl™ site (temporary): Expasyl™ (Pierre Rolland, Merignac, France) was placed into the bone defect with a spatula, flush with the adjacent outer cortex; after 2 min the paste was removed with a dental curette.

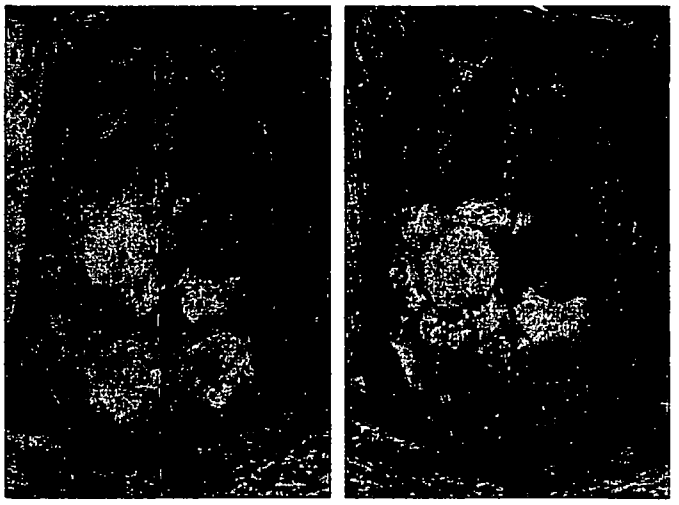

Figure 1 (a) Circular bone defects in the rabbit calvarium following placement of haemostatic agents: site 1, bone wax for 10 min; site 2, control site; site 3, expasyl™ left *in situ*; site 4, Stasis® for 5 s; site 5, Expasyl™ for 2 min and Stasis® for 5 s; site 6, Expasyl™ for 2 min. (b) Assessment of bleeding after removal of the haemostatic agents.

- Expasyl™ site (permanent): Expasyl™ was placed into the bone defect with a spatula, flush with the adjacent outer cortex; the material was left *in situ* throughout the study period.
- Stasis® site: a small foam pellet (3 × 4 × 3 mm) saturated with Stasis® (Belport Co., Camarillo, CA, USA) was placed for 5 s into the bone defect; then the sponge was removed.
- Expasyl™ and Stasis® site: Expasyl™ was placed into the bone defect with a spatula, flush with the adjacent outer cortex; after 2 min the paste was removed with a dental curette. Subsequently, a small sponge soaked with Stasis® was placed for 5 s into the bone defect, and then the sponge was removed.

Following the removal of the test agents with the dental curette (Fig. 1b), no additional bone freshening with drills was performed. The sites were rinsed with saline and wound closure was accomplished in a two-layer technique. The periosteum (galea aponeurotica) was closed using expanded polytetrafluoroethylene (ePTFE) – suturing material (Gore-Tex® Suture CV-5; W.L. Gore & Associates Inc., Flagstaff, AZ, USA). This suture material was chosen to avoid tissue reactions, as ePTFE is an inert and biocompatible material. The skin was closed with single interrupted sutures (Vicryl® 5-0; Ethicon, Johnson & Johnson, Brussels, Belgium).

Sacrifice

Following premedication with ketamine, 65 mg kg^{-1} (Narketan®; Vétoquinol) and xylazine, 4 mg kg^{-1} (Xylapan®; Vétoquinol), a cannula was placed into the lateral ear vein. Death was induced with 1.4 mL kg^{-1} pentobarbital (Nembutal®; Abbott Laboratories, Chicago, IL, USA). After a rectangular skin incision, the calvarium was removed with an oscillating autopsy saw. The retrieved specimens were immediately immersed in a solution of 4% formaldehyde and 1% calcium.

Histological analysis

The nondecalcified specimens were embedded in methyl-methacrylate and stained with combined basic fuchsin and toluidine blue. Transverse sections with a thickness of approximately 80 μm were obtained for descriptive histology (Schenk *et al.* 1984).

Visual analysis of haemorrhage control

Photos were taken before and after the application of the haemostatic agents. The amount of blood per site was assessed on a scale from 0 (completely dry defect) to 7 (profuse bleeding from the defect) (Fig. 2). Three evaluators independently examined the photos and determined the bleeding score per site. A mean bleeding score was calculated per treatment for the different sites before (=initial score) and after (=final score) the application of the haemostatic agents. The difference between the two scores determined the mean haemostatic effect per agent (reduction of bleeding).

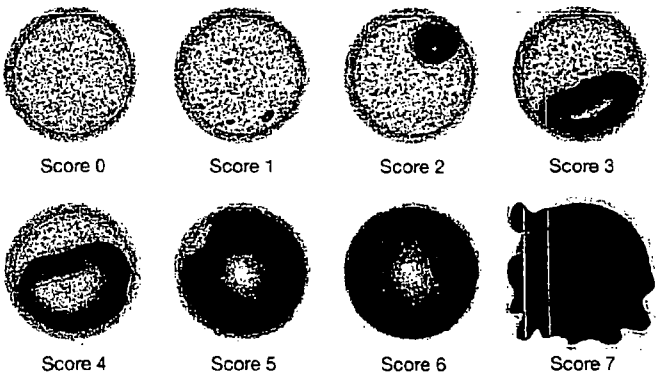

Figure 2 Schematic illustrations of bleeding scores used for visual determination of haemorrhage.

Table 1 Mean bleeding scores (±standard errors of the mean) and mean bleeding reduction (±standard errors of the mean) per treatment ($n = 6$)

Treatment[a]	Initial bleeding score	Final bleeding score	Calculated bleeding reduction[b]
Control	4.22 (±0.82)	5.50 (±0.66)	−1.28 (±0.62)
Bone wax	4.00 (±0.41)	2.72 (±0.57)	1.28 (±0.43)
Stasis®	5.28 (±0.64)	3.28 (±0.57)	2.00 (±0.69)
Expasyl™	4.11 (±0.32)	0.78 (±0.39)	3.50 (±0.41)
Expasyl™ + Stasis®	5.34 (±0.73)	0.56 (±0.25)	4.78 (±0.69)

[a]One treatment (Expasyl™ left *in situ*) not applicable to bleeding assessment.
[b]Positive values represent decrease of haemorrhage and negative values represent increase of haemorrhage.

Table 2 Pairwise comparisons of initial bleeding scores using Wilcoxon's signed rank test ($n = 6$, exact two-sided P-values)

Treatment	Control	Bone wax	Stasis®	Expasyl™
Bone wax	1.00	–	–	–
Stasis®	0.56	0.12	–	–
Expasyl™	1.00	0.41	0.12	–
Expasyl™ + Stasis®	0.31	0.31	1.00	0.12

P-value adjustment method: none.

Table 3 Pairwise comparisons of final bleeding scores using Wilcoxon's signed rank test ($n = 6$, exact two-sided P-values)

Treatment	Control	Bone wax	Stasis®	Expasyl™
Bone wax	0.094	–	–	–
Stasis®	0.125	0.656	–	–
Expasyl™	0.031	0.125	0.031	–
Expasyl™ + Stasis®	0.031	0.062	0.031	0.750

P-value adjustment method: none.

Statistics

The results were compared using Wilcoxon's signed rank test for paired samples. Exact two-sided P-values were computed to detect differences between the various treatment options. As pairwise comparisons were done on the same data, the P-values were adjusted to compensate the multiple testing situation. However, due to the explorative nature of the study and the small sample size, no adjustment was carried out. With regard to the interobserver variation, Cohen's *kappa* values were computed.

Results

All animals healed uneventfully and were killed as scheduled. The visual analysis of the haemorrhage control showed the highest effect for the combined Expasyl™ and Stasis® application (Table 1). All initial and final bleeding scores as well as the calculated bleeding reduction per treatment are summarized in Table 1. No differences were found for the initial bleeding scores per treatment (Table 2). With regard to the final bleeding scores, Expasyl™ and Expasyl™ in combination with Stasis® performed better than the control or Stasis® alone (Table 3). Bleeding reduction was more pronounced for Expasyl™, Stasis® and for Expasyl™ in combination with Stasis® compared with the control, as well as for Expasyl™ and Expasyl™ in combination with Stasis® compared with bone wax (Table 4). The calculated *kappa* values of the pairwise comparisons (three examiners) were 0.56, 0.51 and 0.62. These values indicated fair to strong concordance between the three

Table 4 Pairwise comparisons of calculated bleeding reduction using Wilcoxon's signed rank test ($n = 6$, exact two-sided *P*-values)

Treatment	Control	Bone wax	Stasis®	Expasyl™
Bone wax	0.094	–	–	–
Stasis®	0.031	0.438	–	–
Expasyl™	0.031	0.031	0.188	–
Expasyl™ + Stasis®	0.031	0.031	0.094	0.188

P-value adjustment method: none.

observers. As there were eight possible scores, one might interpret a difference of one as agreement. In this case, *kappa* values increased to 1.00, 0.92 and 0.95 showing that a difference of two or more occurred very rarely. The histological analysis is reported separately for each treatment option.

Control sites/3 weeks

Two of the three defects were bicortical. In those, woven bone formation could be observed on the defect walls without bridging the defects. The third defect showed woven bone formation to the level of the original cortex. In one of the sections, a small area with foreign body reaction was observed in the soft tissue covering the defect. Otherwise, the soft tissue presented without inflammatory reactions.

Control sites/12 weeks

Almost complete osseous healing with woven bone, reinforced with parallel-fibred bone was observed in all defects. In between the bone trabeculae, both fatty and haematopoietic bone marrow could be observed. One minor area of chronic infection could be seen in the top of one of the defects.

Bone wax sites/3 weeks

Bone formation was limited or nonexistent in all three defects. At the bottom of the defects large empty vacuoles, representing bone wax remnants (dissolved during the embedding procedure) could be observed surrounded by a soft tissue with chronic inflammatory changes and many foreign body giant cells.

Bone wax sites/12 weeks

A little more bone formation was seen after 3 weeks, but a slight to severe foreign body and chronic inflammatory reaction consistently surrounded bone wax remnants (Fig. 3).

Expasyl™ sites (temporary)/3 weeks

Sparse woven bone formation could be observed in two of the defects, none in the third. Varying amounts of foreign material were seen in the defects, and all showed abundant chronic inflammation including giant cells and phagocytes containing Expasyl™ remnants.

Expasyl™ sites (temporary)/12 weeks

No or very little bone formation could be seen (Fig. 4). The inflammatory reaction was reduced. There was a small amount of residual foreign material and an

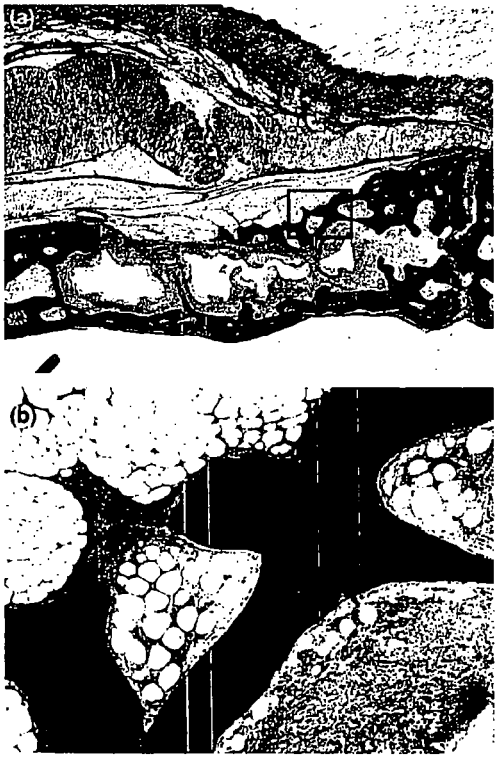

Figure 3 Histology after 12 weeks of defect treated with bone wax for 10 min (basic fuchsin and toluidine blue). A severe foreign body reaction with chronic inflammation is found around bone wax remnants in the centre of the bone (a, original magnification ×10). The enlargement shows the severe inflammatory response on the right side of the picture (b, original magnification ×90).

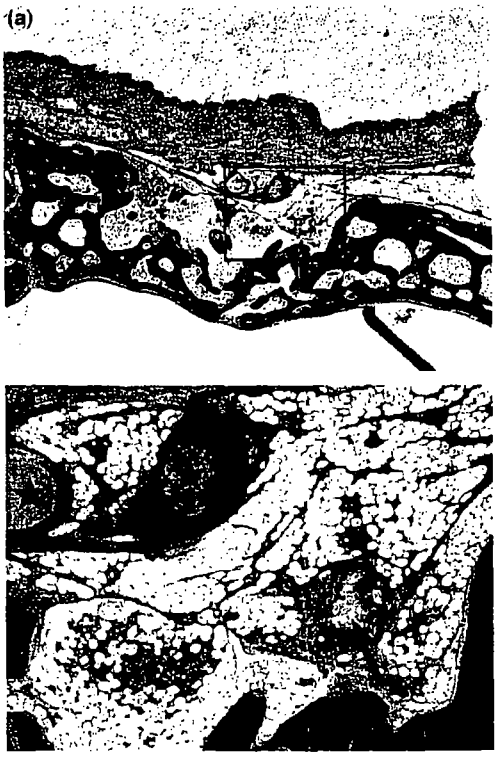

Figure 4 Histology after 12 weeks of defect treated with Expasyl™ for 2 min (basic fuchsin and toluidine blue). New bone formation is limited to the lower portion of the original defect (a, original magnification ×10). The enlargement shows an inflammatory reaction around Expasyl™ remnants (arrow), and in the upper left the cPTFE-suture (asterisk) (b, original magnification ×90).

increasing volume fraction of fatty bone marrow. A moderate amount of phagocytes and foreign body giant cells were identified.

Expasyl™ sites (permanent)/3 weeks

A more or less dense mass of foreign material occupied the main part of all three defects. No bone formation could be observed in any of the defects. Pronounced inflammation and foreign body reaction in the overlying soft tissue was a uniform finding.

Expasyl™ sites (permanent)/12 weeks

There was a limited bone formation on the defect walls. The amount of foreign material was clearly reduced in comparison with the 3-week specimens. Most of the defects were occupied by chronic inflammatory tissue containing giant cells and phagocytes, with Expasyl™ remnants in the cytoplasm.

Stasis® sites/3 weeks

Three unicortical defects showed 0%, 50% and almost 100% bone fill respectively. Areas with brown/yellow discoloration containing a variable amount of foreign material and foreign body giant cells were uniformly found. The overlying soft tissue showed slight to severe chronic inflammation.

Stasis® sites/12 weeks

All three defects showed almost complete osseous regeneration with woven bone, reinforced with parallel-fibred bone (Fig. 5). Apart from one small nidus of chronic inflammation, and one small area of discoloration (as seen in the 3-week specimens), the bone marrow was mature and free of inflammatory reactions.

Expasyl™ and Stasis® sites/3 weeks

The defects were dominated by the presence of chronic inflammation, with multiple multinucleated giant cells around remnants of the materials. Almost no new bone formation could be observed on the defect walls.

Expasyl™ and Stasis® sites/12 weeks

Moderate amounts of new bone formation could be seen. Mature fatty and haematopoietic bone marrow could be seen between areas with remnants of foreign material, chronic inflammation and multinucleated cells.

In general, the observations above were restricted to the defect sites. No chronic or acute tissue reactions could be observed in the marrow spaces surrounding the defects.

Discussion

This experimental study evaluated the immediate haemostatic effect of five different treatment options, and analysed histologically the tissue reactions to them. Both aspects are of clinical interest for surgical management of root structures and associated tissue lesions during periradicular surgery. While effective

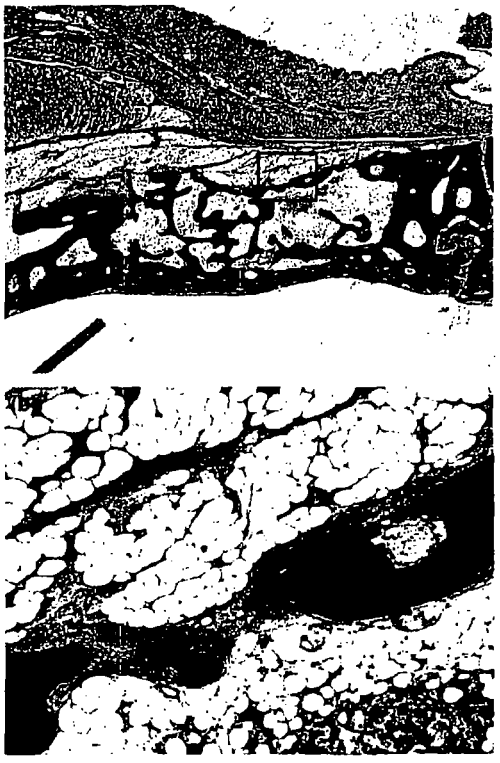

Figure 5 Histology after 12 weeks of defect treated with Stasis® for 5 s (basic fuchsin and toluidine blue). New bone formation is almost complete (a, original magnification ×10). Apart from a small area of chronic inflammation (lower right corner), the enlargement demonstrates mature bone marrow (b, original magnification ×90).

haemostasis is important during surgery for intraoperative diagnostic evaluation and root-end treatment, adverse tissue reactions to the agents applied for haemostasis might negatively influence the healing of the surgical site.

Two human studies have evaluated the haemostatic efficacy during periradicular surgery (Vickers *et al.* 2002, Vy *et al.* 2004). Vickers *et al.* reported adequate haemostasis in all 17 cases when racemic-epinephrine cotton pellets were used, and adequate haemostasis was achieved in 15 of 16 cases following the application of 20% ferric sulphate. Vy *et al.* reported complete haemostasis in 39 of 42 cases in which collagen sponges saturated with racemic epinephrine were applied. In contrast, haemorrhage control was not achieved in five of six cases that were treated with collagen sponges saturated with saline.

In the present study, the degree of bleeding was judged before and after the application of the haemostatic agents by three examiners independently using a score from 0 (no bleeding) to 7 (profuse bleeding) and schematic illustrations. Mean scores of bleeding reduction and the mean final bleeding scores showed that Expasyl™ alone or in combination with Stasis® was efficient in achieving good haemostasis of the surgical site.

Expasyl™, a paste containing aluminium chloride and kaolin, has been advocated for gingival retraction to ensure separation of the marginal gingiva and drying of the sulcus before impression-taking and insertion of restorations (Pescatore 2002, Shannon 2002). However, it has been shown that aluminium chloride elicits inflammatory tissue reactions. In a clinical comparative study on gingival retraction, aluminium chloride (25%) showed slower healing and more inflammatory reactions compared with a Nd:YAG-laser treatment (Abdel Gabbar & Aboulazm 1995). A dermatologic report on four cases demonstrated that aluminium chloride could cause a proliferative histiocytic reaction when used as a topical cauterizing agent (Barr *et al.* 1993). In an experimental study in eight beagle dogs evaluating four different retraction agents, racestyptine containing 25% aluminium chloride showed the most aggressive inflammatory infiltrate in gingival connective tissue (Kopac *et al.* 2002). In the present study, Expasyl™, alone or in combination with Stasis®, demonstrated a typical foreign body reaction including giant cells and inflammatory tissue response after 3 and 12 weeks. In contrast to control sites, new bone formation was minimal and clearly delayed in sites treated with Expasyl™. Although Expasyl™ is hydrophilic and easily washed out with saline, there may be a risk of leaving behind residues in the cancellous bone. It is therefore recommended to clean the surgical site with a bone curette and to freshen the walls of the bony crypt with a round bur before wound closure. In the present study, no attempts were made to completely remove the Expasyl™ employing such procedures. As no chronic or acute tissue reactions could be observed in the marrow spaces in the vicinity of the defects, it can be speculated that the adverse effects of Expasyl™ could be avoided by freshening the bony crypt as mentioned above.

In the present study, ferric sulphate (Stasis®) was found to be less effective than aluminium chloride (Expasyl™) in controlling the bleeding. Vickers *et al.* (2002) reported in their clinical study that in one-third

of the cases where ferric sulphate was used, some oozing of blood occurred in the bony crypt, requiring suctioning to maintain the dryness of the root-end preparation. Ferric sulphate has been used for more than a century in medicine. Ferric sulphate acts by agglutination of blood proteins resulting in plugs that occlude the capillary orifices (Lemon *et al.* 1993). When adequately curetted and irrigated from the surgical site prior to closure, ferric sulphate appears not to cause persistent inflammation or delay osseous repair (Jeansonne *et al.* 1993). In contrast, when ferric sulphate was left *in situ* for maximum exposure, an intense inflammatory response including foreign body reaction and delayed osseous healing were reported histologically after 18 and 46 days (Lemon *et al.* 1993). Interestingly, similar findings were seen in the present study for the shorter healing group of 3 weeks, whereas after 12 weeks, sites treated with ferric sulphate showed osseous regeneration and were free of any inflammatory reaction.

Bone wax containing purified beeswax, paraffin wax and isopropyl palmitate as a softening agent, has been recommended as an effective haemostatic agent in periradicular surgery since 1970 (Selden 1970). However, several reports have shown that bone wax residues are not resorbed and produce a foreign body giant cell reaction and inhibit bone reformation (Ibarrola *et al.* 1985, Alberius *et al.* 1987, Finn *et al.* 1992, Solheim *et al.* 1992, Allison 1994). From a clinical point of view, bone wax (after it was removed from the site) did not provide sufficient reduction in bleeding in the present study. Taking into consideration its adverse effects on tissue healing, it should no longer be used for haemostasis control in periradicular surgery.

Conclusions

- This explorative study in the rabbit calvarium clinically and histologically assessed the effect of various haemostatic agents.
- The key findings were: the visual analysis of pre- and post-application photographs demonstrated excellent bleeding reduction within trephined bony defects using Expasyl™ (aluminium chloride) alone or in combination with Stasis® (ferric sulphate). Histologic analysis showed a marked inflammatory tissue response towards Expasyl™ and bone wax within the immediate site of application, but no adverse tissue reactions were seen in the vicinity of the bone defects.
- Although not assessed directly in the study it is recommended that before wound closure of sites treated with such haemostatic agents, the bony crypt must be curetted to remove any foreign material, or preferably, freshened using rotary instruments.
- A future study should be performed to evaluate whether complete removal of Expasyl™ would prevent an inflammatory foreign body reaction and would allow for complete bone regeneration.

Acknowledgements

The authors gratefully acknowledge the assistance of Dr med. vet. Daniel Mettler and the veterinarian team of the Department of Experimental Surgery, University Hospital, Inselspital, Berne. We also thank Mrs Britt Hoffmann, Department of Oral Surgery and Stomatology, University of Berne, for the histologic preparation of the specimens. The schematic illustrations were provided by Ueli Iff, medical illustrator, School of Dental Medicine, University of Berne. We also thank Dirk Klingbiel and Stefanie Hayoz, Institute of Mathematical Statistics and Actuarial Science, University of Berne, for the statistical analysis. This study was funded by the Foundation for Dental Research and Education (FDR), Basle, Switzerland (grant 1-03/16).

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Safety ... 37

Gingival Inflammatory Response Induced by Chemical Retraction Agents in Beagle Dogs

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Purpose: The aim of this in vivo study on dogs was to investigate and compare the inflammatory potential of four different retraction agents on the gingival connective tissue. **Materials and Methods:** All procedures on eight beagle dogs were performed under general anesthesia: taking oral hygiene measures, placing retraction cords medicated with four chemical agents into the gingival sulci, and taking tissue biopsies. The specimens were evaluated after a 10-minute exposure to chemical agents. The inflammatory response of the connective tissue underlying the sulcular and junctional epithelium triggered by retraction agents was assessed quantitatively. Microscopic images of tissue specimens were morphometrically analyzed using a computer-assisted morphometric method. **Results:** The most intense inflammatory response in the connective tissue underlying the sulcular epithelium was triggered by astringent retraction agents—Racestyptine in specimens taken after 1 day and 1 week and Rastringent after 1 day ($P < .05$). Tetrahydrozoline-sympathomimetic vasoconstrictor (Visine) was found to have the lowest inflammatory potential. Retraction chemicals produced no significant effects on the connective tissue subjacent to the junctional epithelium. The ratio of the connective tissue area to that of the inflammatory infiltrate showed that 25% aluminum chloride (Racestyptine) was the most aggressive and tetrahydrozoline the least aggressive retraction agent used. **Conclusion:** All the retraction chemicals tested increased the infiltration with inflammatory cells in gingival connective tissue. *Int J Prosthodont 2002;15:14–19.*

Temporary displacement of free gingival tissue was introduced in fixed prosthodontic procedures and impression making using elastomeric materials for cast fixed restorations. The procedure allows an accurate recording of preparation finish line and also of uncut tooth surface apically from the tooth preparations.

A 0.2- to 0.4-mm horizontal displacement of the free marginal gingiva provides sufficient space for an adequate bulk of impression material at the apical aspect under the chamfer or shoulder, thereby preventing distortion or disruption on removal of the impression.[1] The impression of the uncut portion of the tooth in the vertical direction apically under the preparation finish line should measure at least 0.5 mm if the die is to be properly trimmed.[2] Identification of the preparation line is a prerequisite for the accurate modeling of the gingival margins of crowns that afford a proper relationship to the gingiva and therefore help to maintain the health of periodontal tissue. This aim can only be attained by the dilation of the gingival sulcus.

Several clinical methods are available for adequate tissue retraction prior to impression making, including mechanical retraction, chemical-mechanical retraction, electrosurgery, and rotary gingival curettage. The gingiva is most commonly retracted by a chemical-mechanical technique that involves the use of cotton cords impregnated with chemical retraction agents.[3] As demonstrated by experimental animal and human studies,[4–6] retraction chemicals used in prosthodontic treatment are potentially harmful to the gingiva. These agents are reported to produce

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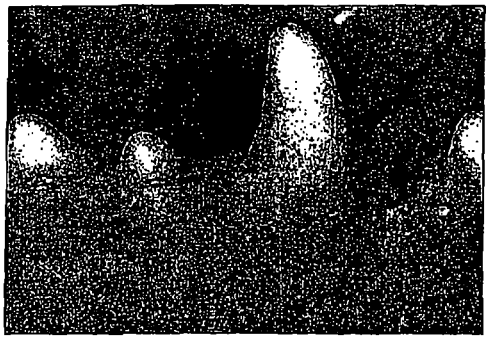

Fig 1a Slight gingival inflammation and plaque accumulation is present.

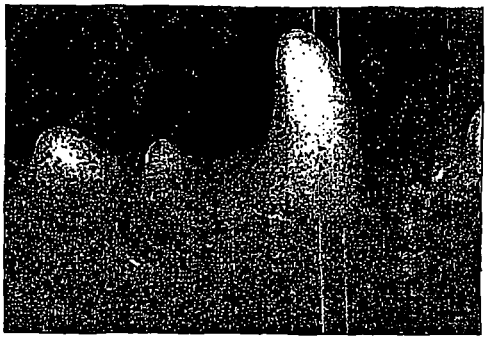

Fig 1b After the oral hygiene phase, the gingiva is clinically healthy.

injury to the sulcular epithelium. In addition, inflammatory cells may also infiltrate the gingival connective tissue underlying the epithelium.[7]

The new retraction agents are sympathomimetic vasoconstrictors with pH values more physiologic than those of standard retraction chemicals.[8] They allow for sufficient gingival retraction and constitute an effective alternative to the standard agents.[9] Their untoward systemic effects have been documented only with excessively high doses.[10] Local inflammatory potential and dynamic of gingival tissue restitution into clinically healthy gingiva following the use of retraction chemicals are still unknown. The authors' in vitro study using fibroblast tissue cultures demonstrated differences in their toxicity.[11]

This in vivo study on dogs was undertaken to evaluate the inflammatory response occurring in the gingival connective tissue treated with four different chemical retraction agents used in fixed prosthodontics.

Materials and Methods

Eight 2-year-old beagle dogs weighing 13 to 15 kg were selected for the study. They exhibited moderate amounts of sub- and supragingival concrement and plaque accummulation, and some parts of the gingivae were slightly inflamed (Fig 1a). Therefore, the following oral hygiene procedures were applied: removal of hard and soft plaque deposits with an ultrasonic cleaner; scaling and planing of dental surfaces, followed by polishing; and daily teeth brushing and application of 0.12% chlorhexidine gel. After 10 days of the hygienic procedures, the clinically healthy gingiva was demonstrated by periodontal parameters: Plaque Index (PI), gingival index (GI), and probing depth (PD) (Fig 1b).

Application of Retraction Agents

A total of 128 twined cotton cords (Reatracto, Roeko) impregnated with selected retraction agents were packed into the gingival sulci at the buccal aspect of lateral incisors, canines, posterior premolars, and first molars. The untreated gingival tissue on the buccal aspects of the second or the third premolar in each quadrant served as controls (32 specimens).

Each dog was treated with all four retraction agents under the following protocol:

- Left superior quadrant: Gingiva Liquid (Roeko), 10% aluminum chloride, pH 1.8
- Right superior quadrant: Racestyptine (Septodont), 25% aluminum chloride, pH 0.8
- Left inferior quadrant: Rastringent Two (Pascal), 20% aluminum sulphate, pH 2.6
- Right inferior quadrant: Visine (Pfizer), 0.05% tetrahydrozoline, pH 5.6

The cords were inserted very carefully and gently to avoid damaging the gingival tissue and were left in place for 10 minutes. The greatest diameter of each cord was placed at the level of the free gingival margin or just slightly below it.

Biopsies for Histologic Studies

Two parallel vertical incisions were made with a scalpel in the buccal gingiva, and one horizontal incision was made at the level of the alveolar bone crest. Tissue specimens of approximately 3 mm × 5 mm were carefully excised from the apical direction using a raspatory.

The first series of gingival specimens (n = 43) was obtained 1 hour after removal of the medicated retraction

Fig 2a Histologic specimen of a clinically healthy gingiva in the control group shows a smooth surface of the sulcular epithelium and minimal inflammatory infiltration of the underlying connective tissue; *arrowheads* = connective tissue cells (original magnification × 340).

Fig 2b Gingival tissue after 10 minutes of treatment with a Racestyptine-medicated retraction cord. The epithelial surface shows desquamation. Connective tissue is infiltrated with inflammatory cells *(arrowheads)* (original magnification × 340).

cords; the second series (n = 43) was taken 24 hours after cord removal; and the third series (n = 42) was taken 1 week after cord removal. Tissues were placed into 10% buffered formalin and stored in 70% ethyl alcohol. Specimens were dehydrated in alcohols of increasing concentrations, ending in xylene; they were then embedded in paraffin, cut into 4-μm-thick sections, and stained with hematoxylin–eosin.

Figure 2a shows a healthy gingiva from the control group, with minimally infiltrated connective tissue. By contrast, the gingivae treated with tested agents exhibited as a rule various degrees of inflammatory infiltration, and the epithelium was usually desquamated (Fig 2b).

Morphometric Analysis

Microscopic images of tissue specimens were morphometrically analyzed using System for Image Processing and Analysis Lucia 4.1 (Laboratory Imaging). Gingival inflammatory infiltration induced by retraction agents was assessed separately for the connective tissue underlying the sulcular epithelium and underlying the junctional epithelium. The surface area of inflammatory connective tissue infiltration (mm^2) was measured, and the ratio (%) of the inflammatory infiltration surface area underlying both epithelia to the total connective tissue surface area was determined (Fig 3). Statistical significance was tested by analysis of variance (ANOVA).

Results

Morphometric measurements showed that the clinically healthy gingivae that served as controls exhibited minimal connective tissue inflammatory infiltration under sulcular and junctional epithelia (Fig 2a). Specimens of gingivae treated with different retraction agents showed epithelial damage and different degrees of inflammatory infiltration.

One hour after cord removal, all treated gingival tissues demonstrated small and nonsignificant changes in the mean area of inflammatory infiltration relative to the control group (Fig 4). At 1 day after cord removal, the inflammatory infiltration area was significantly larger in tissue specimens treated with Racestyptine, Rastringent, and Gingiva Liquid compared to the control group and Visine ($P < .05$). Among specimens taken at 1 week, those treated with Racestyptine demonstrated the largest area of connective tissue inflammatory infiltrate, differing significantly ($P < .05$) from the degree of inflammation in

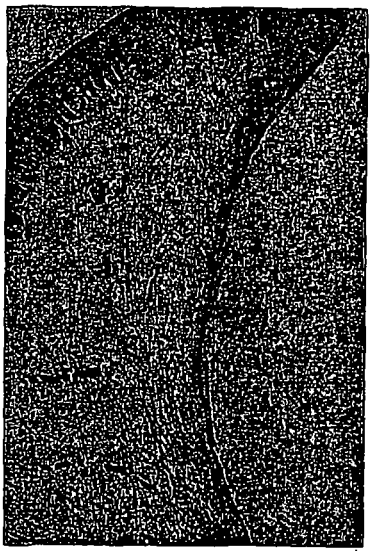

Fig 3a Relatively small inflammatory infiltration area in the connective tissue subjacent to the sulcular and junctional epithelia (green) (original magnification × 40).

Fig 3b Total area of healthy and inflamed connective tissue subjacent to the sulcular and junctional epithelia in the control specimen (green). The *arrow* indicates the transition between the sulcular and junctional epithelia (original magnification × 40).

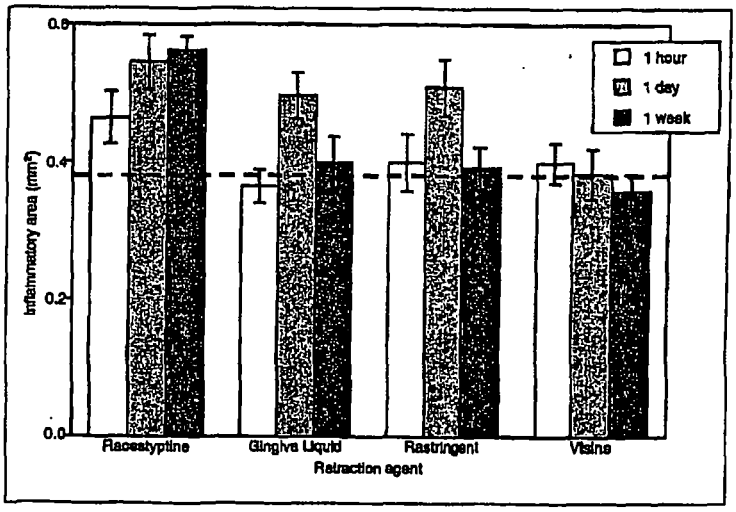

Fig 4 Inflammatory infiltrated area of treated specimens in the connective tissue underlying the sulcular epithelium relative to the control values; dashed line = 0.38 ± 0.03 mm². The areas were measured at three different time intervals after cord removal.

the controls and in specimens treated with the other retraction agents.

Racestyptine-treated tissue showed the largest area of inflammatory infiltration in the connective tissue underlying the junctional epithelium 1 hour, 1 day, and 1 week after cord removal. However, there were no statistically significant differences between specimens treated with Racestyptine and the controls, or specimens treated with the other retraction chemicals.

Discussion

Retraction agents were placed 10 days after the hygienic phase, although morphometric measurements of control specimens showed that there still existed 8.6% ± 0.5% connective tissue infiltrated with inflammatory cells. According to Page and Schroeder,[12] the obtained percentage lies between clinically healthy gingiva and initial gingivitis. Clinically healthy gingiva may contain up to 5% inflammatory cells in the connective tissue, while in early gingivitis this figure may increase up to 15%. After the hygienic phase, clinically healthy gingiva was achieved in the study dogs. Similarly, in clinical practice, prosthodontic treatment should start when clinically healthy periodontal tissues are demonstrated by clinical parameters (PI, GI, PD), without any information about tissue infiltration on the histologic level.

In our study, we applied retraction agents in intact sulci where no crown preparation was performed. This decision was based on the prerequisite that we must not in principle injure the gingiva during clinical preparation of teeth. Mechanical trauma per se may induce an inflammatory response of the gingiva during prosthodontic procedures, and so comparative results regarding the inflammatory effects of agents would not be realistic.

Semiquantitative evaluation of gingival inflammatory infiltration induced by a 10-minute exposure to a single aluminum chloride retraction agent at different concentrations in beagle dogs has been reported in the literature. Tissue specimens were obtained at 30 minutes, 1 day, 3 days, and 14 days after the treatment.[7] A comparable experimental procedure was used in our study, but histologic analysis of specimens was greatly improved due to computer-assisted morphometric measurement of the inflammatory response.

Studies dealing with the effects of retraction agents have mainly dealt with the evaluation of clinical parameters, such as the hemostatic effect following the removal of cords from sulci,[13] clinical effects exerted by different retraction agents and cords,[14] video recording of the rate of closure of the gingival crevice,[15] and assessment of the retraction times necessary for adequately dilated sulci.[16] Our experiment, however, was focused on a comparison of the inflammatory response triggered in the connective tissue, which was assessed morphometrically.

The occurrence of subepithelial inflammatory cell infiltrate was described in a study that compared the effects of a copper band, medicated retraction cords, and electrosurgery on human periodontal tissues. A 5-minute exposure of gingiva to an adrenalin-impregnated retraction cord was reported to trigger an inflammatory response, which declined to the values of control specimens in 8 days.[17] A similar dynamic of inflammatory response was observed in our study for all tested agents, except the 25% aluminum chloride.

Contrary to the above-citied experiment, a semiquantitative study of the effects of three different retraction chemicals on healthy human periodontal tissue showed no significant difference between specimens treated with different retraction agents or between the treated and control specimens at 1 day or 1 week after treatment. The diversity of the results was attributed to physiologic differences among the individuals studied.[6] Beagle dogs with similar genetic characteristics were used in our study to increase the homogeneity of the group studied. The small standard deviations of the data confirm similar gingival response of the treated animals to the applied stimuli.

The retraction agents tested provoked a transitory inflammatory response in the gingival tissues that persisted for more than 1 week only in tissue specimens treated with Racestyptine.

Acknowledgments

The authors acknowledge Prof Zlatko Pavlica, Veterinary Clinic, University of Ljubljana for help with experimental animals, and Mr Marko Slak and Mr Milan Števanec for technical assistance.

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Literature Abstracts

Denture base polymer Alident Sinomer: Mechanical properties, water sorption and release of residual compounds.

This study evaluated a new paste-type denture base polymer, Alident Sinomer, in terms of its flexural properties, water sorption, solubility, and release of residual compounds. The study compared the denture base polymer with or without reinforcement using a preimpregnated continuous glass fiber (Stick). Four groups were included: *(1)* unreinforced, stored dry; *(2)* unreinforced, stored in water for 7 days; *(3)* reinforced with one Stick fiber; and *(4)* reinforced with three Stick fibers. Both reinforced groups were stored in water for 7 days. The flexural strength and flexural modulus were measured using the three-point bending test, and the data were analyzed with one-way ANOVA. Water sorption and solubility were tested according to the ISO 1567 standard. The release of residual compound was determined with the high-performance liquid chromatography method. There were no significant differences in the flexural properties among the first three groups ($P < .05$). The group reinforced with three Stick fibers showed significantly higher flexural strength and modulus compared to the other groups. The released compounds were determined to be methyl(methacrylate) monomer. It was concluded that the mechanical properties, water sorption, and solubility values of the polymer Sinomer are acceptable according to ISO requirements.

Lassila LVJ, Vallittu PK. *J Oral Rehabil* 2001;28:807–813. References: 17. Reprints: Dr L. V. J. Lassila, Institute of Dentistry & Biomaterials Project, University of Turku, Lemminkäisenkatu 2, FIN-20520 Finland. e-mail: lippo.lassila@utu.fi—*Swee-Chian Tan, Iowa City, Iowa*

The relationship between non-working-side occlusal contacts and mandibular position.

The aim of this study was to test the hypothesis that the nonworking-side contact pattern varies with the mandibular position. Occlusal contacts of 86 young adults were examined using shim stock (10- to 15-μm-thick occlusal registration strips) in standardized lateral positions: 0.5, 1, 2, and 3 mm from maximum intercuspation. The 3-mm position was an edge-to-edge position. The frequency of nonworking-side contacts was significantly greater in the 0.5- and 1-mm positions than in the 3-mm position. Nonworking-side occlusal contacts occurred in nearly half of the 0.5-mm positions. There were fewer nonworking-side contacts with canine protection than with group function for the 0.5- and 1-mm positions. It was concluded that the nonworking-side contact pattern varied with the mandibular position. Based on these results, it was suggested that clinical examination should include contact patterns both in a position close to maximum intercuspation and in an edge-to-edge position, ie, in functional and parafunctional ranges. Data from occlusal contact research should also include a standardized definition of mandibular position.

Ogawa T, Ogimoto T, Koyano K. *J Oral Rehabil* 2001;28:976–981. References: 28. Reprints: Dr Takahiro Ogawa, The Weintraub Center for Reconstructive Biotechnology, Division of Advanced Prosthodontics, UCLA School of Dentistry, 10833 Le Conte Avenue (B3-068 CHS), Box 951668, Los Angeles, California 90095-1668. e-mail: tack@dent.kyushu-u.ac.jp—*AW*

in vitro

Electron microscopic analysis of the effects of chemical retraction agents on cultured rat keratinocytes

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Statement of problem. Chemical retraction agents used in fixed prosthodontics for temporary displacement of free gingival tissue before impression making can cause injury to the gingival tissue cells.
Purpose. This study evaluated changes in cultured rat keratinocytes treated with 2 chemical agents used for gingival retraction. Treated cultures were compared with untreated cultures.
Material and methods. Keratinocytes of rat gingiva were grown in a specific medium for 10 days. After treating 1 group of specimens with 0.05% tetrahydrozoline and another group with 25% aluminum chloride, both for 10 minutes, the cultured cells were examined with scanning and transmission electron microscopy and compared with control specimens.
Results. Twenty-five percent aluminum chloride produced a significantly greater extent of cellular damage than 0.05% tetrahydrozoline, which caused only mild changes in the cultured cells.
Conclusion. On the basis of the morphologic and ultrastructural changes in primary cell cultures of rat keratinocytes observed in this study, it was concluded that 25% aluminum chloride was significantly more aggressive than 0.05% tetrahydrozoline.() Prosthet Dent 2002;87:51-6.)

CLINICAL IMPLICATIONS

In this animal study, 0.05% tetrahydrozoline had fewer adverse effects on epithelial cells than the astringent 25% aluminum chloride. Tetrahydrozoline can be recommended for clinical use in fixed prosthodontics.

The use of quality impression materials, proper impression techniques, and temporary displacement of free gingiva before impression making are essential to the accuracy of fixed prosthodontic impression procedures. This is especially the case in shoulder or chamfer preparations with the preparation finish-line located slightly subgingivally or at the level of the free gingiva.

The use of retraction cords impregnated with various chemical retraction agents is one of the most widely adopted techniques for temporary gingival tissue displacement.[1] The optimum retraction agent will enable satisfactory gingival retraction and have as few local or systemic adverse effects as possible. Retraction agents are classified by their chemical composition in a group of commonly used agents, which include aluminum chloride, aluminum sulphate, ferric sulphate, and epinephrine, and in a group of sympathomimetic vasoconstrictors such as tetrahydrozoline.[2] These new agents are supposed to produce only slight local damage and to have no systemic adverse effects.[3]

All standard chemical retraction agents are acidic solutions with pH values from 0.8 to 3.0, and all are potentially harmful to cut dentin and periodontal tissues. In vivo animal and human studies have shown that these chemicals tend to damage the sulcular and junctional epithelium, and the most aggressive among them damage even the connective tissue.[4,5] Toxic effects of chemical agents in clinical studies, corroborated by histologic evidence, have been reported by several authors.[6-9] Recently, cell cultures have been used to determine the irritation potential and toxicity of various agents,[10] whereas in the past, these investigations were performed in vivo with the Draize rabbit eye irritability test.[11] In vitro tests are used for preliminary screening of all chemical agents, which significantly reduces the number of animals required for in vivo tests. In vitro tests therefore constitute a more cost-effective option, provide for greater accuracy and reproducibility, and correlate well with in vivo studies.[12]

Most in vitro cytotoxicity assays use cell lines that are less differentiated (diploid fibroblasts) or permanent (He-La cells).[13,14] A previous study with V-79 fibroblasts indicated that individual chemical retraction agents differ significantly in their degree of cytotoxicity.[15] The greatest proportion of cultured cells were damaged by 25% aluminum chloride (Racestyptine; Septodont, Saint-Maur-des-Fosses

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Cedex, France), and the least proportion by 0.05% tetrahydrozoline (Visine; Pfizer, Arnprior, Ontario, Canada). The same tests are feasible on tissue cells that are more differentiated, yet culturing these cells for experimental work is more laborious.[13]

The purpose of this study was to investigate, with scanning and transmission electron microscopy (SEM and TEM), the potentially destructive effects of 0.05% tetrahydrozoline and 25% aluminum chloride on cultured rat keratinocytes. Rat tissue specimens were used because of the similarity between the histologic patterns of human and rat gingiva[16] and because a large number of specimens was needed for measurements. Although Land et al[17] used SEM to examine cut dentin treated with retraction agents, and although the harmful effects of such agents have been extensively documented, the use of both SEM and TEM for evaluation purposes has not been described in the literature. The use of these complimentary methods and high magnification allowed even subtle morphologic changes in cell surface and ultrastructure to be identified.

MATERIAL AND METHODS

Explants were derived from the gingiva of adult male white Wistar rats that weighed approximately 200 g each. Gingival specimens were obtained from the anterior gingival region buccally and lingually to the maxillary and mandibular incisors and palatally to the maxillary molars. The specimens were cut into 2- to 3-mm^2 pieces and then transferred to a Cyclopore membrane culture support (Falcon, Becton Dickinson, Franklin Lakes, N.J.). The pieces, 3 in each tissue culture well, were spread over the porous bottom of the membrane insert, which provided close contact with the tissue. The total number of pieces was 246.

Culture medium was added and replaced every 3 days. The cultures were incubated at 37°C in a humidified 5%–CO_2 atmosphere for 10 days. One day after the gingival explant attachment to the porous membrane, keratinocytes began to migrate over the membrane, and at 10 days, they formed a culture 4 to 6 layers thick. In this study, only keratinocytes growing over the porous membrane were used.

Retraction agents were applied directly to the cell cultures after removal of the culture medium; this procedure mimicked the clinical use of these chemicals. Thirty-six cultured pieces served as controls. Half of the remaining cultures (N = 105) were treated with 0.05% tetrahydrozoline; the other half (N = 105) were treated with 25% aluminum chloride for 10 minutes and then washed with phosphate-buffered saline solution.

Culture medium

Cell cultures were grown in a differentiated medium consisting of MCDB 153 (Sigma Chemical Co, St. Louis, Mo.) and Dulbecco's modified Eagle's medium (Gibco, Paisley, Scotland) at a ratio of 1:1, supplemented with 0.1 mmol/L ethanolamine, 0.1 mmol/L phosphoethanolamine, 15 μg/mL adenine, 0.5 μg/mL hydrocortisone, 5 μg/mL insulin, 20 ng/mL epidermal growth factor (EGF), 0.7 mmol/L $CaCl_2$, 100 μg/mL streptomycin, 100 U/mL penicillin, and 0.1 mmol/L nystatin. To the epithelial cell culture medium, 10% fetal calf serum (FCS) comprising amino acids needed for culture growth was added. (All cell culture supplements were obtained from Sigma-Aldrich, Diesenhofen, Germany).

Scanning and transmission electron microscopy

All specimens were fixed with 2.5% glutaraldehyde and 4% paraformaldehyde in 0.1M cacodylate buffer (pH 7.4) with 0.05% calcium chloride and 4% saccharide at 20°C for 2 hours. The specimens were rinsed with 0.1M cacodylate buffer, postfixed with buffered 1% OsO_4, and dehydrated with ethanol at increasing concentration. The porous membrane with cultured cells was cut into small pieces. The pieces were dried at a critical point and spattered with gold. The specimens then were examined at 15 kV under an electron microscope (JSM840A; JEOL Ltd, Tokyo, Japan).

The fixation procedure for transmission electron microscopy was the same as described above. The specimens were rinsed with 0.1M cacodylate buffer and postfixed in 1% OsO_4 at 40°C for 1 hour. After dehydration at increasing alcohol concentration, the specimens attached to the porous membrane were cut into small pieces and embedded in epoxy resin (Epon 812; Serva, Heidelberg, Germany). Ultra-thin sections (40 nm) were contrasted with lead citrate and uranyl acetate and examined under a transmission electron microscope (100 CX; JEOL Ltd).

RESULTS

Control group. Flattened polygonal superficial cells were covered with microvilli, which sometimes formed short microcrests and expanded from the cell periphery toward the center. Occasionally, the whole cellular surface was covered with crests (Fig. 1, *A*). Morphologically, cells at the periphery differed significantly from cells contained in layers. The stellate cells were 1-layer thick, were covered with microvilli, and had long and thin protrusions resembling filopodia (Fig. 1, *B*).

The multilayered epithelium-like structure was visible under the transmission electron microscope as well. All cultured cells, from basal to superficial, were markedly flattened and contained large oval nuclei. Numerous mitochondria and a well-developed endoplasmic reticulum were discernible in the basal cell layers. Junctions between cellular basolateral mem-

branes were provided by numerous desmosomes. Tonofilament bundles were present in the cytoplasm, predominating in the intermediate and superficial cell strata. Occasionally, intermediate type filaments were present in the form of intertwined tonofibrils (Fig. 1, *C*).

Cell culture treated with 0.05% tetrahydrozoline. No relevant changes were noted in the superficial structure of the epithelial cells after a 10-minute treatment with 0.05% tetrahydrozoline compared with that of the control specimens. Superficial cells remained flat and polygonal in shape and were covered with numerous microvilli. They were mostly connected (Fig. 2, *A*), yet some cell surfaces were without close contact to adjacent cells and were only sparsely covered with microvilli, which gave them a smoother appearance than the control cells. Stellate cells at the periphery were 1-layer thick and had a number of filopodia-like protrusions that were shorter than those in the control group. The cells bore large numbers of microvilli on their surface (Fig. 2, *B*).

Under the transmission electron microscope, several (6 or fewer) layers of cells were seen; their ultrastructure was similar to that in the control group. Intercellular junctions were provided by desmosomes or long protrusions, separated by large intercellular spaces, which were discernible mostly in the superficial layer cells (Fig. 2, *C*).

Flattened cells of the basal layers contained large oval nuclei and a well-developed endoplasmic reticulum. There was an increase in the number of tonofilament bundles and a decrease in the number of cellular organelles from the base to the surface of the multilayered culture. The superficial cell layers were separated from the lower ones and had numerous cytoplasmic elongations. In the superficial layer cytoplasm, no cellular organelles but rather a variety of vacuoles and large numbers of tonofilaments were noted.

Analysis by means of the scanning and transmission electron microscopes showed no significant differences in terms of shape, surface, or ultrastructure between treated and control cells, which confirmed the relatively mild effect of 0.05% tetrahydrozoline.

Cell culture treated with 25% aluminum chloride. Structural features of cells exposed to 25% aluminum chloride for 10 minutes differed significantly from those of the control group. The cells remained flattened, but there was no contact between them. The extent of cellular damage was notably greater than that in the control group and in the 0.05% tetrahydrozoline group. As a result of exposure to 25% aluminum chloride, not only superficial intercellular junctions but also lower cell layers were destroyed. Microvilli on the cell surface were less distinctive than in the control group (Fig. 3, *A*). Among numerous flattened cells without

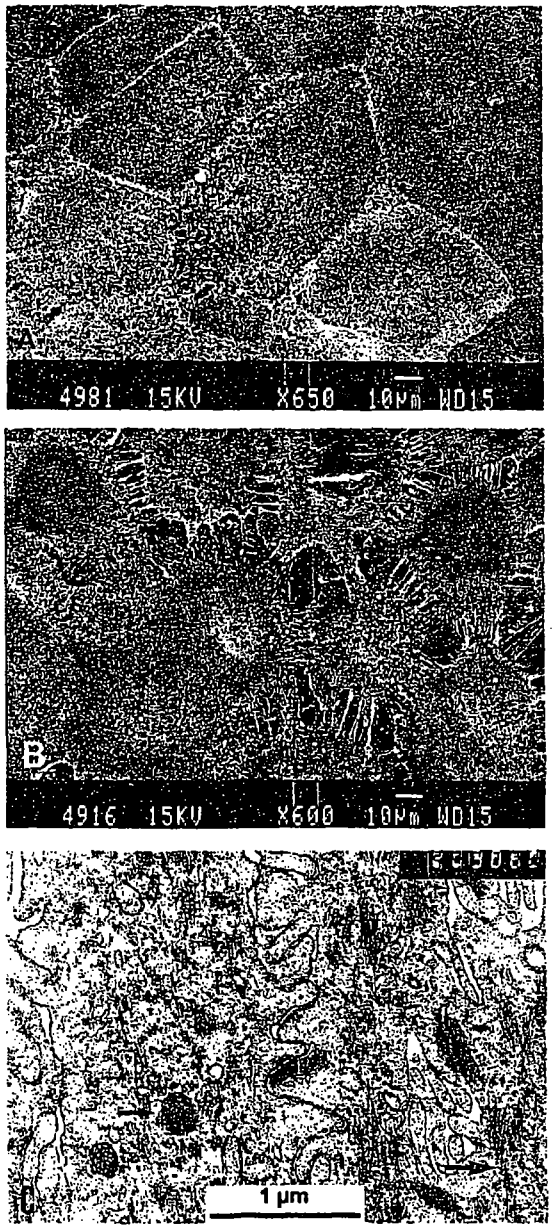
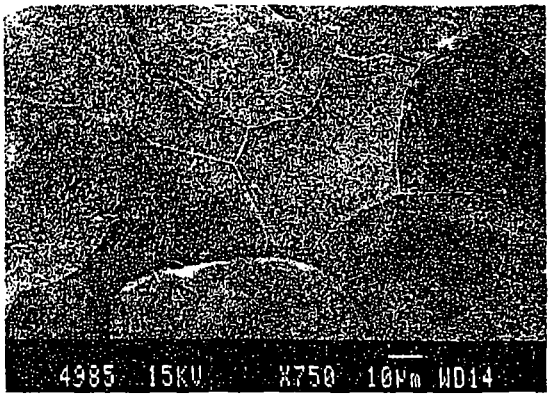
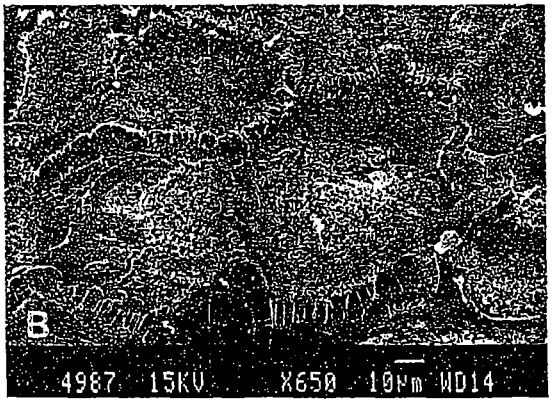


Fig. 1. A, Tight adhesion between polygonal cells of superficial keratinocyte layers in control group. Cellular surface was covered with large number of microcrest-forming microvilli (SEM, original magnification ×650). **B,** One-layer-thick epithelial cells at periphery of explant culture. Numerous long structures resembling filopodia grew from cell surface (SEM, original magnification ×600). **C,** Cells in intermediate layer were connected with numerous desmosomes and contained tonofilament bundles (large arrow), intensely staining dense granules (small arrow), and sparse mitochondria (TEM, original magnification ×20,000).





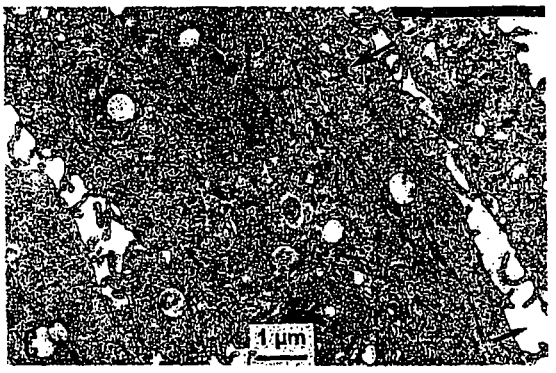
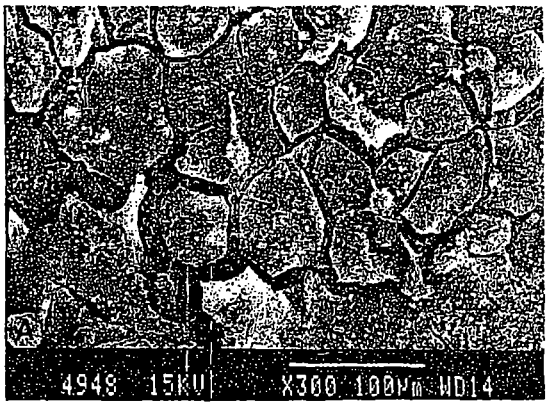
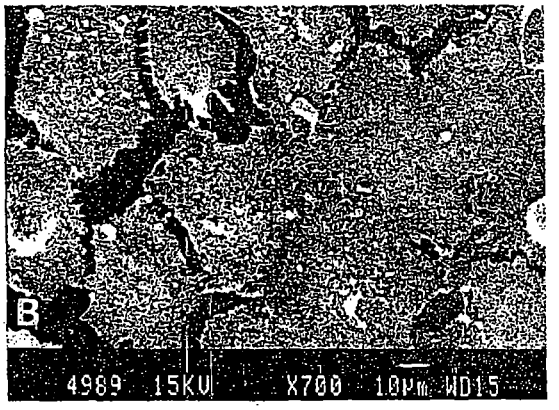


Fig. 2. A, Surface of explant culture central area after 10-minute treatment with 0.05% tetrahydrozoline. Flattened polygonal cells resembled cells in control samples, were closely connected, and bore numerous microvilli on surface (SEM, original magnification ×750). B, Epithelial cells from periphery of explant culture after 10-minute treatment with 0.05% tetrahydrozoline. Stellate cells had short filopodia that provided junction with adjacent cells (SEM, original magnification ×650). C, Cell cultures maintained for 10 days and treated with 0.05% tetrahydrozoline were connected by desmosomes *(large arrow)*, yet there was loss of adherence between superficial and basal layers *(small arrow)*. Various vacuoles were present in intermediate layer cells (TEM, original magnification ×6600).





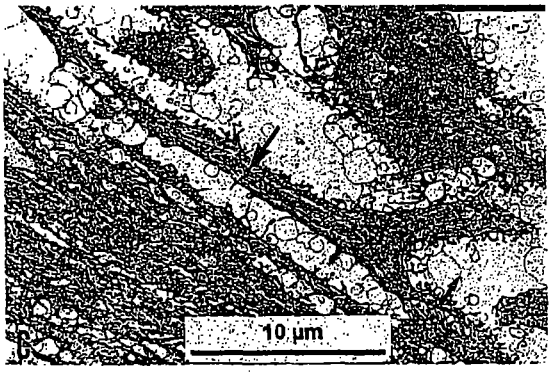


Fig. 3. A, Epithelial cells after 10-minute exposure to 25% aluminum chloride were flattened, polygonal in shape, and separated from each other (SEM, original magnification ×300). B, Cells at periphery of explant culture were extremely flattened and polygonal in shape and had very short, filopodia-like protrusions. Occasional spherical cells were discernible between individual polygonal cells (SEM, original magnification ×700). C, Cross section of epithelial cell layers after 10-minute exposure to 25% aluminum chloride disclosed notable changes in all cell layers compared with those of control samples. No organelles were discernible in cytoplasm. Cell layers were separated by large intercellular spaces *(small arrow)*. Chromatin was condensed at nuclear lining *(large arrow)* (TEM, original magnification ×3300).

regions of cell junctions, sparse spherical, flattened, and elongated cells were seen at the periphery. They were 1-layer thick and had no filopodia (Fig 3, *B*).

Electron microscopic images indicated that cultures exposed to 25% aluminum chloride demonstrated a considerably greater extent of cell damage than cells treated with 0.05% tetrahydrozoline and control samples. The most evident change was a nearly complete destruction of cell junctions in the studied group of specimens.

Under the transmission electron microscope, multilayered keratinocyte cultures formed long threads of cells, which in some areas were completely separated from each other. Between the cells joined by long and thin projections, there were large intercellular spaces. Desmosomes were discernible only in the cells of the basal strata. Cell ultrastructure was notably altered. Mitochondria, ribosomes, and endoplasmic reticulum were no longer discernible in the cells. The nuclei were notably flattened and contained condensed chromatin clusters at the nuclear envelope. Cell separation extended into deeper layers of the explant culture. The cytoplasm had a fine-grained texture and contained no cell organelles. Sparse electron-dense areas and a number of vacuoles were noted (Fig. 3, *C*). Alterations caused by the harmful effects of 25% aluminum chloride involved even the basal cell layers of the explant culture. The aggressiveness of this chemical relative to 0.05% tetrahydrozoline was confirmed by the observed loss of intercellular junctions and notable changes in the cellular ultrastructure.

DISCUSSION

The effects of retraction chemicals on keratinocytes may differ from those induced in fibroblasts. Since healthy gingival epithelium forms a barrier to physical and chemical insults,[18] it is supposed to reduce direct harmful effects exerted by retraction chemicals. In clinical practice, agents are placed directly on the sulcular epithelium in their original concentrations by means of cotton cords. By analogy, the retraction agents in this assay were applied directly to the cell cultures. If they had been added to the culture medium, their concentrations would not have been the same as those used clinically.

Terminal differentiation of the surface cells of the sulcular epithelium can be established experimentally in human beings only after supervised, meticulous daily plaque control for several weeks. Keratinocytes in the culture did not reach terminal differentiation, which leads to the speculation that the effects of retraction agents are more pronounced in in vitro conditions. In clinical practice, the action of chemical retraction agents may be less intense because they are diluted by gingival fluid. Despite incomplete differentiation, epithelial cell cultures provided a suitable model for this kind of study given that, in normal clinical conditions, the sulcular epithelium does not reach the terminal stage of cytodifferentiation.

It may be that cell differentiation in the superficial layers of the explant culture did not reach the stage of differentiation observed in rat gingival keratinocytes in vivo. This observation accords with the results of another study on long-term cell culture.[19] In the process of differentiation, immature cells acquire morphologic and functional characteristics of mature cells. Compared with lower cell layers, superficial keratinizing layers of the differentiated oral epithelium contain an increased number of desmosomes, keratin-containing cytoplasm, and intermediate filaments (cytokeratins), which is characteristic of the terminal stage of cell differentiation.[20]

The absence of intercellular junctions in cell cultures treated with 25% aluminum chloride probably was the result of protein denaturation. Specific characteristics of astringens have been described by Felpel.[21] Nonselective protein denaturation seems to be responsible for the loss of intercellular junctions, which are provided by transmembranous proteins. Changes in the number and arrangement of microvilli on the epithelial cell surface most likely were caused by the direct denaturation effect of the chemical agents as well. These changes were characteristic of cells treated with 25% aluminum chloride, whereas cultures exposed to 0.05% tetrahydrozoline showed greater similarity to control cell specimens. In view of the small differences in both the superficial structure and ultrastructure of tetrahydrozoline-treated and control cells, it can be concluded that the treated specimens retained the essential functions characteristic of epithelial cells.

The marked morphologic changes in the aluminum chloride-treated specimens seemed to be reflected in altered cellular and, consequently, epithelial functions. The disappearance of cell organelles results in a loss of ability to maintain and provide energy for metabolic function and growth. Intercellular junctions are disconnected, which leads to cellular separation and desquamation; these, in turn, cause a breakdown of epithelial integrity. Typically, chromatin condenses next to the nuclear membrane, which suggests that the concentration of aluminum chloride used in this study causes apoptotic cell death.

Morphologically altered cells with impaired basic cellular functions cannot perform their original roles. A healthy epithelium has a protective function, but the action of aggressive agents causes desquamation and cell death, advancing deep into the culture and reaching even the most inferior layers. Viewed from the clinical aspect, the damaged epithelium not only loses its protective role but exposes the gingiva even more to harmful effects from the environment.

The described methodology and results obtained

show promise for further investigations into the harmful effects of retraction agents used in dental care.

CONCLUSIONS

Scanning and transmission electron microscopy were used to evaluate ultrastructural changes in keratinocytes after treatment with chemical agents. The results disclosed that the effect of 25% aluminum chloride on primary cultures was significantly more adverse than that of 0.05% tetrahydrozoline. The latter agent can be recommended for clinical use in fixed prosthodontics.

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0022-3913/2002/$35.00 + 0. 10/1/119681

doi:10.1067/mpr.2002.119681

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Dynamic Oxidoreductive Potential of Astringent Retraction Agents

(gingival margin retraction agents / cytotoxicity / human gingival fibroblasts). Abstract. The aim of this study was to evaluate the dynamics of the cytotoxicity of gingival margin retraction astringents based on aluminium chloride, aluminium sulphate, and ferric sulphate (solutions and gels) in human fibroblasts isolated from gingiva. The cytocompatibility of ten astringent-based chemical retraction agents: Gingiva Liquid, Alustin, Racestypine, Orbat sensitive, Astringedent®, Alustat, Hemostat, Racécord, Gel cord and ViscoStat®, in dilutions of 1 : 10 and 1 : 20, with human gingival fibroblasts was investigated. The MTT assay was performed to determine oxidoreductive mitochondrial function after 3, 5, 10 min and 24 h of incubation. Cell viability was determined according to the chemical group, concentration, exposure time, and the clinical form of the gingival retraction agents. Ferric sulphate-based agents were the most cytotoxic, followed by aluminium chloride and aluminium sulphate. The form of the astrigents influenced cell viability. The evaluated astringents may have cytotoxic potential for gingival margin tissues under clinical conditions.

Previous article: La Bataille du rail

Next article: Corrections

Publication: Folia Biologica
Author: Nowakowska, D
Date published: November 1, 2010

Introduction

Gingival margin retraction is a commonly accepted procedure in modem restorative dentistry. Providing visibility and easy access to a clean and dry gingival sulcus, it creates optimal conditions for performing direct and indirect tooth restoration. This is especially important for subgingival finish-line imaging using conventional impression materials or CAD/CAM digital/ optical techniques, for fixed dental restoration, and for adhesive methods very useful in aesthetic dentistry (Bennani et al., 2008).

Gingival retraction agents (GRAs) are used in clinical practice in the form of gingival retraction fluids (GRFs) or gingival retraction gels (GRGs) (Nowakowska and Panek, 2007). With respect to the pharmacological effects of the active substance, they belong either to class 1 (vasoconstrictors, adrenergics) or class 2 (haemostatics, astringents) (Nowakowska, 2008). Chemical retraction agents based on aluminium chloride, aluminium sulphate, ferric sulphate, and, less frequently, zinc chloride and aluminium potassium sulphate are astringents (Shillingburg et al., 1980). The above-mentioned survey demonstrated that over 80 % of dentists applied astringents for gingival margin retraction in clinical practice (Donovan et al., 1985; Hansen et al., 1999, Nowakowska et al., 2006b). Chemically, all the retraction agents containing astringents are characterized by a relatively high level of acidity, with their original concentrations ranging from pH 1 to pH 3 for solutions (Woody et al., 1993; Land et al., 1994, 1996; Ayo-Yusuf et al., 2005). Our previous study of the pH levels of commonly used astringents in solution and gel form found that the pH values of these agents both in the original concentrations and in dilutions of 1 : 10 and 1 : 20 were surprisingly low (Nowakowska and Raszewski, 2009).

Astringents containing conventional non-injectable (packing) materials and the newly developed injectiontype retraction materials to be placed in the gingival sulcus remain in direct contact with free gingival margin tissues for some time and are also in contact with mineralized tooth structures prepared

by cutting. The practical application time of these substances reported in clinical studies were from 2 to 30 min (De Gennaro et al., 1982; Akca et al., 2006).

In numerous studies, the effectiveness of astringents under clinical conditions was evaluated positively. However, in vivo and/or in vitro observations showed that they induce undesirable local side effects on gingival margin tissues (De Gennaro et al., 1982; Azzi et al., 1983; Nemetz et al., 1984; Weir and Wiliams, 1984; Benson et al., 1986; Kopac et al., 2002a,b,c; Akca et al., 2006; Kumbuloglu et al., 2007; Al-Hamad et al., 2008). These authors demonstrated studies with human and animal models using various research methods that confirmed inflammatory response of the surrounding soft tissues. This was demonstrated by different methods: histomorphometric (De Gennaro et al., 1982; Kopac et al., 2002b,c; Akca et al., 2006), gingival crevicular fluid (GCF) flow measurements (Feng et al., 2006; Wöstmann et al., 2008), and of GCF analysis, for example TNF-a proinflammatory cytokine levels (Feng et al., 2006). The inflammatory response was normally transitory and its severity depended on the type and concentration of the retraction agent. Results obtained by SEM-EDX techniques reported an altered morphology of prepared human dentine surface after exposure to conventional astringents containing gingival retraction fluids (Land et al., 1994, 1996; Ayo-Yusufet al., 2005).

Cytotoxicity evaluation of human cell colonies is one of the most objective methods for assessing the biocompatilibity of dental materials and agents (Phillips, 1973; Mosman, 1983). Only Kopac et al. (2002a) studied this on Chinese hamster diploid lung fibroblasts (V-79-379 A) and Lodetti et al. (2004) evaluated keratinocyte viability after treatment with astringent-based agents. In an attempt to determine the safety level of retraction agents by human fibroblast viability evaluation, a newly developed method by Saczko et al. (2008) seems most valuable and appropriate.

The aim of this in vitro study was to evaluate the dynamic cytotoxic effects of different gingival retraction astringents, both solutions and gels, on human fibroblasts isolated from patients' gingival tissues.

Material and Methods

Retraction astringents

Ten gingival retraction agents from three different chemical groups (aluminium chloride, aluminium sulphate, and ferric sulphate), including five solutions and five gels, were selected for this study. Experiments with the original concentrations of all the gingival astringents, cell culture viability from 0 to 2 % were determined. The commercially available agents were diluted 1:10 and 1 : 20 with deionized water. Their characteristics and pH values are presented in Table 1 .

Cell cultures

The tissue cultures of human gingival fibroblasts (Fig. 1) were obtained from patients with healthy periodontium undergoing tooth extraction. The gingival biopsies were provided by the Department of

Dental Surgery of Wroclaw Medical University. The cells were isolated from the healthy gingival tissues according to the procedure described by Saczko et al. (2008). The cells were grown routinely in Dulbecco's Modified Eagle's medium (DMEM). DMEM (Sigma, St. Louis, MO) supplemented with 10% FBS and glutamine with penicillin/streptomycin (Sigma) in 25-cm2 flasks (Falcon, Franklin Lakes, NJ). The cells were maintained in a humidified atmosphere at 37 oC and 5% CO,. For experimental purposes, the cells were removed by trypsinization (0.25% Trypsin-EDTA, Sigma).

Cytotoxicity test

The MTT (3-(4,5-dimethyl-2-thiazollyl)-2,5-diphenyl-2H tetrazolium bromide) assay (Sigma) was used to evaluate the cytotoxicity of the gingival retraction astringents. Cells were seeded onto 96-well plates at a concentration of 5 ? 10"' cells/well. For the viability assay the cells were exposed to different gingival retraction agents. Following incubation for 3, 5, and 10 min and 24 h at 37 oC, the cells were washed twice in phosphate-buffered saline (PBS) (Invitrogen, Carlsbad, CA) and treated according to the manufacturer's protocol. The absorbance was determined using a multi-well scanning spectrophotometer at 570 nm (Multiscan MS, Helsinki, Finland). The results were expressed as the percentage of untreated control cells.

Statistics

The significance of differences between the mean values of different groups of cells compared with the control group (untreated cells) was assessed by Student's /-test, with values of $P < 0.05$ taken to imply statistical significance.

Results

The influence of three retraction astringent groups on gingival fibroblasts was investigated. Oxidoreductive mitochondrial function is shown in Fig. 2. In the group of retraction astringents that contained aluminium chloride (solution- and gel-based), the oxidative mitochondrial function of the fibroblasts was similar at a dilution of 1:10. After 3 min of incubation, the levels of viability were about 100 %, i.e. comparable to that of the control cells (Fig. 2 A). The 10% aluminium chloride agent (Gingiva Liquid) was the least cytotoxic of all the agents in the 1 : 20 dilution. Cells treated for 5 min with these compounds displayed significantly lower oxidative mitochondrial function at both dilutions than the control cells (1 : 10, 1 : 20) (Fig. 2 A), whereas after 10 min of incubation an increase in oxidative mitochondrial function in Gingiva Liquid-treated cells was observed, higher than in the control cells. The level of viability was comparable to that of the control cells for cells incubated with 20% (Alustin) and 25% aluminium chloride (Racestypine) at both dilutions (Fig. 2 A). The greatest damage to mitochondrial function was observed in cells treated with 25% aluminium chloride in gel form (Racécord gel). The results for the 20% aluminium chloride gels (Hemostat and Alustat) indicated cell viability (40

to 70 %) for both 3 and 5 min incubation (Fig. 2 B). Twenty-four-hour incubation with the retraction astringents resulted in the highest level of damage to mitochondrial function (Fig. 2 B).

For the agents containing aluminium sulphate we noted a significant increase in mitochondrial function compared with those based on aluminium chloride. Oxidative mitochondrial function was 1 10% for the 1:10 dilution and 140% in the cells treated with 25% aluminium chloride in liquid form (Orbat sensitive) and from 1 20% (1 : 1 0) to 1 30% (1 : 20) in the gel form (Gel cord) (Fig. 2 C). The level of viability decreased significantly in cells after 5 min of incubation and was similar to that of the cells after 10 min (Fig. 2 C). The levels of fibroblast viability were higher with the 1 : 20 dilutions and increased similarly to the control cells for sulphate aluminium, but were on the same level as that of sulphate aluminium in the gel form. Both forms of the astringents were cytotoxic after 24 h of incubation.

The agents based of ferrous sulphate demonstrated the statistically significant lowest level of viability (Fig. 2 D). After 3 min of incubation, oxidative mitochondrial function was below 50 % in the 1:10 dilution and at 1 : 20 viability increased to 90 %. Oxidative mitochondrial function decreased to below 50 % after 5 min and was on the same level for both dilutions, but after 1 0 min it rose to above 50 % for both ferrous sulphate retraction agents (Astringedent" solution and ViscoStaf gel, Ultradent Product, South San Francisco, CA).

Discussion

According to the guidelines of the American National Standards Institute (ANSI) and the Technical Report ISO-TR 7405 of the ISO Technical Committee concerning dentistry (TC 1 06), in vitro cytotoxic screening investigations of different cell cultures is commonly accepted as adequate for dental devices for the primary determination of their biocompatibility (Kopac et al., 2002a). In clinical practice, retraction agents are applied with retraction materials or incorporated in retraction materials directly into the gingival sulcus. They remain there until effective shrinkage and displacement of free gingiva away from tooth structures and haemostasis is obtained. Hence they remain in direct contact with the thin monolayer of epithelial cells in the gingival sulcus and the connective epithelium (epithelial attachment) at the bottom of the sulcus. Many authors observed an inflammatory response or even necrosis of the sulcular epithelium and subepithelial connective tissue induced by gingival margin retraction agents with an astringent base (De Gennaro et al., 1982; Azzi étal., 1983;Nemetz et al., 1984; Weir and Wiliams, 1984; Benson et al., 1986; Akca et al., 2006; Kumbuloglu et al., 2007; Al Hamad et al., 2008). Under these conditions, chemical agents influence the gingival connective tissues directly. The choice of primary cells cultured from fibroblasts obtained from patients with healthy periodontal tissue undergoing tooth extraction seems to be the most appropriate for constructing an adequate in vitro study model.

Only Kopac et al. (2002a) and Lodetti et al. (2004) studied the cytotoxic effects of gingival retraction fluids on cell cultures using the MTT assay. Kopac et al. (2002a) evaluated the viability of fibroblasts

obtained from Chinese hamster diploid lung (V-79-379 A) treated with astringents based on aluminium chloride and sulphate. After 1 min of exposure, all chemical agents in the original concentrations caused stronger cytotoxic effects than in 1 : 10 dilution. At a 1 : 10 dilution of the agents, the viability of Chinese hamster lung fibroblasts treated with 25% aluminium chloride was significantly lower than that of fibroblasts incubated with 10% aluminium chloride and 20% aluminium sulphate. The study of Lodetti et al. (2004) demonstrated the cytotoxic effects of astringent retraction solutions on human oral keratinocytes. The most damaging was the agent Astringedent X", which contains ferric sulphate and ferric subsulphate.

Kopac et al. (2002c) also observed changes in primary cell cultures of rat keratinocytes after 1 0 minutes of treatment with 25% aluminium chloride used for gingival retraction. The cells, examined by scanning and transmission electron microscopy, differed significantly from those of a control group.

Chemo-mechanical methods based on two-element systems may pose the additional danger of accumulation of the cytotoxic effects of the gingival retraction agent and material. Liu et al. reported that even non-impregnated cords were cytotoxic for human gingival fibroblasts cultured from gingival expiants. Evaluation after 1 0 min and 24 h of exposure to retraction cords impregnated with aluminium sulphate also demonstrated a significant potential for gingival toxicity (Liu et al., 2004).

In clinical conditions, the duration of the chemo-mechanical retraction procedure should range from 3 to 10 min (Nowakowska et al., 2006c). Our experiments took place in four time intervals: from 0 to 3 min, 3 to 5 min, 5 to 10 min, and 10 min to 24 h after treatment with three chemical groups of astringents in different concentrations and clinical forms. The results after 3 min showed that aluminium sulphate-based retraction agents and aluminium chloride-based fluids and gels ensure a relatively high oxidoreductive potential of fibroblasts. The statistically significant lower oxidoreductive functions of cells cultured with ferric sulphate-based astringents in the first 3 min of incubation suggest limitations in their use in clinical practice. The cytotoxic effects on fibroblasts after 5 min incubation to all evaluated retraction astringents exhibited the lowest viability. The increase of the viability of fibroblasts after 10 min of exposure to all of the evaluated chemical groups provided the interesting insight that oxidoreductive mitochondrial potential was activated, which may suggest a reactive defensive action of the cells to the impact of the retraction agents. The observation after 24 h showed that all the retraction agents (except for the ferric sulphate agents) caused a cytotoxic effect. According to the results it can be stated that cell viability increases with decreasing concentration of the astringents and decreases with increasing exposure time. Retraction agents composed of ferric sulphate proved to be the most cytotoxic, followed by aluminium chloride and aluminium sulphate. It seems that the lower pH of the agent, the higher the cytotoxicity.

The agent's form proved to have a significant influence on human gingival fibroblast viability. This experiment is most probably the first examination of the cytotoxic effects of gel-based retraction

astringents on gingival cells. The results obtained at the shortest exposition, i.e. 3 min, on fibroblasts (except for the ferric sulphate gel-based agent) revealed that the agents do not induce any significant increase of the cells' mitochondrial oxidoreductive functions. The use of gel-type astringents allows reducing the area of gingival tissue exposure to the effect of the retraction agent. Additionally, gel type agents diminish the scratching effect involved when applying and removing the retraction material into and from the gingival sulcus (Nagler et al., 2002; Nowakowska et al., 2006a).

Our results can be directly extrapolated to clinical conditions, but they are predictive of the probability of the behaviour of these agents under in vivo conditions. Healthy gingival epithelium and epithelial attachment constitute a natural barrier protecting the connective gingival tissues and reducing the level of damage. Additionally, the aggressive clinical action of chemical retraction agents may be less intense because their concentration is diluted by water spray, human saliva, and natural gingival fluids (Edgar, 1990; Nagler et al., 2002). A systematic in vivo review of the impact of retraction astringents on gingival margin tissues reported that the healing period after retraction with chemical agents in their original concentrations was from seven to ten days (Nowakowska, 2009).

The presented results may also suggest the need for reducing the use of retraction astringents in their original concentrations, especially ferric sulphates. This is particularly important when damage to the gingival margin tissues occurs during mechanical tooth preparation. In this case, retraction with the use of chemical retraction agents should be postponed until the tissues have recovered in order to reduce the potential cytotoxic effect on human gingival fibroblasts. These investigations suggest that the evaluated chemical retraction agents can have cytotoxic potential towards gingival tissues under clinical conditions. It can be concluded that there is a need to obtain oxidoreductive stress markers and determine the type of cell death induced by the retraction agents.

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Received May 14, 2010. Accepted September 5, 2010.

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Abbreviations: ANSI - American National Standards Institute, DMEM - Dulbecco's Modified Eagle's medium, GCF - gingival crevicular fluid, GRA - gingival retraction agent, GRF - gingival retraction fluid, GRG - gingival retraction gel, MTT - 3-(4,5-dimelhyl-2-thiazollyl)-2,5-diphenyl-2H tetrazolium bromide, PBS - phosphate-buffered saline.

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Dent Clin N Am 48 (2004) 433–444

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Current concepts in gingival displacement

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Indirect restorations, including cast gold inlays, onlays, partial veneer restorations and complete crowns, metal-ceramic and all-ceramic crowns, and bonded ceramic inlays and onlays are routinely used to restore defective teeth. These restorations frequently have cervical margins that are intentionally placed in the gingival sulcus for esthetic or functional reasons. In these situations, the clinician must make impressions that accurately capture the prepared cervical finish lines and permit the fabrication of accurate dies on which the restorations are fabricated.

There is evidence that inadequate impressions are frequently forwarded to commercial laboratories, and the chief deficiency seen in such impressions is inadequate recording of the cervical finish lines [1,2]. The primary reason for not adequately capturing marginal detail is deficient gingival displacement technique.

The procedure used to facilitate effective impression making with intracrevicular margins is gingival "displacement" as opposed to gingival "retraction" [3]. The goal of the procedure is to reversibly displace the gingival tissues in a lateral direction so that a bulk of low-viscosity impression material can be introduced into the widened sulcus and capture the marginal detail (Fig. 1) [4,5].

A bulk of impression material is required to obtain maximum accuracy and to improve the tear strength of the material so that it can be removed from the mouth intact with no tearing [6,7]. The critical sulcular width in this regard seems to be approximately 0.2 mm. A width of less than 0.2 mm results in impressions that have a higher incidence of voids in the marginal area, an increase in tearing of the impression material, and a reduction in marginal accuracy [8]. It is imperative that a small amount of impression material flows beyond the prepared margin (Fig. 2). This permits accurate trimming of the recovered die (Fig. 3).

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doi:10.1016/j.cden.2003.12.012

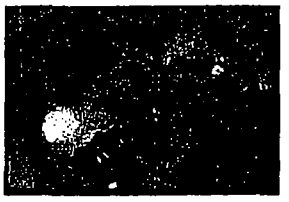

Fig. 1. The gingival tissues need to be displaced laterally to permit injection of a bulk of low-viscosity impression material into the sulcus.

Many clinicians have difficulty with gingival displacement procedures primarily because they have not mastered effective soft tissue management procedures [9,10]. One critical factor in this regard is to ensure that the gingival tissues are in an optimum state of health before making the impression [11]. Making impressions with inflamed marginal gingival tissues can be difficult and requires aggressive procedures that may result in gingival recession.

Quality provisional restorations are essential to establish an improved environment to facilitate oral hygiene procedures to improve and maintain gingival health [12,13]. The location of the prepared cervical margin within the sulcus is critical to long-term gingival health and to impression making. The optimum position of the margin is 0.5 mm from the healthy free gingival margin or 3.0 to 4.0 mm from the crest of the alveolar bone and must follow the natural scalloped form of the attachment and alveolar housing [14,15].

If the gingival tissues are healthy and the cervical margin is placed in the appropriate position, gingival displacement is a relatively simple, atraumatic procedure. Most of the difficulties with gingival displacement result from attempting to make impressions when the tissues are clinically inflamed, when clinically there is inadequate attached gingiva, or when prepared margins are placed too deep in the sulcus.

Techniques for gingival displacement have been classified as mechanical, chemical, surgical, and combinations of the three [16,17]. The method of gingival displacement used by the majority of practitioners is a combination of mechanical-chemical displacement using gingival retraction cords along with specific hemostatic medicaments [18]. A small number of dentists use

Fig. 2. A definite amount of impression material must flow beyond the prepared margin to facilitate trimming of the gypsum die.

Fig. 3. Trimming of gypsum die is a simple procedure when effective gingival displacement procedures result in excellent impressions.

surgical methods, including rotary gingival curettage and electro-surgery, but these are generally used as ancillary procedures in conjunction with mechanical-chemical techniques.

There are three main variations of the mechanical-chemical technique for gingival displacement. They include the single cord technique, the double cord technique, and the infusion method of gingival displacement [19–21]. Each of these techniques can be used effectively and are described in detail below. Before describing these techniques, a discussion of differences in retraction cords and medicaments may be useful.

Retraction cords are supplied in three basic designs, including twisted cords, knitted cords, and braided cords. There is little scientific evidence to differentiate one type of cord from another; thus, the selection of which design of cord to use is determined by operator preference. The authors prefer to use braided or knitted cords [22].

One key to effective displacement is to use a cord of sufficient diameter to provide adequate displacement so that adequate bulk of impression material can be introduced into the sulcus. The largest cord that can be atraumatically placed in the sulcus should be used (Fig. 4) [5,16]. The primary error made by inexperienced dentists is to use a cord that is too small in diameter. These small-diameter cords are placed with minimal trauma; however, they do not provide adequate lateral displacement of the gingival tissues.

There are numerous hemostatic medicaments that have been advocated for use with gingival retraction cords, and some of these medicaments have been extensively studied [23–33]. A review of the literature demonstrates that four medicaments seem to provide adequate displacement and fluid control and seem to be "safe" in that they do not produce iatrogenic soft tissue damage when used appropriately [18]. These medicaments include aluminum potassium sulfate, aluminum sulfate, aluminum chloride, and epinephrine.

The local use of epinephrine as a gingival displacement medicament has the potential to cause significant systemic side effects. The systemic effects of epinephrine have been studied extensively, and most researchers have concluded that epinephrine should not be used for routine gingival displacement [34–47].

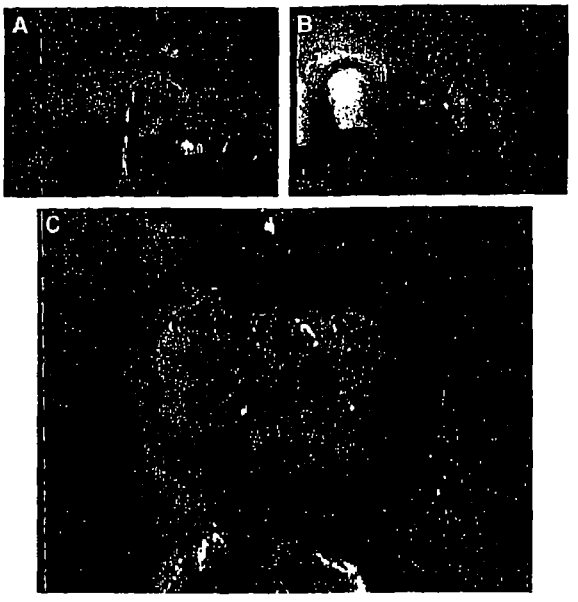

Fig. 4. The largest diameter cord that readily fits into the gingival sulcus should be used.

The literature on the absorption and effects of epinephrine from gingival retraction cords is somewhat contradictory. In correlating data from various studies, it is safe to conclude that under certain conditions epinephrine from retraction cords is absorbed systemically. Conditions that limit absorption are not clear, but increased absorption seems to occur with increased exposure of the vascular bed and with an increase in the total amount of epinephrine used. Increased doses may occur with the use of stronger concentrations of the medicament or with the use of multiple cords when making impressions of multiple prepared teeth.

Other factors related to the total dose of epinephrine received by a patient include the epinephrine administered in the local anesthetic solution and any endogenous epinephrine that may be secreted by the patient in reaction to stress or discomfort associated with the dental procedures. Epinephrine is contraindicated in patients with hyperthyroidism and in patients taking monoamine oxidase inhibitors or tricyclic antidepressants for depression, β-blockers, or cocaine. It also is contraindicated in diabetics and cardiovascular patients.

Determining which patients may be classified as cardiovascular patients can be difficult. Although many patients are clearly identified as a result of taking a careful medical history, many patients are unaware of incipient problems. Even though the majority of dentists routinely take blood pressure

and pulse records, resting pulse rates, resting blood pressure records, and resting electrocardiograph records miss approximately 45% of latent cardiovascular problems [48].

Clinicians should avoid using epinephrine for gingival displacement because of the significant number of contraindications for the use of epinephrine and the uncertainty of any given patient's cardiovascular status. Other equally effective medicaments have no systemic manifestations and are preferred. Fortunately, the use of epinephrine for routine gingival displacement has decreased over the years. In 1985, 79% of dentists routinely used epinephrine for retraction [18]. A recent article indicated that routine use had declined to 25% of respondents [49].

Techniques for gingival displacement

Gingival displacement can be accomplished using several different techniques. Common to all of them is the use of a retraction cord along with a chemical medicament. No clinical study has demonstrated the superiority of one technique over another, so the choice of which procedure to use depends upon the presenting clinical situation and operator preference.

The single cord technique

The single cord technique is indicated when making impressions of one to three prepared teeth with healthy gingival tissues. It is relatively simple and efficient and is probably the most commonly used method of achieving gingival displacement.

1. Tooth preparation is accomplished and cervical margins are dropped carefully to their pre-determined intra-crevicular position.
2. A length of gingival retraction cord is selected to specifically match the anatomy of each individual gingival sulcus. The largest-diameter braided (First String; Clinician's Choice Dental Products, London, Ontario) or knit cord (Ultrapack Cord; Ultradent Dental Products, Salt Lake City, Utah) that fits in the sulcus should be used.
3. The cord is soaked in the medicament of choice (eg, Hemodent; Premier Dental Products, Norristown, Pennsylvania).
4. Excess medicament is blotted from the soaked cord with a sterile cotton sponge. The cord is carefully packed into the sulcus in a counterclockwise direction.
5. After the cord is in place, the tooth preparation is carefully inspected to ascertain that the entire cervical margin can clearly be visualized and that there is no soft tissue impediment to easy injection of the impression material to capture all of the cervical margin detail (Fig. 5). If there is excess soft tissue blocking easy access, it can be displaced with an additional small section of cord or excised with an electro-surgery unit or soft tissue laser (Fig. 6).

Fig. 5. After the cord is in place, the prepared tooth should be carefully examined to determine that the entire cervical margin can be visualized.

6. At this point it is critical to wait 8 to 10 minutes before removing the cord and making the impression. The cord needs time to effect adequate lateral displacement, and the medicament needs time to create hemostasis and crevicular fluid control.
7. Before removing the cord, the cord should be soaked in water to allow it to be easily removed from the sulcus. Removal of the cord when dry is traumatic and tears the inner epithelial lining and initiates hemorrhage [50].
8. The tooth preparation(s) should be gently dried and the impression made.

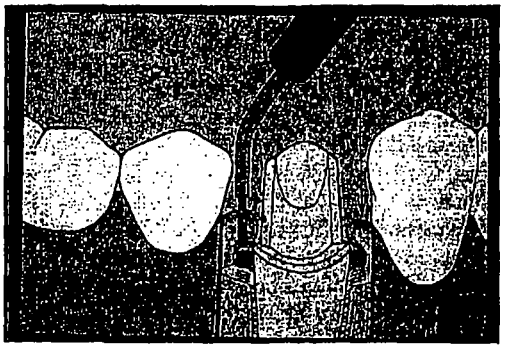

Fig. 6. If excess soft tissue obscures the prepared cervical margin, it should be removed using electro-surgery or a soft tissue laser.

The double cord technique

The double cord technique is routinely used when making impressions of multiple prepared teeth and when making impressions when tissue health is compromised and it is impossible to delay the procedure [20]. Some clinicians use this technique routinely for all impressions (Fig. 7).

1. A small-diameter cord (Deknatal 2/0 Surgical Silk Suture Material; J. Deknatal, Queens Village, New York) is placed in the sulcus. The ends of this cord should be cut so that they exactly abut against one another in the sulcus. This cord is left in the sulcus during impression making, and if the cord is too short (creating a space between the ends) or too long (creating overlapping ends), it may become impregnated into the

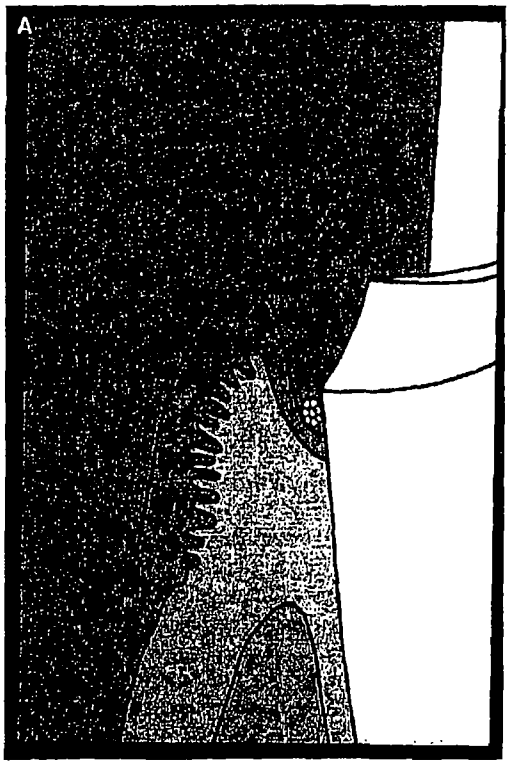

Fig. 7. With the double cord technique: (*A*) A small-diameter cord with no medicament is first placed in the depth of the sulcus. (*B*) A larger-diameter cord with the medicament is placed above the small-diameter cord. After waiting 8 to 10 minutes, the large-diameter cord is soaked in water and removed. The small-diameter cord is left in the sulcus during impression making.

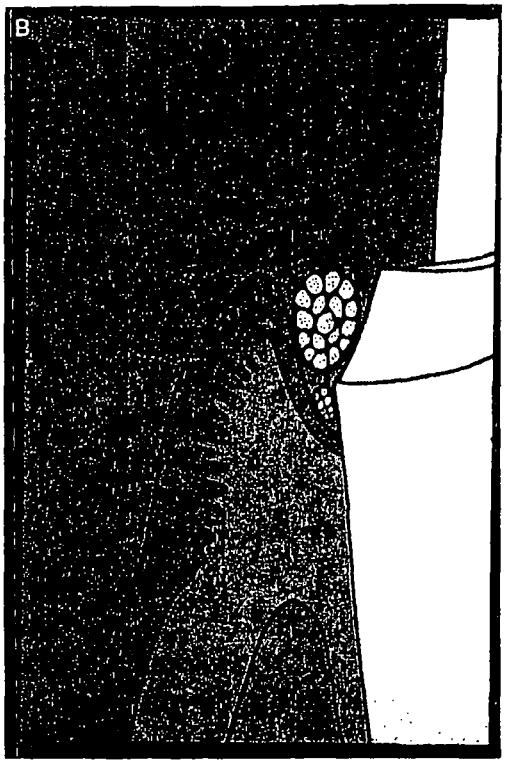

Fig. 7 (*continued*)

impression. This can create difficulties later in pouring the impression and trimming the dies.

2. A second cord, soaked in the hemostatic agent of choice, is placed in the sulcus above the small-diameter cord. The diameter of the second cord should be the largest diameter that can readily be placed in the sulcus.
3. After waiting 8 to 10 minutes after placement of the large cord, the second cord is soaked in water and removed. The preparation(s) are dried, and the impression is made with the primary cord in place.
4. After successfully making the impression, the small-diameter cord is soaked in water and removed from the sulcus.

This technique can be used with single or multiple preparations. It is especially useful with multiple preparations where gingival fluid exudate can seep over the prepared cervical margins of the last teeth to be impressed after cord removal.

The infusion technique of gingival displacement

The infusion technique for gingival displacement uses a significantly different approach from the single or double cord techniques [21].

1. After careful preparation of the cervical margins in an intra-crevicular position, hemorrhage is controlled using a specifically designed dento-infusor with a ferric sulfate medicament. Two concentrations of ferric sulfate, 15% (Astringedent; Ultradent Dental Products, Salt Lake City, Utah) and 20% (Viscostat; Ultradent Dental Products, Salt Lake City, Utah), are available. The 20% material is preferred because it is less acidic than the 15% solution and does not remove the smeared layer of dentin from the prepared tooth.
2. The infusor is used with a burnishing motion in the sulcus and is carried circumferentially 360° around the sulcus. The medicament is extruded from the syringe/infusor as the instrument is manipulated around the gingival sulcus.
3. When hemostasis is verified, a knitted retraction cord (Ultrapack Retraction Cords; Ultradent Dental Products) is soaked in the ferric sulfate solution and packed into the sulcus.
4. Advocates of this technique recommend leaving the cord in place 1 to 3 minutes.
5. The cord is removed, the sulcus is rinsed with water, and the impression is made.

In the opinion of the authors, this technique is effective in achieving hemostasis, but, because the cord is left in place for only 1 to 3 minutes, it may not provide adequate lateral displacement to permit an adequate bulk of impression material into the sulcus. It is not recommended that the cord be left in the sulcus for longer times because histologic data are not available to demonstrate that it is safe to do so.

The dento-infusor and the 20% ferric sulfate have proven to be an effective ancillary technique for control of hemorrhage when using the single cord technique. Occasionally, even with careful technique, isolated areas of bleeding may occur when the cord is removed from the sulcus. In such situations, the infusor and medicament can be used in the sulcus with firm burnishing pressure for approximately 15 seconds. This predictably controls hemorrhage.

When using ferric sulfate materials, patients should be forewarned that the tissues may be temporarily darkened. The tissues take on a blue-black appearance that usually disappears in a few days.

The "every other tooth" technique

When making impressions of anterior tooth preparations, it is critical that no damage is done to the gingival tissues that may result in recession. With teeth with root proximity, placing retraction cord simultaneously

around all prepared teeth may result in strangulation of the gingival papillae and eventual loss of the papilla. This creates unesthetic black triangles in the gingival embrasures.

This undesirable outcome can be prevented with the "every other tooth" technique. This can be used with the single or double cord technique. Retraction cord is placed around the most distal prepared tooth. No cord is placed around the prepared tooth mesial to this tooth. Retraction procedures are completed on alternate teeth. If, for example, teeth #5 through #12 are prepared, cords would be placed around teeth #5, #7, #9, and #11. The impression is made; gingival displacement is accomplished on teeth #6, #8, #10, and #12; and a second impression made. A subsequent pick-up impression allows fabrication of a master cast with dies for all eight prepared teeth.

New materials

As with other procedures in restorative dentistry, a few relatively new products and techniques have been introduced. These include strips of a sponge-like synthetic polymer that expands after insertion into the sulcus. This material can theoretically be placed in the sulcus with no local anesthetic and thus results in minimal trauma [51,52]. Another material is supplied in a syringe and is designed be injected into the unretracted sulcus (Expasyl; Kerr Dental Products, Romulus, Michigan). Once in the sulcus it theoretically expands and provides displacement and hemostasis. The predictability and efficacy of these materials has yet to be established.

Summary

Gingival displacement is an important procedure with fabricating indirect restorations. Gingival displacement is relatively simple and effective when dealing with healthy gingival tissues and when margins are properly placed a short distance into the sulcus.

The most common technique used with gingival displacement is use of gingival retraction cords with a hemostatic medicament. Retraction cords of sufficient diameter should be used to provide adequate lateral displacement to create a mean sulcular width of 0.2 mm. Epinephrine containing retraction cords should be avoided.

Several techniques have proven to be relatively predictable, safe, and efficacious. No scientific evidence has established the superiority of one technique over the others, so the choice of technique depends on the presenting clinical situation and operator preference.

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Effective Hemostasis and Tissue Management

Written by Dean Elledge, DDS, MS Wednesday, 06 October 2010 18:01

INTRODUCTION

A common clinical challenge dentists face with restorative procedures is blood contamination. There are a variety of reasons that the gingiva can bleed, including from plaque, trauma, and/or an encroached biologic width. Plaque causes gingivitis, caries, and periodontitis. Trauma that happens during the restorative procedure can cause bleeding. Wedges can press laterally and aggressively against the gingival papilla, and metal or plastic matrix bands' sharp edges can cut healthy/inflamed tissue during the isolation of the cavity. Burs are used to excise the caries, excise inflammatory tissue, and widen the gingival sulcus. Cords are packed to deflect or retract the gingiva in attempt to expose the cavity margin. Any of these events can result in blood contaminating the restorative field, thus negatively affecting impressions, cavity preparation, restorative materials, and cementation.

There is an association between restorative care and periodontal health. An encroachment of the biologic width happens when the restorative margins are placed too deep within the sulcus. Inadequate restorations can have ledges or areas that are not cleansable, which can contribute to plaque accumulation. Adolescents and geriatrics alike can have poor oral hygiene. New restorations are often needed because plaque control has been compromised. In addition, a high-carbohydrate (sugary, carbonated beverages) and nutrient-poor (refined foods) diet is a primary contributing factor in the patient examples presented in this article.

To eliminate gingivitis and a periodontal condition, there must be an accurate marginal fit of the restoration. A good example is a fixed prosthodontic restoration. The fit of the restoration is related to the completeness of the impression. An inadequate impression from blood contamination creates a problem with the restoration if the impression is forwarded to the dental laboratory. The impression will produce an inaccurate die due to negative voids or positive bubbles (Figure 1).

If the dental laboratory technician team fabricates a restoration to an inaccurate die, the dentist receives an unacceptable restoration that will be rejected. The doctor must reappoint the patient and send a new impression back to the lab. The revenue stream is broken for all involved. The patient may have to take time off from work, the dentist has to provide additional chair time, and the dental technicians involved in the case will be expected to accommodate the process.

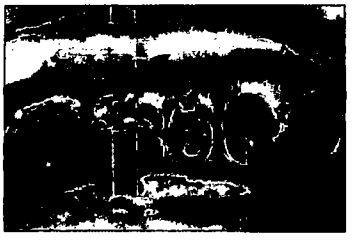

Figure 1. (Case 1) Blood has contaminated first impression to create voids.

When there's a problem, we tend to blame someone else. To the dentist, it feels like a personal failure, but it is often actually a systems failure. If the system is not corrected, profits for both the dentist and laboratory are negatively impacted. The challenge is to look at the system of controlling blood and fluids in the restorative treatment site to see how the technical steps and/or materials being used can be improved.

With case examples, this article will demonstrate how one can improve the quality of one's indirect restorative work by changing his or her technique protocol (system) to effectively control bleeding and manage the soft tissues.

HEMOSTASIS: A CHALLENGE IN THE PRESENCE OF TISSUE INFLAMMATIOn

Case 1

The system that produced the defective impression seen in Figure 1 was a standard cord soaked in a hemostatic solution and a one-step impression. The cord was placed on inflamed tissues after restorative techniques were accomplished for subgingival caries. Subgingival caries required a subgingival core buildup, which led to a subgingival crown preparation. Inflamed tissue usually bleeds, and it was unlikely that the aforementioned system would have been able to effectively control bleeding during the impression-taking procedure.

For this patient, a new impression was necessary to optimize the accuracy of the indirect technique in the dental laboratory. To correct a faulty system, a new impression-taking protocol needed to be utilized. One change that was incorporated into the impression retake steps included the use of Traxodent (Premier Dental Products). This paste system is used prior to taking impressions for both gingival retraction and hemostasis. Traxodent contains aluminum chloride (Hemodent) that causes contraction and shrinkage of tissues, protein to precipitate, blood vessels to contract, and fluids to be removed from tissues. Aluminum chloride paste also reduces the risk of postoperative inflammation. According to the scientific literature, it is the least irritating of the retraction medicaments.[1] In addition, it produces no detectable recession of the gingiva after placement into the sulcus.

Before retaking the impression, the bleeding tissue was rinsed, and attempts were made to dry the oozing area. A straight cannula was applied to the Traxodent syringe and, in this case, the cannula was formed over a mirror handle to make a 90° bend. The bend helps placement in the posterior regions of the mouth where direct access is not possible. The Traxodent paste was then applied on top of the bleeding tissue and slowly injected above the sulcus and around the periphery of the preparation margin. It should be allowed to remain in the sulcus from 1 to 2 minutes (Figure 2). When using Traxodent paste, one first notices that the gingiva blanches, and then, any oozing blood will become brown and stagnant. These are the 2 signs of hemostasis, ensuring a successful outcome of the impression.

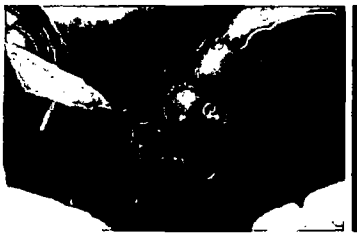

Figure 2. Hemostatic paste (Traxodent [Premier Dental Products) was extruded into bleeding sulcus. (It is left in place for one to 2 minutes.)

Figure 3. The impression was retaken. Note the blood-free retake impression without voids as a result of using a different and improved protocol (system).

The paste was then rinsed thoroughly with an air-water spray and dried. Once these steps were done, hemostasis was achieved and the gingival sulcus was dry. A light and medium-body impression material (Honigum [DMG America]) was used to make a one-step impression (Figure 3).

The techniques employed in this case, Traxodent with Honigum, resulted in an excellent impression without additional cord packing. (Other impression materials/techniques could be used effectively as well.) Note also that a small amount of impression material has flowed beyond the prepared margin (Figure 3), allowing the dental technician to accurately trim the gypsum die. This will permit the fabrication of a precise fitting restoration.

HEMOSTASIS AFTER ROTARY CURETTAGE
Case 2

Figure 4. (Case 2) Blood and fluid were evident in the gingival trough.

Figure 5. Hemostatic paste was placed in direct contact with the bleeding tissues.

Figure 6. A retraction cap (Premier Dental Products) adds pressure for additional gingival deflection.

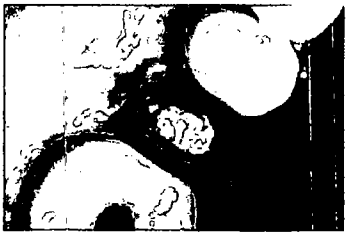

Figure 7. The hemostatic paste was rinsed away and dried, prior to taking the impression.

The tooth in Figure 4 had an amalgam core buildup supported by pins. The tooth needed the support of a full crown. It had a healthy sulcus and sufficient attached gingiva. The full crown here required the incorporation of a ferrule in the preparation design for an improved long-term prognosis. Creating the ferrule in this case required that the tooth be prepared to the bottom of the gingival sulcus. Rotary curettage with a high-speed diamond (Curettage GCP 254.SB [Premier Dental Products]) was used to trough and quickly excise the sulcular lining adjacent to the margin. Research shows that rotary curettage has little effect on the marginal heights of gingiva if adequate keratinized gingiva is present.[2] Rotary curettage was also needed to create a 0.2-mm space in the sulcus to maintain adequate thickness of polyvinyl siloxane impression material. This thickness of impression material is needed to prevent tearing and to prevent distortion upon removal from the mouth.[3] The removal of the sulcular lining resulted in bleeding (Figure 4). Traditional methods would require cord placement for 4 to 10 minutes for sulcular expansion. In this case, the Traxodent paste was placed for 2 minutes to stop the bleeding created by the rotary curettage (Figure 5). Additional deflection was achieved using a retraction cap (Premier Dental Products) (Figure 6). After thoroughly rinsing the paste off with an air-water spray, only amalgam debris remained. The sulcus was dry, and hemostasis had been effectively achieved (Figure 7).

HEMOSTASIS PRIOR TO CEMENTATION

Case 3

Bleeding is sometimes an unexpected event. In this case, when the temporaries were removed, there was bleeding throughout the treatment site (Figure 8).

Figure 8. (Case 3) Bleeding obscures finish lines.

Figure 9. Hemostatic paste was applied to the inflamed and lacerated tissues and left in place for 2 minutes.

Figure 10. Hemostatic paste was rinsed away to expose finish lines.

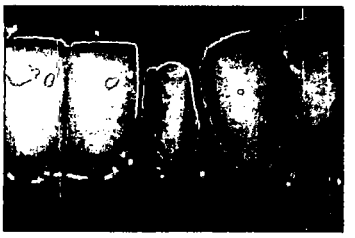

Figure 11. (Case 4) Veneer preparation with a bleeding sulcus.

Many times the operator will encounter blood in a cementation site. If blood were to intermix with cement, it would be detrimental to the physical properties of the cement. If blood were to remain on the tooth prior to cementation of a restoration, it would function like a separating medium with a resultant loss of retention. Additional problems could include pulpal inflammation with sensitivity to a stimulus such as cold, heat, or pressure. Pulpal inflammation would initially be reversible; however, the potential for irreversible pulpitis and loss of the tooth are a possibility. Sometimes, the patient is aware of bleeding near the treatment site when flossing. More often, bleeding comes from not flossing the interproximal tissue regularly to remove plaque. The tissue becomes inflamed and poorly keratinized, and it will bleed with minimal stimulation. The gingival tissue has the signs of erythema owing to the proliferation of capillaries.

In this case, Traxodent paste was applied immediately to the sulcular area (Figure 9). After 2 minutes, it was rinsed away, and the teeth were ready to receive their cemented crowns (Figure 10). Traxodent effectively controlled the bleeding and allowed for visualization/isolation of the treatment site for an intact cementation without contamination.

AESTHETIC ZONE TREATMENT

Case 4

In anterior aesthetics, it may not be desirable to create a trough around the margin with a bur, a cord, or laser since this may be detrimental to the aesthetic outcome. Cosmetic restorations are challenging because the preparation line is in close contact with the gingiva. When the root shade is very dark, it can create a dark line in the cervical area. Patients are aware of this problem as an aesthetic concern. Cord placement could lead to ulceration or inflammation of the junctional epithelium. The problem is that it is hard to accurately control the forces used in the placement of cord. If the facial gingiva is a thin biotype, there is a chance of gingival line migration. Other trauma, such as mechanical pressure or surgical trauma, can cause an undesirable migration of the gingival line away from the margin. Like Magic FoamCord (Coltène/Whaledent), using a hemostatic paste is a less traumatic method to dry the field and to achieve mild retraction of the tissue.[4]

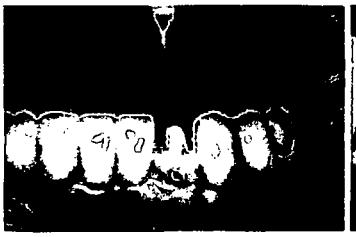

Figure 12. The hemostatic paste was extruded with the cannula aligned parallel to tooth.

Figure 13. Hemostatic paste was then rinsed away.

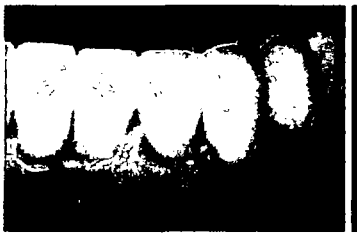

Figure 14. Full gingival rebound at a 3-month recall. Ceramic veneer (Root Dental Lab) fabricated of Empress (Ivoclar Vivadent).

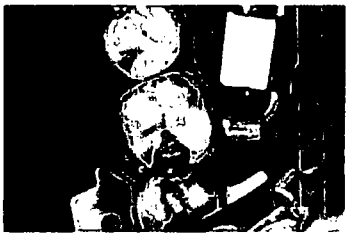

Figure 15. (Case 5) The gingiva was inadvertently lacerated during caries excavation.

The patient in Figure 11 has high aesthetic concerns and dislikes the dark and contrasting colors along the gum line. She presented with a fractured porcelain veneer that required replacement. The tooth had already been prepared at the crest of the gingival sulcus. The veneer was removed with a high-speed diamond bur, with the location of the margin left in the same location. Inadvertent bur contact to sulcular tissue resulted in lacerated areas that bled. To prepare the tooth for the impression-taking procedure, Traxodent was placed into the sulcus and allowed to remain (Figure 12). After 1 to 2 minutes, the tooth was rinsed with air-water spray and dried (Figure 13). A one-step impression (light body on the tooth and a medium-body tray material) produced an accurate impression without bubbles or voids. The replacement veneer was cemented with a subgingival margin. At the 3-month recall, the margin level remained stable and within the aesthetic zone (Figure 14).

HEMOSTASIS WITH DIRECT RESTORATIONS

Case 5

Blood contamination during a Class II filling has the same risk as a crown and bridge procedure. It can mean lengthening of the procedure for the patient and disruption of the patient schedule for the doctor.

In this case, the problem began with interproximal caries (Figure 15). Interproximal hemorrhage can often be associated with caries. Caries seen on the radiograph is an approximation of the depth of the caries. In the mouth, the caries is often more extensive, and its removal requires an expansion in cavity size. Other times, the subgingival preparation is used to obtain an adequate resistance and retention form for clinical crown length. With these patients, bleeding is common and upregulated if the patient is on a blood thinner such as Warfarin, aspirin, or Plavix. Bleeding begins from the inflamed interproximal gingiva if it is touched with a bur during caries excavation.

Figure 16. Hemostatic paste was applied directly to the bleeding tissue.

Figure 17. The hemostatic paste was rinsed away, revealing effective hemostasis.

Bleeding can also occur during isolation procedures when the band, wedge, or rubber dam is placed in contact with inflamed tissue (Figure 16). In this case, Traxodent was applied to the bleeding area located in the deepest part of the interproximal box and allowed to remain for the recommended time (Figure 17). Then, it was rinsed away with air-water spray, dried, and hemostasis was confirmed. Visualization of the entire cavosurface was evident. The direct filling was then placed in a routine manner.

DISCUSSION

These case reports demonstrate a hemostatic system (Traxodent paste) that effectively addressed the common problem of bleeding in the restorative treatment sites. The paste has a thixotropic property that allows entrance into restrictive sulcular spaces and then remains in position. This property is important when treating the maxillary arch or the mandibular arch because the medicament remains in the sulcus, not in the vestibule or throat. Once applied, the product remains in position, even if contact is made by the tongue or cheek. This is important to the patient because it allows a less offensive procedure.

In general, hemostatic agents are strong astringents that create a dry, puckering feel in the mouth with a sandpapery sensation. This delivery system is important to the dentist because it allows the medicament to remain with intimate contact and at full strength in the gingival sulcus, thus preventing the need for reapplication due to dilution by saliva or gravity runoff. The paste differs from liquid hemostasis agents because it has the ability to absorb fluids in a manner similar to Expasyl (Kerr) paste.

Treatment sites adjacent to alveolar mucosa may communicate to deeper spaces. The operator should be aware of the problems of a poor treatment site that lacks attached, keratinized tissue. One precaution would be the risk of washing hemostatics into deep spaces between tissues where the product is not intended to be applied. Traxodent paste is intended to be injected on top of tissue, not submucosally. It is also not intended to be used for the treatment of gingivitis, periodontitis, or other conditions. The operator needs to supervise its application in the dental treatment site.

CONCLUSION

Hemorrhage is a common problem that is encountered during restorative procedures. Common causes are a plaque-induced erythema from gingivitis next to the treatment site or inadvertent instrumentation that lacerates gingival tissues in the restorative procedure. Any trauma to inflamed tissue or healthy tissue results in bleeding into the restorative field. Bleeding results in distorted impressions, unbonded fillings, and contaminated cements.

It is vital to control gingival bleeding and to manage the soft tissue without additional tissue damage to produce successful restorations for the dentist and patient.

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J Indian Soc Periodontol. 2010 Jan-Mar; 14(1): 35–39.
doi: 10.4103/0972-124X.65436
PMCID: PMC2933527

Effect of retraction materials on gingival health: A histopathological study

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Abstract

Go to:

Background:

Gingival retraction methods are used in dentistry for impressions of subgingival crown margins, such as, mechanical, chemical, chemicomechanical, and surgical. These methods may injure the gingival sulcular epithelium. Hence, the present study is carried out to evaluate the effect of different retraction materials, such as, Expasyl, Magic Foam Cord, and impregnated retraction cord on the gingival sulcular epithelium.

Materials and Methods:

This study included 30 cases of bilateral premolar extraction patients with Loe and Silness gingival index zero. Retraction materials were kept in the dry, isolated labial gingival sulcus for the required time. The retraction materials were removed by rinsing with water. Retracted gingiva of 2 – 3 mm from the gingival margin along with the tooth was extracted and the decalcified sections were microscopically studied. Data analysis: Data were analyzed by applying the chi-square test.

Results:

This study showed better results with retraction paste as compared to the retraction cord, and there was a significant association between retraction materials and the relative degree of injury to the sulcular epithelium.

Conclusion:

There is a significant association between retraction materials and gingival sulcular epithelium. It can be stated that impregnated retraction cord, may be used commonly but it needs proper tissue manipulation and is technique sensitive. Newly advanced material in the form of retraction paste like Expasyl or Magic Foam Cord was found to be better than cord as assessed histologically, it respects periodontium.

Keywords: Expasyl, magic foam cord, junctional epithelium, retraction cord

INTRODUCTION

Go to:

Impressions for subgingival crown margins require gingival tissue retraction. Conservative retraction methods involving tissue displacement include the placement of copper bands or cords with or without caustics and astringents. In other methods, the gingival tissue is excised, as in resection by electrosurgery. Copper-band impression was indicated as the major factor producing gingival recession. Also sulcus damage with electrosurgery was reported to vary depending on the type of unit used.[1]

The relationship between periodontal health and restoration of teeth is intimate and inseparable. For restoration to survive long term, the periodontium must remain healthy so the teeth are maintained. For the periodontium to remain healthy, restoration must be critically managed in several areas so that they are in harmony with the surrounding periodontal tissue. Restorations play an important role in the ecological balance of plaque and maintenance of the periodontium.[2] If a margin of restoration has to be placed supragingivally or equigingivally then there is no need for gingival retraction. However, in unavoidable conditions, like in anterior restorations, for esthetic purposes, margins must be placed subgingivally; hence, it needs gingival retraction procedures, which may cause a violation of biological width. The dimension of the space that the healthy gingival tissue occupies above the alveolar bone is called the 'biologic width'. This comprises of 1.07 mm of connective tissue attachment and 0.97 mm of junctional epithelium. The biologic width should not be violated in any restorative procedure. The average biological width is 2.04 mm.[3]

Various gingival retraction methods are mechanical, mechanochemical, electrosurgery, rotary gingival curettage, etc. The most commonly used method is the mechanochemical one. Use of the mechanochemical method leads to violation of biological width, causing bone loss and recession. Studies on the chemicomechanical and purely mechanical cord retraction techniques have shown various degrees of necrosis and/or stripping of the gingival sulcus.[4] Gingival electrosurgery for crevicular troughing involves a considerable risk of producing permanent periodontal damage.[5]

Very few histological studies have been reported on the effects of using retraction materials on the gingival sulcular tissue, although disruption of the sulcular epithelium could be expected. Hence, this study has been carried out to identify whether chemicomechanical and mechanical retraction materials injure the gingival sulcus epithelium. If so, which retraction material is better and causes less injury.

Aims and objectives

Dental surgeons generally believe that retraction materials do not cause injury to the gingival sulcus epithelium. As injury to sulcular epithelium cannot be detected clinically, except after the most severe damage, this study is based on histological findings.

1. To determine the effect of the most commonly used retraction materials: Expasyl, Magic Foam Cord, and impregnated retraction cord on gingival sulcular epithelium.
2. To find out the association between Expasyl, Magic Foam Cord, and the impregnated retraction cord and gingival sulcular epithelium.

MATERIALS AND METHODS

Go to:

Thirty patients of age 11–17 years, with bilateral first premolar extraction cases in both maxillary and mandibular arches, were selected, irrespective of sex, who referred to the Orthodontia Department Rural Dental College, Loni, with Loe and Silness gingival index zero. Patients with improper oral hygiene, crowding, bleeding on probing, periodontal pocket, gingival recession or enlargement and any systemic diseases or conditions were excluded from the study. The protocol was clearly explained to all the patients and informed consent was obtained from all the recruits.

Material

A) Retraction paste

i. Expasyl – Aluminum chloride (15%), Kaolin, Water (Satelec ACTEON group)
ii. Magic Foam Cord – Polyvinylsiloxane, addition type silicone elastomer

vailable in form of Base – White; Catalyst – Blue (Coltene / Whaledent AG, Switzerland)

B) Retraction cord

Impregnated retraction cord with 5% Aluminum Chloride (Ultrapak, Ultradent products, Inc., Germany)

Retraction procedure for Expasyl

Expasyl is a paste for temporary gingival retraction that ensures separation of the marginal gingiva and drying of the sulcus. The material is supplied in capsules (cartridges), and comes with a preformed gun-type of device into which the capsule has to be placed and then the material is expressed. Labial gingival sulcus of the maxillary right first premolar was rinsed with water, dried with air stream and isolated with cotton rolls. The retraction paste was slowly injected into the sulcus (2 mm/s) with the tip parallel to the long axis of the teeth, as shown in Figure 1a. The point of the cannula must create a closed space between the tooth and the marginal edge of the gingiva. Clinically, the complete filling of the sulcus can be discerned by a slight blanching of the gingival marginal area.[6] Depending on the tonicity of the gingiva it is kept in place for one minute in the thin and two minutes in the thick marginal gingiva. It is easily visible because of its color. Subsequently, it is removed by air and water spray.

Figure 1a

Expasyl paste in gingival sulcus of maxillary right 1st premolar

Retraction procedure for Magic Foam Cord

As shown in Figure 1b, the labial gingival sulcus of the mandibular left first premolar was rinsed with water and dried with an air stream. A Magic Foam Cord cartridge was placed in the dispenser and the cartridge cap removed. The handle was compressed to express some material onto a paper until the base and catalyst flowed out of the opening in equal amounts, which ensured an optimum mixture. The oral tip was placed onto the mixing tip. The Magic Foam Cord was slowly injected into the sulcus and then the Comprecap Anatomic was placed. Due to the counter pressure of the Comprecap Anatomic, there was an expansion of the Magic Foam Cord in the sulcus. It was kept in place for five minutes. Subsequently, after proper setting, both the Magic Foam Cord and Comprecap were removed in one piece. Next the Magic Foam Cord was completely removed by air and water spray.

Figure 1b

Magic Foam Cord in gingival sulcus of mandibular left 1st premolar

Retraction procedure for retraction cord

The use of gingival retraction cords with 5% aluminum chloride has been shown to be safe and effective.[7] The labial gingival sulcus of the maxillary left-sided first premolar is rinsed, dried, and isolated with cotton rolls [Figure 1c]. An Ultrapak, 00 #, 5% aluminum chloride impregnated retraction cord is cut for the required length and placed in the sulcus with a cord packer and placed for ten minutes. It is suggested that the placement starts at the interproximal gingival crevice, where there is usually more tissue, and continues circumferentially. After the required period, the time cord was removed, and the gingival sulcus washed and dried.[8]

Figure 1c

Retraction cord in gingival sulcus of maxillary left 1st premolar

In this case the retraction procedure was performed by the same expert prosthodontist to minimize interexaminer error.

Extraction and laboratory procedure

As microscopically the features of acute inflammation can be seen as early as within 48 hours, the patients were considered for extractions after 48 hours of retraction. The patient was anesthetized using 2 ml of 2% lidocaine with 1: 50,000 epinephrine. An incision using a No. 15 surgical blade was made facially 2 – 3 mm away from the marginal gingiva. The extraction was performed mainly with an elevator to reduce tissue trauma. The tooth was extracted with the adjacent marginal gingiva, decalcified with 10% formic acid, processed with a series of 70, 80, and 90% absolute alcohol, xylene2, and xylene1. Microscopic sections were obtained by cutting the labiolingual block sections at eight microns, with microtome and staining done with hematoxylin and and eosin stain.[9]

Histological examination

As the cellular response to the retraction materials was the main interest, the following criteria were used to determine the changes depending upon the relative injury caused by the retraction materials.[9]

Normal – Normal gingival epithelium
Mild – Stripping and desquamation of the epithelium

Moderate – Hydropic degeneration, hyperemia, inflammatory cells
Severe – Epithelial proliferation and necrosis

RESULT

Go to.

The histological specimen of the retraction cord revealed that the cord was pressed past the cementoenamel junction with facial displacement of the entire gingival unit. The sulcular epithelium was present, but disrupted. The junctional epithelium was sometimes missing from the outermost border. The residual junctional epithelium displayed intracellular hydropic degeneration, stripping, and desquamation of the epithelium [Figure 2a].

Figure 2a

Histologic view with Expasyl

However, the histological specimen of the retraction paste shows only eight cases of disrupted junctional epithelium and sulcular epithelium, as compared to the retraction cord. The remaining specimens show an intact junctional epithelium [Figure 2a and b].

Figure 2b

Histologic view with Magic FoamCord

Thus, mechanical and mechanochemical methods do cause injury to the gingival sulcus epithelium, but the injury varies from slight with retraction paste to severe with retraction cord [Figure 2c].

Figure 2c

Histologic view with retraction cord

From the observations shown in Table 1, it was perceived that out of the 30 cases studied, mild injury was noticed with the use of Expasyl, Magic Foam Cord, and impregnated retraction cord, of 6.67, 20, and 36.67%, respectively. Moderate injury was observed with the use of impregnated retraction cord in 20% of the cases. No severe injury was observed with the use of different retraction materials.

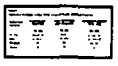

Table 1

Distribution of relative degree of injury caused by the retraction materials

By applying the chi-square test, it has been proved that there is a significant association between different retraction materials and the relative degree of injury to the gingival sulcular epithelium, that is, $P<0.05$.

DISCUSSION

Go to:

Although, from periodontal point of view, it is preferable to place the margins of restorations supragingivally, for esthetic or other reasons, the dentist may be forced to place them subgingivally.[10] Other studies using clinical and histopathological evaluation of gingival retraction in humans show that gingival retraction with the cord caused destruction of the junctional epithelium, which took about eight days to heal. The average postoperative gingival recession seen with cord retraction was 0.2±0.1 mm.

The most widely used and popular method is the use of retraction cords. A study by Van der Velden and De Vries has shown that the epithelial attachment sustains injuries at a force of 1 N/mm², while it ruptures at 2.5 N/mm². The cord technique requires almost 2.5 N/mm². The retraction cord achieves the desired retraction, but placing a retraction cord is not an easy method.[6] It needs physical manipulation of the tissue, leading to gingival bleeding. Thus, use of a retraction cord has the risk of epithelial attachment injury, pain during cord placement, sometimes requiring local anesthesia. Also, more time is required, and it may initiate gingival bleeding and oozing.

A complete paradigm shift has been made with the introduction of a very novel idea to achieve retraction and hemostasis at the same time. In our study we compared the two retraction materials: Expasyl and Magic Foam Cord with the conventional retraction cord. We used the maxillary right first premolar for gingival retraction with Expasyl and the mandibular left first premolar with Magic Foam Cord. The fundamental principle of the Expasyl was to insert a stiff, hemostatic, plastic, non-setting material into the gingival sulcus under mild pressure and allow the material to stay in place for 1 – 2 min6. In our study, the histological specimen of the retraction cord revealed that the disrupted sulcular epithelium and junctional epithelium were sometimes missing. Also, the junctional epithelium displayed intracellular hydropic degeneration, stripping, and desquamation of epithelium. These findings are similar to Jon Ruel *et al.*[8] and R. Azzi *et al.*[10] The histological specimens of the retraction paste showed only six cases of disrupted junctional epithelium and sulcular epithelium as compared to the retraction cord. The remaining specimens showed an intact junctional epithelium. According to Patrick Lesage and Mona Kakar, the material under pressure caused sufficient displacement of the gingival tissue and this displacement stayed in place long enough for either recording of the impression or to carry out the restorative or bonding procedures. [6] It was noninvasive, simple to use, painless, reliable, a hemostatic agent, effective, safe, increased patient comfort, and saved time.

Magic Foam Cord is a product for an easy, nontraumatic, and less time consuming retraction of the sulcus. It is biologically very compatible, with no adverse side effects or interactions. Polyvinylsiloxane has a high tear resistance. The technique is faster and easier than the use of retraction cords or scalpel / rotary instruments.

CONCLUSION

Go to

To conclude, the results of the present study clearly reveal that there is a significant association between retraction materials and the gingival sulcular epithelium. It can be stated that the impregnated retraction cord, may be used frequently, but it needs proper tissue manipulation and is technique sensitive.

A definite alternative for gingival retraction now exists in the form of retraction paste (Expasyl / Magic Foam Cord). In regard to hemostasis, there is no doubt about the efficacy of these materials and their ability to be extremely effective clinically. The retraction procedure also appears very safe and easy to use. Thus, the newly advanced material in the form of retraction pastes like Expasyl or Magic Foam Cord have been found to be better than the cord, as assessed histologically, with respect to the periodontium. The patient tolerance was observed to be very good. No anesthesia was required and the material exhibited total biocompatibility.

Future research

The long-range effects of the marginal fit are probably the most important factors for enhancing periodontal health. This study has involved only healthy periodontal subjects. Different effects on the junctional epithelium may be observed in tissues, characterized by gingivitis or periodontitis. A broader study involving a greater range of procedures and conditions is recommended, to evaluate each retraction technique. This study has involved teeth that have an adequate zone of attached gingiva. More complicated and perhaps altered sequences may be observed if the procedures are performed on gingival margins of alveolar mucosa, thin gingival walls or areas of root prominence and thin cortical bone.

Acknowledgments

Go to

Contributions that need acknowledging, but do not justify authorship, here I acknowledge Mr. Hemant Pawar (Asso. Prof.), Department of Medical Bioinformatics, Rural Medical College, Loni, for his valuable guidance regarding the statistical analysis of the data. I would also like to thank the technicians in the Department of Oral Pathology Mr. Sunil and Mrs. Manisha for their help in the laboratory.

Footnotes

Go to

Source of Support: Nil

Conflict of Interest: None declared.

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Bond Strengths of Resin Cements to Astringent-contaminated Dentin

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Clinical Relevance

The contamination of the dentin surface with an astringent-containing aluminum chloride does not reduce the bond strength of either the resin cement used in conjunction with an etch-and-rinse or the resin cement with a self-etching adhesive. However, the contamination probably interferes with the etching ability of the self-etching primer and the adaptation of the resin cement to the dentin surface.

SUMMARY

The current study evaluated the micro-shear bond strength of two resin cements to astringent-contaminated dentin. Twelve occlusal dentin discs were prepared from extracted caries-free human molars and divided into two groups subjected to two types of resin cements, Panavia F (PF) and Variolink II (VL). Each disc was ground with 600 grit SiC paper and sectioned into two semi-disks, one for the normal dentin surface and the other for the contaminated dentin surface. For contaminated dentin, an astringent containing aluminum chloride was applied for two minutes and rinsed before the bonding procedures. A micro tygon tube was placed on the dentin surface following the bonding application and then filled with a resin cement. After the resin was polymerized, the specimen was kept in water for 24 hours before the micro-shear bond strengths evaluation. The micro morphology of the treated surfaces and resin-dentin interfaces were observed under a scanning electron microscope (SEM). Aluminum content under different dentin conditions was also examined. No significant differences were found between the dentin bond strengths to normal dentin and contaminated dentin surfaces in both the PF and VL groups ($p>0.05$). PF showed similar bond strengths to VL on normal and contaminated dentin ($p>0.05$). SEM observations of the VL groups revealed no

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DOI: 10.2341/08-107

differences in the treated dentin surfaces and the resin-dentin interfaces between normal and contaminated dentin. However, for the PF group, an inconsistent etching pattern of the self-etching primer and gap formation at the interface of resin cement to contaminated dentin were observed.

INTRODUCTION

The use of adhesive resin cements for bonding indirect tooth-colored and casting restorations, such as inlays, onlays and crowns, is increasing. These cements bond to both the fitting surface of the restoration and the tooth structure. At the tooth surface, an adhesive system is used to bond the resin cement to both enamel and dentin surfaces. Currently, adhesive resin cements can be categorized according to the adhesive system used as either etch-and-rinse or self-etching system.[1]

During the cementation procedures of indirect restorations at the cervical area, gingival fluid and blood sometimes appear as a result of trauma from tooth preparation. In this clinical situation, hemostatic agents are frequently used to control bleeding and gingival fluid. The pH of these hemostatic agents has been reported to vary from 0.7-3.0.[2,3] The tooth structure, especially dentin, which is a major part of the preparation, may be contaminated with these highly acidic astringents. Of these hemostatic agents, aluminum chloride, with a concentration between 20%-25%, is frequently used.[3] Land and others[4] reported that dentin surfaces treated with 21.3% aluminum chloride for five minutes exhibited complete smear layer removal with some degree of demineralization.[3,4] Since some effects of the smear layer on the adhesion of self-etching adhesives have been reported,[5,6] smear layer removal by hemostatic agents could affect the bonding mechanism of the self-etching adhesive used with a resin luting cement.

In a previous study by the current authors, a light-cured, two-step self-etching adhesive used in conjunction with a direct resin composite exhibited lower bond strength to dentin contaminated with 25% aluminum chloride solution compared to normal dentin, but an etch-and-rinse adhesive exhibited similar bond strength to both contaminated and normal dentin.[7] However, there is no report regarding the bonding efficiency of adhesives used with resin cements to dentin contaminated with a hemostatic agent. Therefore, the purpose of the current study was to evaluate the microshear bond strengths of two resin cements to astringent-contaminated dentin, one used with an etch-and-rinse adhesive and the other with a self-etching adhesive. The null hypothesis is that the bond strengths to astringent-contaminated human dentin of resin cements used with these adhesives are not different from the bond strengths to normal dentin. To observe the micro morphological differences among the test groups, non-stress, resin-dentin interfaces and dentin surfaces with and without contamination were observed under SEM. The aluminum content under different dentin conditions was also determined.

METHODS AND MATERIALS

Preparation of Dentin Surface (Figure 1)

Twelve 2-mm thick dentin discs were prepared by perpendicular section to the long axis of the extracted caries-free human molars using a slow-speed diamond saw (Isomet, Buehler Ltd, Lake Bluff, IL, USA) under water lubrication. The surfaces of the dentin discs were hand ground with 600 grit silicon carbide papers (Struers, Ballerup, Denmark) under running water to standardize the resulting smear layers. The ground dentin discs were then hemi-sectioned into 12 pairs of dentin semi-discs. All semi-discs were equally divided into two groups, the control and contaminated groups. In the control group, the dentin surface of each semi-disc was rinsed and dried. In the contaminated group, the dentin surface of each semi-disc was treated with 25% aluminum chloride (Racestyptine, Septodont, Cedex, France) for two minutes, rinsed with water spray for 30 seconds and dried with oil-free air. Semi-

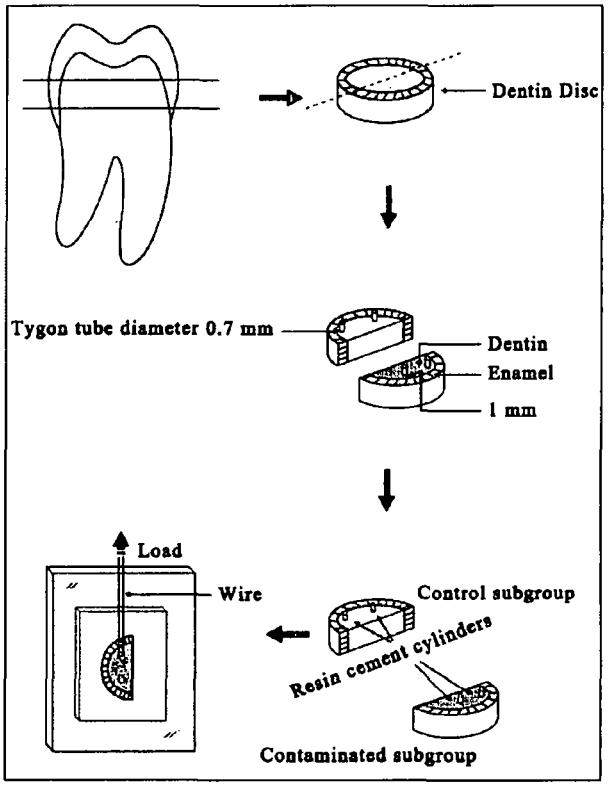

Figure 1. *Schematic illustration of the experimental design.*

Table 1: *Resin Cements and Their Adhesives Used*

Resin Cements	Composition	Manufacturer	Batch #
Panavia F ED II Primer	Primer A: HEMA, MDP, 5-NMSA, water, accelerator	Kuraray Medical Inc Okayama, Japan	00225A
	Primer B: 5-NMSA, accelerator, Water, sodium benzene sulfinate		00104A
Luting Resin	Base paste: hydrophobic aromatic (and aliphatic) dimethacrylate, hydrophilic dimethacrylate, sodium aromatic sulfinate (TPBSS), N,N-diethanol-p-toluidine, functionalized sodium fluoride, silanized barium glass		00197A
	Catalyst paste: MDP, hydrophobic aromatic (and aliphatic) dimethacrylate, hydrophilic dimethacrylate, silanized silica, photoinitiator, dibenzoyl peroxide		00108A
Variolink Excite DSC	Etchant Total Etch: 37% phosphoric acid	Ivoclar Vivadent, Schaan, Liechtenstein	F40503
	Primer-adhesive: HEMA, DMA phosphoric acid acrylate, silica (0.5 wt%), ethanol, initiators		
Luting Resin	Base paste: Bis-GMA, UDMA, TGDMA, fillers (72.3 wt%), pigments and stabilizers		G26397
	Catalyst paste/low viscosity: Bis-GMA, UDMA, TGDMA, fillers (71.2 wt%), pigments, stabilizers and catalysts		H17779

discs of both the control and contaminated groups were further divided into two subgroups of six pairs of semi-discs each according to the resin cement systems used (Table 1).

Bonding Procedures

The composition and batch number of the adhesive resin cements used are presented in Table 1.

Subgroup 1 (PF) ED primer A and B were mixed and applied to the dentin surfaces of both the control and contaminated groups, left for 30 seconds and gently air dried. Irises that had been cut from micro bore tygon tubing (TYG-030, Small Parts Inc, Miami Lakes, FL, USA), with an internal diameter and a height of approximately 0.75 and 0.50 mm, respectively, were placed at two positions on the primed dentin surface 1 mm from the dentino-enamel junction. Freshly mixed dual-cured resin cement of Panavia F (Kuraray Medical Inc, Okayama, Japan) was used to fill the tubing and then light cured for 20 seconds using a halogen light-curing unit (Curing Light XL 3000, 3M ESPE, St Paul, MN, USA) with an output of 700 mW/cm². The bonding interface was covered entirely with liquid glycerin gel (Oxyguard II, Kuraray Medical Inc) for three minutes to enable optimal anaerobic polymerization and the gel was then rinsed out. The bonded specimens were left at room temperature (25°C) for one hour before removal of the tygon tubing by longitudinally cutting with a razor blade. This resulted in 12 resin cement cylinders bonded to the dentin surface of the control and contaminated groups.

Subgroup 2 (VL) The dentin surfaces of the semi-discs of both the control and contaminated groups were etched with 37% phosphoric acid for 15 seconds, then thoroughly rinsed with water spray. Excess water on the dentin surface was blot-dried with lint-free absorbent tissue prior to the application of primer-adhesive (Excite DSC) and agitated gently for 30 seconds. The treated dentin surface was gently air dried for three seconds and light cured for 20 seconds before placing the tygon tubing in the same manner as in Subgroup 1. Variolink II low viscosity base and catalyst paste (1:1 ratio) were mixed, filled the tygon tubing and were light cured for 20 seconds. The specimens were left at room temperature for one hour before removing the tygon tubing as in Subgroup 1. All the specimens were stored in distilled water at 37°C for 24 hours before the micro-shear bond test.

Micro-shear Bond Test

After 24 hours, the resin cement cylinders were checked under an optical microscope (30x) for bonding defects. The cylinders, which showed interfacial gap formation and/or bubble inclusion, were excluded and replaced. Twelve specimens were tested for each test group. The micro-shear bond test was performed with

the bond test apparatus (Bencor-Multi-T, Danville Engineering Co, San Ramon, CA, USA) attached to a universal testing machine (EZ-test 500N, Shimadzu Co, Kyoto, Japan).[8] The dentin semi-disc with the resin cement cylinder was fixed to the apparatus with a cyanoacrylate adhesive (Zapit, DVA, Corona, CA, USA). A thin wire (0.2 mm in diameter) was looped around the resin cement cylinder, making contact through the lower half of its circumference and gently held flat against the resin/dentin interface. The resin cement cylinder and the center of the load cell were aligned as straight as possible to ensure the desired orientation of the shear test force. A shear force was applied to each specimen at a crosshead speed of 1 mm/minute until fracturing occurred.

After debonding, bond strengths were recorded and the fracture modes of all the specimens were observed under a SEM (JSM-5310V, JEOL Ltd, Tokyo, Japan). The fracture mode was classified as follows: adhesive failure at the resin-dentin interface, cohesive failure in dentin or cohesive failure in resin cement. The percentage of each type of failure in the specimens was recorded.

The data were statistically analyzed by two-way ANOVA (type of dentin, adhesive resin cement system) followed by *post hoc* multiple comparisons with the Student's *t*-test. For the fracture modes, the Kruskal-Wallis test was used to compare differences among each experimental group. All analyses were performed using the SPSS program. Statistical significance was considered to be $p<0.05$.

EDS Microanalysis of the Dentin Surfaces

The surfaces of normal dentin after grinding as a control, the surfaces of astringent contaminated dentin and both dentin conditions after etching with phosphoric acid and self-etching primer (ED primer) were all measured for aluminum (Al) content on the surface using an energy dispersive spectrometer (Oxford ISIS Pentafet link model 6647, Highwy Combe, England) operated at 20 KV. The relative amounts of Al to Ca were measured at 500x magnification.

SEM Observation of the Treated Dentin Surfaces and the Bonding Interface

The surfaces of ground dentin and astringent-contaminated dentin and both dentin conditions after etching with phosphoric acid and self-etching primer were observed. For the PF group, ED primer A and B were mixed and applied to the dentin surface for 30 seconds before being thoroughly rinsed with acetone and water to remove residual resin. They were then air-dried. The morphological changes induced on the dentin surfaces were observed using SEM.

The interfacial morphology between both normal and contaminated dentin and the resin cements were also observed after the acid-base challenge. Another 12 pairs of semi-discs were divided into four groups of three semi-discs each and received the same treatment as for the micro-shear bond test. Twenty-four hours after bonding, the specimens were sectioned perpendicular to the bonded surface using the slow-speed diamond saw (Isomet, Buehler Ltd) under water spray. The cut specimens were fixed in 10% buffered formalin before being embedded in a self-cured epoxy resin (Epon 812, Nisshin M Co, Ltd, Tokyo, Japan), then ground and polished using wet silicon carbide papers and diamond pastes of decreasing abrasiveness down to 0.25 µm. The surfaces of the polished specimens were subjected to 10% phosphoric acid for five seconds and 5.25 % NaOCl for five minutes. After rinsing thoroughly, the specimens were dried overnight, sputter coated with gold and observed under high vacuum in SEM.

pH Measurement

The pH determination of the astringent was preformed using a pH meter (Twin pH, Horiba, Tokyo, Japan). The pH reference solutions at pH 7 and pH 4 were used to standardize the electrode. The measurements were done in triplicate.

RESULTS

The pH of the 25% aluminum chloride Racestyptine was 0.8. The micro-shear bond strength of both resin cements to normal and contaminated dentin and the mode of fracture are presented in Tables 2 and 3, respectively.

The bond strengths of both resin cements to contaminated dentin were not significantly different from those of normal dentin. The bond strengths of PF and VL to normal and contaminated dentin were also not signifi-

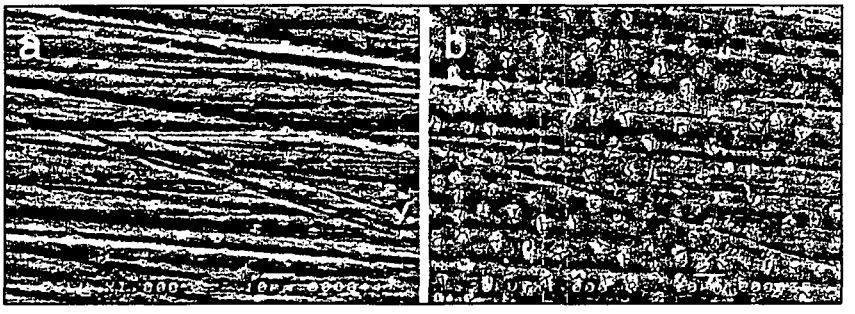

Figure 2. *(a) SEM photomicrograph of a normal dentin surface after grinding with 600 grit SiC paper. A thick smear layer covered the entire surface. (b) Dentin surface after two-minute contamination with 25% aluminum chloride and washed out. Part of the smear layer was removed. Opening of the dentinal tubules were occluded with smear plug (original magnification 1000x).*

Table 2: *Micro-shear Bond Strengths (MPa) of Panavia F and Variolink II to Normal Dentin and Contaminated Dentin (n=12)*

Groups	Normal Dentin	Contaminated Dentin
Panavia F (PF)	22.23 (9.94)[a]	24.72 (5.72)[a]
Variolink II (VL)	22.29 (5.86)[a]	23.89 (3.19)[a]

Groups with the same superscript are not statistically different (p<0.05).

Table 3: *Mean Percentage of Failure Mode After Micro-shear Bond Test*

		Cohesive Failure[b]	
	Adhesive Failure[a]	In Dentin	In Composite
Variolink			
Normal Dentin	96.67	3.33	0
Contaminated Dentin	97.72	0	2.08
Panavia F			
Normal Dentin	83.33	9.58	7.09
Contaminated Dentin	72.08	0	27.92

There is no significant difference among each group (p<0.05).
[a]Adhesive failure = failure between resin and dentin.
[b]Cohesive failure = failure that occurred within the dentin or in the resin composite.

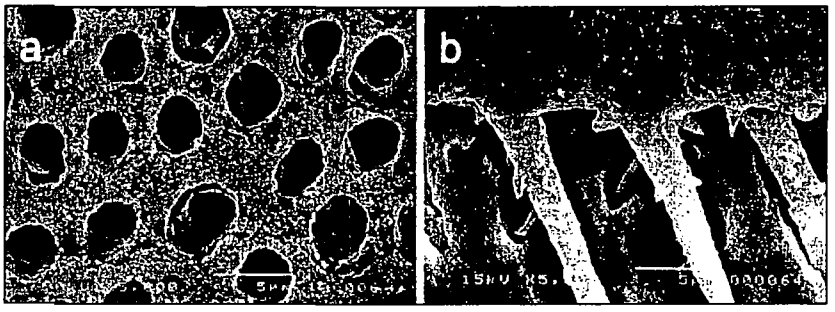

Figure 3. *(a) SEM photomicrograph of the normal dentin surface after etching with 37% phosphoric acid. The smear layer was completely removed. Widening of the dentinal tubules was observed. (b) The interface between Variolink resin cement and normal dentin with a 2 µm thick hybrid layer and funnel-shape resin tags with lateral branches (original magnification 5000x).*

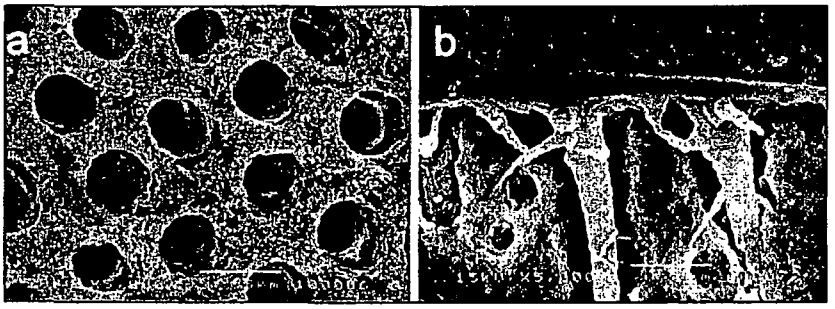

Figure 4. *(a) SEM photomicrograph of the contaminated dentin surface after etching with 37% phosphoric acid and (b) the interface between Variolink resin cement and contaminated dentin, which was not different from that of normal dentin (original magnification 5000x).*

cantly different from each other. Most failures were adhesive (Table 3). For the VL groups, analysis of the mode of failure did not show significant differences between that of normal and contaminated dentin. Most failures were adhesive. Variation in failure mode was found in the PF groups, which demonstrated a slight increase in cohesive failure in resin, especially in the contaminated group.

Surface morphological study showed that, in the control group, a thick smear layer was left on the dentin surfaces (Figure 2a). In the contaminated group, noticeable etching effects were observed. The smear layer was partially removed and the dentinal tubules can be located with smear plugs still occluding the tubule orifices (Figure 2b). The surfaces of normal and contaminated dentin after phosphoric acid etching were similar, with the absence of the smear layer and peritubular dentin, as well as clearly visible patent dentinal tubules (Figures 3a and 4a). The normal dentin after treatment with ED primer revealed consistent etching patterns of a clear surface without the smear layer and with opened dentinal tubules with the remaining peritubular dentin (Figure 5a). However, the contaminated surfaces treated with ED primer showed inconsistencies in etching patterns. The surfaces were clear without the smear layer and also with open dentinal tubules with and without peritubular dentin. In a few tubules, the remaining smear plugs still occluded the tubule openings (Figure 6a).

No difference was found between the SEM's appearance of the bonded interfaces of VL II to normal dentin and contaminated dentin (Figures 3b and 4b). Approximately 2 µm thick hybrid layers with funnel-shaped resin tags were observed. Many resin tags showed lateral extension of the microtags branching off from the main tags in the dentinal

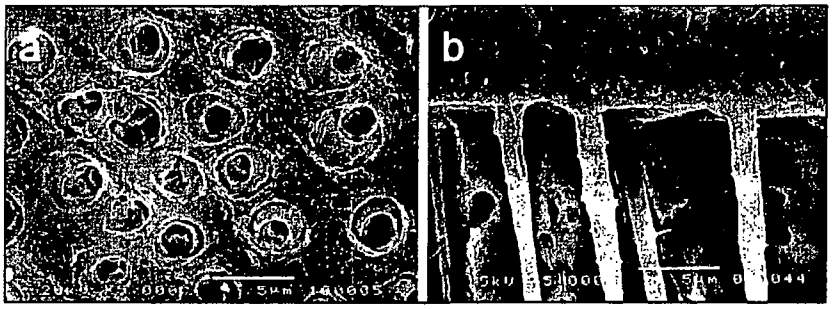

Figure 5. *(a) SEM photomicrograph of a normal dentin surface after application of the ED primer. The smear layer was removed and most dentinal tubules were opened with the remaining peritubular dentin. (b) The interface between Panavia resin cement and normal dentin with approximately a 0.5 µm thick hybrid layer and long cylindrical resin tags (original magnification 5000x).*

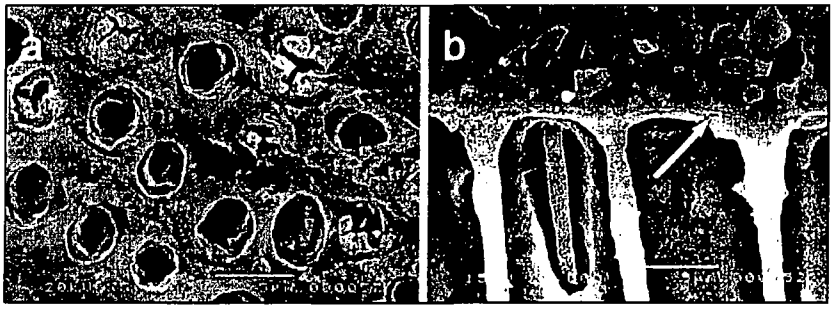

Figure 6. *(a) SEM photomicrograph of the contaminated dentin surface after the application of ED primer. The smear layer was removed. Dentinal tubules are clearly visible with different degrees of tubular opening. (b) The interface between Panavia resin cement and contaminated dentin. A thin hybrid layer with small gaps between resin cement and the top of the hybrid layer (arrow). Funnel-shape and cylindrical resin tags are observed in the same area (original magnification 5000x).*

tubules. The interface between PF to normal and contaminated dentin was similar, with a 0.5 µm thick hybrid layer and cylindrical resin tags with lateral protrusion of micro tags from the side of the main tags (Figures 5b and 6b). However, at the interface of the PF and contaminated dentin, small gaps were found at the junction between the top of the hybrid layer and the bottom of the resin cement layer, which were not found in normal dentin. In addition, regular cylindrical tags extending into the dentin were found in the normal dentin. In the contaminated dentin, irregular shapes of resin tags were observed, especially at the upper part of the tags. Cylindrical resin tags were frequently revealed, but funnel-shaped resin tags were also observed in some areas due to more aggressive etching patterns that removed the peritubular dentin. Fewer resin tags exhibited a constriction at the upper end next to the hybrid layer.

EDS analysis showed slightly higher aluminum content in the groups of contaminated dentin treated with ED primer (2.46%Al) compared with normal dentin treated with ED primer (0.75%Al) and contaminated dentin treated with phosphoric acid (0.46%Al).

DISCUSSION

Many studies have reported that the results of the bond strength test will vary due to different dentin substrate conditions, such as the age of the tooth and storage conditions.[9-10] However, these factors could be omitted in the current study, since all specimens in the control and contaminated groups were prepared from the same dentin disks. In addition, the location of the bonding area was controlled by placing the resin cement cylinders at the same distance from the dentino-enamel junction.

In the current study, the bonding ability of two resin cements, one utilizing an etch-and-rinse, single bottle adhesive, and the other utilizing a self-cured, all-in-one self-etching adhesive to astringent-contaminated dentin were comparable to those in normal dentin. The results of the current study thus lead to acceptance of the null hypothesis that the bond strengths to a hemostatic agent-contaminated human dentin of both resin cements are similar to that of normal dentin.

The self-etching ED primer of PF with pH 2.4 has less etching effect on the dentin surface than phosphoric acid. On the normal dentin surface, this weak acid removed the smear layer and the smear plug as well as slightly demineralizing the intertubular dentin, but it was not strong enough to demineralize the peritubular dentin. This resulted in a 0.5 µm thick hybrid layer and uniform cylindrical resin tags of PF compared to a 2 µm thick hybrid layer and funnel-shaped resin tags of the etch-and-rinse adhesive in the VL group.

The hemostatic agent containing 25% $AlCl_3$ Racetyptine and the two-minute application time used in the current study were in accordance with the methods used in the previous study conducted by the current authors.[7] The results showed that the two-minute application of this agent removed the smear layer on the surface and, to a small extent, it removed the smear plug from most dentinal tubules. The demineralization effect of $AlCl_3$ also seems to have enhanced the etching effect of the self-etching ED primer on the contaminated dentin in some areas, since few open dentinal tubules without peritubular dentin were observed (Figure 6a). Even though the results of the EDS analy-

sis showed that, after application of the ED primer, a higher Al content (2.46%) remained on the contaminated dentin surface than on the normal non-contaminated dentin surface (0.75%), the remaining Al seemed to have no obvious effect on the etching ability of the ED primer. This result is in contrast to the previous study in which a self-etching primer of a light-cured, two-step self-etching adhesive, Clearfil SE Bond, was applied for 20 seconds on the contaminated dentin and showed a subsequently less etching effect than to normal dentin. The authors of the current study ascribe this to the displacement of Ca in the hydroxyl apatite by Al, which resulted in the formation of the insoluble $Al(OH)_2H_2PO_4$ compound. The compound might have increased resistance to acid of the dentin surface.[11] However, this explanation could only be partially applied to the contaminated dentin of the PF group, since the results of SEM observation revealed inconsistencies in etching patterns on the contaminated dentin. More or less localized etching effects were found on the same surfaces of contaminated dentin after the ED primer was rinsed off. This varied etching effect corresponded to the SEM pictures of the resin-contaminated dentin interface of PF, which showed greater variation in resin tag formation.

The finding that the contamination of dentin with the $AlCl_3$ solution did not adversely affect the bond strength of this self-cure, self-etch primer used with Panavia was different from the results of previous studies.[7,12] In previous studies, the light-cured, self-etch adhesives used with direct resin composite restoration showed lower bond strengths to astringent-contaminated dentin. The main reason is probably the greater etching ability of the self-cured ED primer compared to that of the light-cured self-etching SE primer. The greater etching effects of the ED primer may not be explained by the acidity of the primer, since the pH of the ED primer (pH 2.4) is higher than that of the SE primer (pH 2).[13,14] This is probably due to the longer etching time (30 seconds) of the ED primer compared to the 20 second-etching time of the SE primer as per the manufacturer's instructions. This may support the previous study, in which the etching effect of self-etching primer was greater when priming time was extended from 20 seconds to 40 seconds.[7] The other reasons may be the different composition of the self-etching primer/adhesives utilized and the different mode of curing that may have enabled a good infiltration of the ED primer into the dentin. These reasons may have resulted in substantially similar bond strengths to that of normal dentin.

Although the bond strength of Panavia to contaminated dentin was not different from that of normal dentin, this result should be cautiously interpreted, since the ultramorphology of the bonding interfaces of Panavia to contaminated dentin revealed small gaps between the top of the hybrid layer and the resin cement (Figure 6b). Previous studies have reported that no correlation was found between the bond strength values and degree of microleakage.[15,16] These gaps may be the result of either incompatibility between the dual-cured resin cements and the acidic monomers in the ED primer or the semi-permeable property of the cured one-step self-etch primer/adhesive as reported in a previous study.[17] This may result in the susceptibility of this adhesive system to microleakage or lower durability of the bonding. However, in the current study, this adverse effect was noticeable only with bonding to astringent-contaminated dentin, since no such gaps were found at the interface between this cement and normal dentin. The remaining aluminum content on the surface of hemostatic-contaminated dentin may increase the adverse effect of ED primer on the adaptation and strength of resin cement. This may be the reason why a higher cohesive failure of resin was found in the contaminated subgroup of PF when compared to that of the normal dentin subgroup.

In many studies regarding the bond of adhesives to dentin contaminated by other agents, such as zinc oxide eugenol, hydrogen peroxide or astringents, the etch-and-rinse adhesive generally provided similar bond strengths to contaminated dentin compared with normal dentin.[7,18-21] It was assumed that the phosphoric acid used in etch-and-rinse adhesives would remove most of the contaminants from the dentin surface before the adhesive resin application.[20] This may explain the similar bond strengths to normal and astringent-contaminated dentin of the etch-and-rinse system of VL in the current study. The aggressive etching effect of phosphoric acid with pH 0.5 might have demineralized and removed all contaminant-induced effects on the dentin surface. This was supported by the result of the EDS analysis, which showed similar remaining aluminum content on the surfaces of normal and contaminated dentin after etching with phosphoric acid. The acid etching patterns of the dentin surfaces of the normal and contaminated groups of VL were also similar.

The astringent used in the current study contained 25% aluminum chloride. Its acidity had a demineralizing effect on dentin surfaces. However, this did not affect the dentin bond strengths of both resin cements. From the SEM pictures, the ED primer has less of an etching effect when compared with the phosphoric acid used in the adhesive of Variolink II. It seems that, in terms of bond strength, this self-etching effect is sufficient to remove any contaminants from the astringents and provides similar bond strength. However, further study regarding the sealing ability and long-term durability is needed.

CONCLUSIONS

Dentin contaminated with astringent containing 25% aluminum chloride, Racestyptine, had comparable bond strengths to normal dentin of both resin luting cements. These results are limited to the materials used in the current study. Other materials might exhibit differently from the current report.

Acknowledgment

This research was supported by the NRCT-JSPS Core University Program in Dentistry and the Faculty of Dentistry, Mahidol University.

(Received 11 August 2008)

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Bond Strengths of Two Adhesive Systems to Dentin Contaminated with a Hemostatic Agent

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P Senawongse • J Tagami

Clinical Relevance

A self-etching adhesive exhibited significantly lower bond strength to dentin contaminated with 25% aluminum chloride solution compared to normal dentin, but a total-etching adhesive exhibited no difference in bond strength to either contaminated or normal dentin. Longer primer application of the self-etching adhesive significantly increased the dentin bond strength of the contaminated group.

SUMMARY

This study evaluated the bond strength of a total-etch and a self-etch adhesive to dentin contaminated with a hemostatic agent containing aluminum chloride ($AlCl_3$). Eighteen occlusal dentin discs were prepared from human molars. Each disc was ground and sectioned into two halves, one for normal dentin and the other for contaminated dentin. The specimens of both normal and contaminated dentin were randomly divided into three groups and treated with the following materials: 1) Excite (EX); 2) Clearfil SE Bond with 20-second primer application time (CB 20) and 3) Clearfil SE Bond with 40-second primer application time (CB 40). The microshear bond strength specimens were prepared using the resin composite Clearfil APX. The bond strengths were evaluated on a universal testing machine. Statistical analysis was performed at α=0.05. The surface micromorphology and aluminum content of the different dentin conditions were also examined. In EX, no significant difference was found between the bond strengths of normal dentin and contaminated dentin. The bond strength of CB20 to contaminated dentin was significantly lower than that to normal dentin. The

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DOI: 10.2341/06-121

extension of primer application time from 20 to 40 seconds significantly increased the bond strength of CB to contaminated dentin.

INTRODUCTION

Moisture and blood contamination have a detrimental effect on bond strength between adhesives and tooth structures.[1-3] As a result, the use of a rubber dam is mandatory for all adhesive restorations.[4] In general practice, however, operators do not routinely work with a rubber dam, instead, other moisture control techniques are used. In some clinical situations, such as the gingival area, blood and sulcular fluid frequently appear as a result of gingival trauma from tooth preparation or gingival inflammation. Currently, in that condition, dry operative fields can be obtained after the application of hemostatic agents to control bleeding and decrease gingival fluid. Examples of these materials are aluminum chloride, aluminum sulfate and ferric sulfate. Previous studies have demonstrated that these hemostatic agents are highly acidic and their pH varies from 0.7-3.0.[5-6] Aluminum chloride ($AlCl_3$), with a concentration between 20%-25%, is a commonly used hemostatic agent.[7] It has been shown that dentin surfaces treated with 21.3% $AlCl_3$ exhibit various degrees of demineralization. Complete smear layer removal with some dentin demineralization can be observed after applying this agent for five minutes.[6]

Currently, adhesive systems can be classified into two groups, total-etching and self-etching systems. Since some effects of the smear layer to the adhesion of self-etching adhesive have been reported,[8] smear layer removal by hemostatic agents could affect the bonding mechanism of this adhesive system. It has been shown that the bond strength of a self-etching adhesive to dentin contaminated with ferric sulfate or $AlCl_3$ dramatically decreased, compared to the normal dentin group.[9]

One of the problems that occurs in bond testing is fracture of the specimens within the materials, not at the interface. Micro-tests, including a microtensile and a microshear bond test, have been developed to improve their efficiency.[10-12] This has resulted in an increase in specimens fracturing at the interface. Therefore, the bond strengths obtained from these tests should be more reliable and represent the true bond strength between materials. Also, the microshear bond test has some advantages, such as ease of specimen preparation and reliable results with a narrow standard deviation.[11-12]

This study evaluated the microshear bond strengths of a total-etch and a self-etch adhesive to human dentin contaminated with a hemostatic agent containing $AlCl_3$.

METHODS AND MATERIALS

Eighteen 2 mm-thick dentin discs were prepared by perpendicular sectioning to the long axis of extracted caries-free human molars using a low-speed saw, under copious water spray (Isomet, Buehler, IL, USA). The dentin surfaces were then hand ground with 600-grit SiC paper under running water and hemi-sectioned, resulting in 18 pairs of dentin semi-discs. Next, the pairs of semi-discs were randomly assigned to three groups of six pairs each. For each group, the six pairs of semi-discs were separated and subdivided into control and contaminated subgroups. The diagram of specimen preparation is shown in Figure 1 and the composition of the materials used in this study is shown in Table 1.

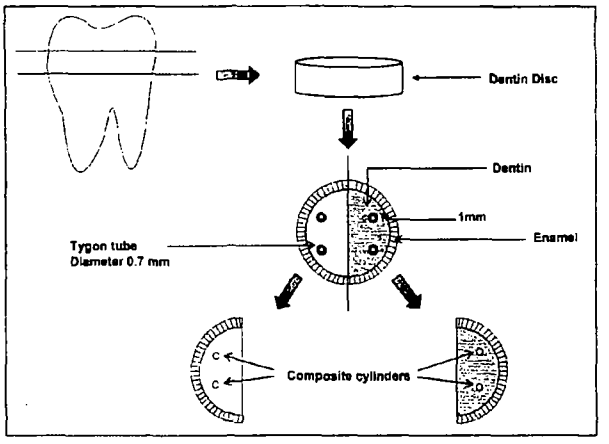

Figure 1. *Diagram illustrating bonding procedures for microshear bond strength test.*

The treatment protocol for each group was as follows: for Group 1 Excite (EX), the dentin surface of each semi-disc in the control subgroup was dried with oil-free air to remove excess water. In the contaminated subgroup, further dentin surface treatment was performed. The hemostatic agent Racestyptine (Septodont, Cedex, France) was applied to the dentin surfaces for two minutes, then the dentin was rinsed with water spray for 30 seconds and dried with oil-free air. Consequently, the dentin surfaces of both the control and the contaminated groups were etched with 37% phosphoric acid for 15 seconds and thoroughly rinsed using water spray. Excess water was blot-dried from the surface with lint-free paper (Kimwipes, Kimberly Clark Corp, Roswell, GA, USA) to achieve moist dentin. The adhesive Excite was used according to the manufacturer's instructions by applying the adhesive resin onto the dentin surface for 15 seconds, then drying with oil-free air for five seconds. The irises that were cut from micro bore tygon tubing (TYG-030, Small Parts Inc, Miami Lakes, FL, USA) with an internal diameter and height of approximately 0.75 and 0.50 mm, respectively, were then positioned at two locations on each dentin semi-disc, 1 mm from the dentino-enamel junction. Light polymerization was performed for 10 seconds with a light-curing unit

Table 1: *Materials Used in This Study*

Material	Composition	Batch #	Manufacturer
Racestyptine	25% m/V hexahydrate aluminum chloride, oxyquinol, hydroalcoholic excipient	M1 115	Septodont, Cedex, France
Clearfil SE Bond	*Primer*: HEMA, MDP, Hydrophilic dimethacrylate, water, ethanol, dl-camphorquinone, N,N-Diethanol-p-toluidine	00443 A	Kuraray, Osaka, Japan
	Adhesive: HEMA, MDP, Bis-GMA, Hydrophilic dimethacrylate, dl-camphorquinone, N,N-Diethanol-p-toluidine, silanated colloidal silica	00609 A	
Excite	*Etchant*: 37% phosphoric acid *Adhesive*: Dimethacrylate, alcohol, phisphonic acid acrylate, HEMA, SiO_2, initiators, stabilizers	F 40503 F 63821	Ivoclar Vivadent, Schaan, Liechtenstein
Clearfil APX	BisGMA, TEGDMA, barium glass, colloidal silica	01028 A	Kuraray, Osaka, Japan

(Curing Light XL 3000, 3M ESPE, St Paul, MN, USA). A hybrid resin composite, Clearfil APX shade A2, was used to fill in the tubing and was light-cured for 40 seconds. The tubing was then removed from the composite cylinder by longitudinal cutting with a razor blade. This resulted in 12 composite cylinders for this adhesive, each in the control and contaminated groups. For Group 2 Clearfil SE Bond, 20 second primer application (CB 20), after the dentin surfaces were prepared for the control and contaminated subgroups in the same manner as in Group 1, Clearfil SE Bond was used according to the manufacturer's instructions. The primer was applied to the dentin surfaces with agitation, left for 20 seconds, then dried with oil-free air for five seconds. The adhesive resin was then applied to the primed surfaces. Next, the composite cylinders were prepared in the same manner as in Group 1. For Group 3 Clearfil SE Bond, 40-second primer application (CB 40), only the contaminated subgroup was performed. The specimen preparation and preparation for the microshear bond test were performed as in Group 2, except that the primer application time was extended from 20 to 40 seconds. Therefore, only 12 composite cylinders in the contaminated group were prepared. After storage in distilled water at 37°C for 24 hours, all specimens were inspected under an optical microscope (30x). The specimens with defects, such as interfacial gap defect and bubble inclusion, were excluded and replaced.

The microshear bond test was performed on the microshear bond test apparatus (Bencor-Multi-T, Danville Engineering Co, San Ramon, CA, USA) attached to a universal testing machine (EZ-test 500 N, Shimazu Co, Kyoto, Japan) as described by Shimada and others.[11] The dentin disc was placed on the apparatus with a cyanoacrylate adhesive (Zapit, Dental Venture of America, Corona, CA, USA). A thin wire, 0.2 mm in diameter, was looped around the small resin composite cylinder. This procedure makes the lower half of the cylinder contact the wire, which is gently held flush against the resin-dentin interface. The resin cylinder and the center of the load cell were aligned as straight as possible (Figure 2). A shear force was applied to each specimen at a crosshead speed of 1 mm/minute until fracture. Two-way ANOVA and multiple comparisons at $p<.05$ were used to analyze the data.

Morphological changes of the normal dentin surface after grinding, dentin contamination with a hemostatic agent and both dentin conditions after etching with phosphoric acid and self-etching primer application for 20 and 40 seconds were observed using a scanning electron microscope (JSM-5310V, JEOL Ltd, Tokyo, Japan). The specimens were observed and analyzed for aluminum content using an energy dispersive spectrometer (EDS, Oxford ISIS Pentafet Link Model 6647, High WyCombe, England) operated at 20 KV.

A pH meter (Twin pH, Horiba, Tokyo, Japan) was used to determine the pH of the hemostatic agent.

RESULTS

The pH of the hemostatic agent, Racestyptine, consisting of 25% $AlCl_3$, was 0.8. Table 2 shows the microshear bond strengths of the adhesives used in this study to normal and contaminated dentin. The microshear bond strength of Excite adhesive to normal dentin and contaminated dentin were 18.42 ± 2.28 and 22.49 ± 5.89 MPa, respectively. No statistically significant difference between these two groups was exhibited ($p>.05$). The microshear bond strength of the self-etching adhesive Clearfil SE Bond to normal dentin was 36.59 ± 5.94 MPa, which was significantly higher than the microshear bond strength of this adhesive to contaminated dentin (CB20), 19.35 ± 6.05 MPa ($p<.05$). The microshear bond strength of Clearfil SE Bond to contaminated dentin, when the primer application time was extended to 40 seconds, 29.09 ± 6.93 MPa, was significantly higher than that of the contaminated group with a 20 second primer application ($p<.05$). Nevertheless, the bond strength of the 40 second primer application group was still significantly lower than that of the control group ($p<.05$), which was the highest bond strength obtained in this experiment.

Scanning electron micrographs of the dentin surface in the control group revealed that the thick smear layer was left intact on the surfaces and the dentinal tubules could not be seen (Figure 3). In the contaminated group, noticeable etching effects were observed. The smear layer was partially removed and the dentinal tubule opening was located. However, the smear plug still occluded the tubule orifices (Figure 4). The surfaces of normal and contaminated dentin after phosphoric acid etching were similar, with the absence of the smear layer and peritubular dentin, and the clearly visible patent opening of the dentinal tubules were exhibited (Figures 5 and 6). After treatment with SE primer for 20 seconds, normal dentin revealed clear surfaces without smear layers and open tubules with the remaining peritubular dentin (Figure 7), while the contaminated surface treated with SE primer for 20 seconds showed surfaces without smear layers, with some tubules still occluded (Figure 8). With the 40 second SE primer application, the contaminated dentin surface exhibited a more pronounced etching effect, with the surface of the smear layer depleted and more widely open dentinal tubules without peritubular dentin. Well-defined peritubular collagen fibers could be observed inside the tubules (Figure 9).

EDS analysis showed more aluminum content in the groups of contaminated dentin and contaminated dentin treated with SE primers at both 20 and 40 seconds (3.22%-4.76%Al) compared with normal dentin (0.49%Al) and contaminated dentin treated with phosphoric acid (0.46%Al).

Table 2: *Microshear Bond Strengths (MPa) of a Total-etching Adhesive, Excite and a Self-etching Adhesive, Clearfil SE Bond, to Normal Dentin and Contaminated-dentin*

Groups	Normal Dentin	Contaminated Dentin
Excite (EX)	18.42 ± 2.28[c]	22.49 ± 5.89[c]
Clearfil SE Bond: 20 seconds primer (CB20)	36.59 ± 5.94[a]	19.35 ± 6.05[c]
Clearfil SE Bond: 40 seconds primer (CB40)	--	29.09 ± 6.93[b]

Groups with the same superscript are not statistically different (p>0.05).

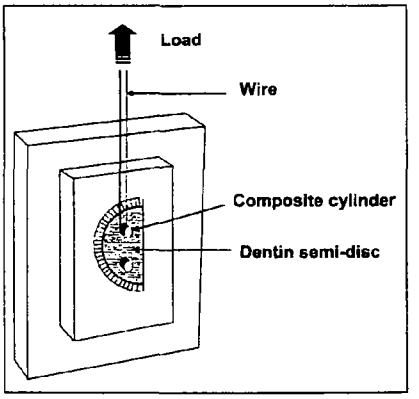

Figure 2. *Schematic of the microshear bond test.*

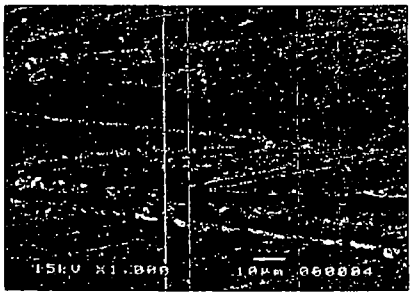

Figure 3. *Scanning electron micrograph of normal dentin after grinding with 600 grit SiC paper. Thick smear layer covered the dentin surface. No dentinal tubule opening was visible (1000x).*

DISCUSSION

In this study, specimens in the contaminated group and control group were prepared on the same dentin disks. Therefore, variables from different dentin substrates, such as age of the tooth and storage condition, could be excluded. Since dentin depth is one factor affecting the dentin bond strength of adhesives,[13,14] the dentin level was controlled in this study by fabricating resin composite cylinders at the same distance, 2 mm from the dentino-enamel junction.

Bond strength of the total-etch system in this study was significantly lower than that of the self-etching system. Results appear to be similar to the 2006 study by De Munck and others.[15] The low bond strength of a total-etching adhesive (Scotchbond 1), 11.9 MPa, compared with that of a self-etching system (Clearfil SE Bond), 41.3 MPa was also demonstrated. The explanation may be that the total-etching system is very technique sensitive. The dentin should be properly moist. Moreover, the dentin etched by an acid may be too deep to be penetrated by the adhesive. This results in nanoleakage, which possibly occurs with the total-etching system. Dentin bond strength in the microtest, microtensile or microshear bond strength test of Clearfil SE Bond was frequently found to be a high value, 32.9 MPa[16] and 39.81 MPa.[17] In contrast, studies showed the wide range of microtensile bond strength of Excite to be 6.03 MPa[18] and 40.8 MPa.[19]

The hemostatic agent containing 25% $AlCl_3$, Racestyptine, was selected as a representative agent, because it is effective in controlling bleeding and is frequently used in clinical practice. The two-minute con-

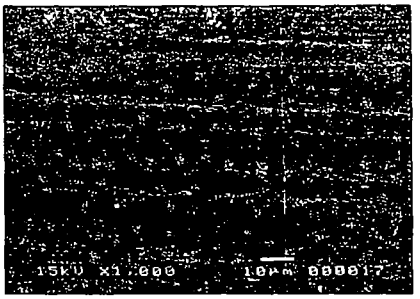

Figure 4. *Scanning electron micrograph of dentin contaminated with 25% aluminum chloride for two minutes. The smear layer was partially removed and the dentinal tubule orifices can be localized (1000x).*

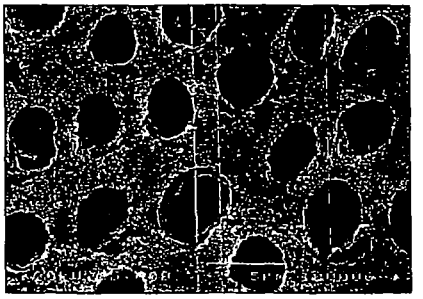

Figure 5. *SEM observations demonstrating the absence of the smear layer, peritubular dentin and patent tubule openings of normal dentin after etching with 37% H_3PO_4 (5000x).*

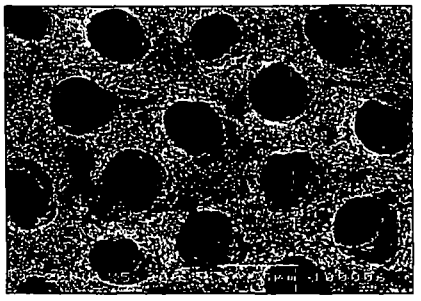

Figure 6. *Contaminated dentin appears similar to normal dentin after etching with 37% H_3PO_4, as shown in Figure 5 (5000x).*

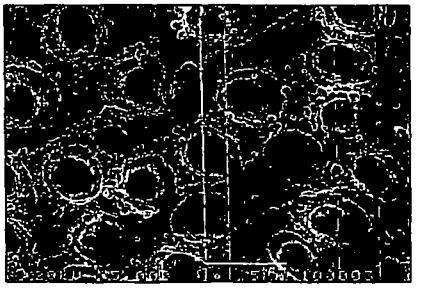

Figure 7. *Normal dentin after Clearfil SE Bond primer application for 20 seconds. The smear layer is completely removed; dentinal tubules with peritubular dentin are observed (5000x).*

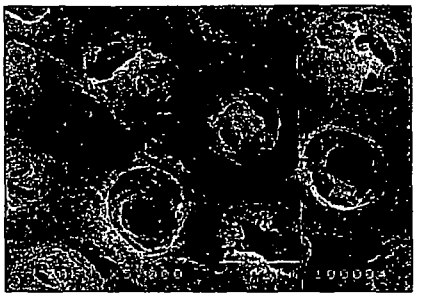

Figure 8. *Contaminated dentin after Clearfil SE Bond primer application for 20 seconds reveals no smear layer, but some tubules are occluded with smear plug (5000x).*

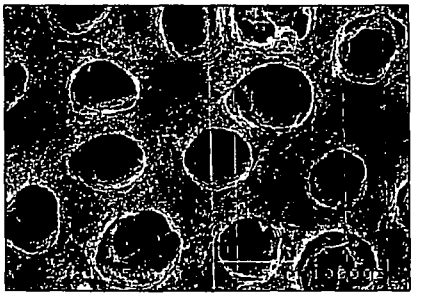

Figure 9. *Contaminated dentin after Clearfil SE Bond primer application for 40 seconds. More aggressive etching pattern is detected, compared with Figure 8. Complete smear layer removed; wide open dentinal tubules without peritubular dentin are exhibited (5000x).*

tamination time was chosen, as it is the average application time when this solution is applied onto soft tissues to control bleeding before restoration is initiated. The results indicated that the $AlCl_3$ solution had some demineralizing effect on the dentin surface. However, the degree of demineralization was less than the previous study,[7] which showed an aggressive etching pattern with complete smear layer removal. An explanation might be the shorter contamination time in this study, two minutes, instead of five minutes, as in the previous study. The degree of dentin surface changes after exposure to 21.3% $AlCl_3$ solution, Hemodent, has been shown to depend on contamination time. Dentin exposed to 21.3% $AlCl_3$ solution for two minutes exhibited smear layer removal and partially occluded dentinal tubules, while dentin exposed to this solution for

five minutes revealed a totally removed smear layer, including demineralized peritubular dentin. Nevertheless, at the 30-second and 2-minute exposure times, the affected dentin surfaces were similar.[7]

Although some demineralization of dentin contaminated with the $AlCl_3$ solution was exhibited in the current study, application of the self-etching primer on contaminated dentin did not enhance its demineralization effect. In contrast, after priming with the self-etching adhesive, the contaminated dentin showed a less etching effect compared to the control group, where the dentin was normal. In addition, the dentin bond strength of CB 20 on the contaminated group was dramatically decreased, compared to that of the control group. The same result was also reported in a previous investigation.[9]

It has been shown that enamel treated with $AlCl_3$ solution for 20 minutes could uptake aluminum (Al) from the solution, especially within the first 20 μm of enamel.[20] Moreover, this $AlCl_3$ treated enamel revealed inhibition of the demineralization process of hydroxyapatite (HAP), which was exposed to a demineralizing solution,[21,22] even though the Al concentration was as low as 0.1 μmol/l.[23] This mechanism has been explained by displacement of calcium in the HAP by Al, which results in the very insoluble Al $(OH)_2$ H_2PO_4 compound.[24] Because HAP is also the major part of dentin-like enamel, the influence of $AlCl_3$ solution on dentin could be similar to enamel.

Since the Clearfil SE primer has weak acidity, with the pH being approximately 2,[25] the demineralizing effect on dentin contaminated with $AlCl_3$ solution might be similarly inhibited. For self-etching adhesives, the dentin bonding mechanism is due to the exposed collagen network and smear layer modification by self-etching primer incorporated into resin adhesives. As a result, less dentin etching effect of the primer could result in bond strength decreases, as shown in this study. The results of EDS analysis confirmed that a higher aluminum content remained on the contaminated dentin surface following application of SE primer for either 20 or 40 seconds. Nevertheless, the 40-second primer application might be a proper method to use for Clearfil SE Bond when the dentin surface is contaminated with this hemostatic agent, since the bond strength in this group was significantly higher than that in the CB 20 group. The surface morphology of the CB 40 group showed more aggressiveness of the etching pattern. Extending the primer application time of the self-etching adhesive might enhance the etching effect of the primer and can result in higher dentin bond strength of this adhesive system.

However, for the total-etching adhesive used in this study (EX), the contamination of dentin with $AlCl_3$ solution did not have a detrimental effect on bond strength. The microshear bond strengths of the control and contaminated group were comparable. This might be due to the aggressive etching effect of phosphoric acid, with pH 0.5,[26] which simultaneously demineralized and removed all contaminants on the affected dentin surfaces. This was suggested by the fact that contaminated dentin and normal dentin, after phosphoric acid etching, revealed similar remaining aluminum content that was less than that of contaminated dentin and contaminated dentin treated with SE primer for both 20 and 40 seconds. Moreover, the dentin etching patterns of the control and contaminated group of EX after acid etching were similar.

From the SEM of this study, the total-etching adhesive showed the complete smear layer and peritubular dentin removal after phosphoric acid etching; therefore, it could enhance fluid movement across the resin-dentin interface. In contrast, the self-etching system could result in less fluid movement due to a less aggressive etching pattern, resulting in superior dentin sealing compared with the total-etching system.[27] This might be the reason why the self-etching adhesives exhibited less incidence of post-op sensitivity.[28]

Currently, few studies have reported the effect of hemostatic agent on the bond strength of adhesives to tooth structures. The different composition of the hemostatic agents might affect tooth structure differently. Thus, future studies reporting on this aspect are needed. Given the results of this study, care should be taken when the hemostatic agent is used before application of self-etching adhesives. Extending the primer application time of the self-etching adhesive or using the total-etching systems might be appropriate in this situation.

CONCLUSIONS

When self-etching adhesive was used, dentin contaminated with the hemostatic agent Racestyptine, containing 25% aluminum chloride, had significantly lower bond strength compared to normal dentin. The hemostatic agent did not have any effect on dentin bond strength of the total-etching adhesive. These results are limited to the materials used in this study. Other materials might perform differently from these findings.

Acknowledgement

This research was supported by the NRCT-JSPS core university program in dentistry and the Faculty of Dentistry, Mahidol University. The authors are grateful to assistant professor Dr Thomas Hoy and the Language Center, Faculty of Graduate Studies, Mahidol University for kindly reviewing the article.

(Received 18 September 2006)

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Dental Research

Effect of 3 medicaments on the dimensional accuracy and surface detail reproduction of polyvinyl siloxane impressions

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Karen Williams, RDH, MS[3]/James Corcoran[4]

Objective: The purpose of this study was to determine the effect of retraction cord medicaments (aluminum chloride, ferric sulfate, and ferric subsulfate/ferric sulfate) on the dimensional accuracy and surface detail reproduction of polyvinyl siloxane impressions. **Method and materials:** Polyvinyl siloxane impressions were made of standardized metal dies (American Dental Association [ADA] specification No. 19) treated with 1 of the 3 retraction cord medicaments. Dimensional accuracy was evaluated by comparing the average length of a line in the impressions to the standard die. Surface detail reproduction was evaluated by viewing the impressions under low-angle illumination at ×10 magnification. Reproduction was considered satisfactory if 2 of 3 horizontal lines were reproduced continuously. The dies were also evaluated under the microscope before the impression was made. **Results:** The medicaments did not significantly effect the dimensional accuracy; mean shrinkage was within ADA guidelines in the treatment groups. All of the medicaments had an adverse effect on surface detail reproduction. These effects were statistically significant compared to the untreated control. **Conclusion:** Although the changes in dimensional accuracy were within ADA guidelines, the surface detail reproduction was modified such that the impression would be considered clinically unacceptable. For optimal results, care must taken to remove all traces of these retraction cord medicaments prior to recording of a polyvinyl siloxane impression. (Quintessence Int 2000;31:201–206)

Key words: dimensional accuracy, polyvinyl siloxane impression material, retraction cord medicament, surface detail reproduction

CLINICAL RELEVANCE: The 3 retraction cord medicaments used in this study adversely affected surface detail reproduction in polyvinyl siloxane impressions. All traces of these medicaments must be removed from the preparation prior to making a polyvinyl siloxane impression.

The popularity of polyvinyl siloxane (PVS) impressions has been attributed to several characteristics, including the dimensional accuracy and stability of this material.[1] Dimensional accuracy is a critical property, because imperfections in the impression can result in an inaccurate die and restoration. Dimensional stability means that, in general, impressions made with these materials will not distort even when stored for periods up to 1 week.[2] These properties of PVS materials, in addition to their ease of manipulation and excellent elastic recovery, contribute to their wide acceptance.

Polyvinyl siloxane impression materials do, however, suffer from 1 severe limitation: they are hydrophobic. The hydrophobic nature of these materials compromises their application in areas where moisture control is difficult. Some manufacturers have addressed this problem by incorporating surfactants into the material, but this only makes the PVS less hydrophobic, not hydrophilic.[1] The hydrophobic nature of these materials demands that the clinician pay particular attention to those techniques and/or reagents that control moisture in problematic areas such as the gingival sulcus.

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Presented at the American Association for Dental Research, Annual Meeting, Vancouver, British Columbia, Canada, March 1999.

TABLE 1 Chemical medicaments used in the study

Material	Brand name	Manufacturer	Batch No.
Aluminum chloride	*Buffered Hemodent*	*Premier*	*18964*
Ferric sulfate	Hemodent FS	Premier	18952
Ferric subsulfate/ ferric sulfate	Astringedent X	Ultradent	2RRQ

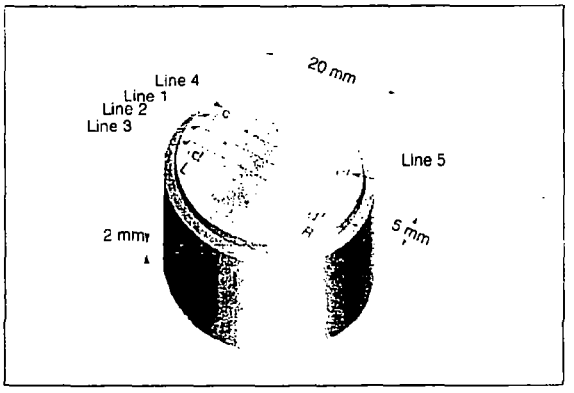

Fig 1 Standardized stainless steel metal die with 3 horizontal lines (1, 2, and 3) and two vertical lines (4 and 5). The intersections of the cross lines are labeled c, c', d, and d'. (L) Left; (R) right.

Clinically, many fixed prosthesis preparations finish at or below the gingival margin; blood, gingival fluid, and saliva can severely compromise the ability to register margins in these areas. Retraction cords, with or without chemical medicaments, are commonly used to improve access to the margins of the preparation.[3,4] The retraction cords displace the gingiva laterally while the medicaments prevent or control hemorrhage in the gingival sulcus.

Commonly used medicaments include racemic epinephrine, 25% buffered aluminum chloride, aluminum sulfate, aluminum potassium sulfate, ferric sulfate, and ferric subsulfate. It has been reported anecdotally that these chemical medicaments, especially those medicaments containing sulfur, may retard or inhibit the set of PVS impression materials, particularly "hydrophilic" PVS.[5] These conclusions were based largely on earlier studies that indicated that the platinum catalyst in PVS materials was contaminated by the sulfur compounds from latex gloves and rubber dam, resulting in an inhibited or retarded set.[6,7]

Other investigators have questioned the effect of retraction cord medicaments on the set of PVS impression materials.[2,8-10] These investigators suggested that the inhibited polymerization, described in earlier reports, is attributable to inadvertent contamination by latex rubber gloves rather than to exposure to gingival retraction cord medicaments.[8-10]

The effect of retraction cord medicaments, particularly those containing sulfur, on the set of PVS impression materials remains controversial. The purpose of this study was to determine the effect of 3 medicaments–aluminum chloride, ferric sulfate, and ferric subsulfate/ferric sulfate–on the dimensional accuracy and surface detail reproduction of polyvinyl siloxane impression materials. If either of these properties is adversely affected by the retraction cord medicaments, the accuracy of the die and, ultimately, the restoration will be compromised.

METHOD AND MATERIALS

Preparation of specimens

Twenty-one sample impressions were made of metal dies treated with each of the 3 retraction cord medicaments (Table 1) for a total of 63 treated specimens. Twenty-one additional impressions of the untreated dies served as the controls. Five standardized stainless steel dies (similar to those described in American Dental Association [ADA] specification No. 19)[11] with 3 horizontal and 2 vertical lines were used (Fig 1). The width of all 3 lines was 160 µm. The dies were individually numbered and marked with an arrow to facilitate orientation. The horizontal lines were numbered 1, 2, and 3, and the vertical lines were numbered 4 and 5. Four intersections (cross lines) were labeled c, c', d, and d' (see Fig 1). The horizontal lines (1, 2, and 3) measured 20 mm between the cross lines, and the vertical lines (4 and 5) measured 5 mm between the cross lines.

All 3 of the commercially available retraction cord medicaments used in this study are astringents. A medium-bodied type I polyvinyl siloxane impression material (Reprosil, batch No. 980307, LD Caulk) was used to make the impressions.

Gauze squares were soaked in the medicaments; excess fluid was removed by blotting, and the gauze was placed on the master die for 30 seconds. The gauze was removed and the die was blown dry with

compressed air for 1 minute. Care was taken to ensure that the medicament was dried on the die before the impression was made. For the control specimens, no medicament was placed on the die. Between each impression, the dies were sonicated for 2 minutes in alcohol and air dried to ensure dies were free of any surface contaminants.

Prior to the actual study, a pilot study showed that water, used in the same manner as the medicaments with gauze, did not affect the surface detail reproduction or dimensional accuracy of the impression material. Therefore, no change could be attributed to the gauze or water.

An impression gun was used to automix prepackaged cartridges of the impression material. The material was loaded into an impression syringe with a fine tip. Care was taken to push the impression material ahead of the syringe tip. Based on the results of the pilot study, this technique yielded the most accurate impressions.

The PVS was dispensed onto the dies with the impression syringe, and then 5-mm-high molds were placed on top of the dies to support the impression material (Fig 2). This resulted in a consistent impression thickness of 3 mm. First polyethylene strips and then flat metal pieces were placed on top of the molds, to keep the polyvinyl siloxane in the mold. The dies were transferred into a water bath; to ensure that the dies did not move, 500-g weights were placed on top of the flat metal plates. A water bath maintained at 32°C ± 1°C was used in accordance with ADA specification No. 19.[11]

The entire assembly, that is, dies, weights, flat metal sheets, and polyethylene, was removed from the water bath after 10 minutes. As recommended by ADA specification No. 19, this was 3 minutes longer than the manufacturer's published time for complete set.[11] The impression material was marked with an arrow pointing to the corresponding arrow on the die. These marks were used as a reference for orienting the specimen prior to measurement. The mold and die were then removed from the impression, and the impression was numbered on the back. The specimens were coded to ensure blind evaluation by the examiner.

Evaluation of dimensional accuracy and surface detail reproduction

Dimensional accuracy was evaluated by measuring the length of horizontal lines c–c' on each impression. Readings were made in triplicate to the nearest 0.001 mm by 2 calibrated examiners using an Unitron Bi5-3174 measuring microscope at ×10 magnification. These readings were then averaged to minimize measurement error. The percentage of change was then calculated by subtracting the known standard line length on the die from the averaged impression value and dividing by the standard line value.

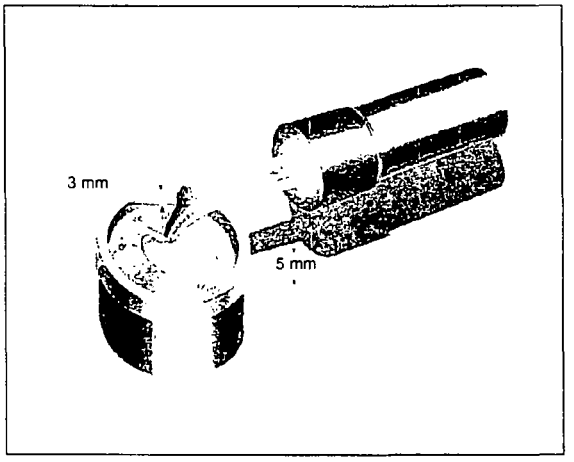

Fig 2 Polyvinyl siloxane impression material injected onto a standardized stainless steel die with a 5-mm high plastic mold in place. This mold supports and provides a consistent 3-mm thickness of impression material.

Surface detail reproduction was evaluated 1 hour after removal of the impression from the water bath. Each of the horizontal lines (numbered 1, 2, and 3) was viewed under a Unitron Bi5-3174 at ×10 magnification using low-angle illumination.[11] The reproduction was considered acceptable if 2 of 3 of the horizontal lines were reproduced continuously and well defined for the full 20 mm between the cross lines. The reproduction of a line was considered unacceptable if any part of the line was indistinct, eg, appeared melted or flattened, or the borders of the line were fuzzy or blurred. In addition, if the medicament pooled on the impression material and obscured the line or was incorporated into the material and destroyed the line's integrity, the line was considered unacceptable. If any impression had 2 indistinct lines, the surface detail reproduction was considered unacceptable. An impression was considered successful if at least 2 of the 3 lines were considered acceptable; anything less than this was considered unacceptable.

The standard and treated dies were also evaluated under the Unitron Bi5-3174, at ×10 magnification, before the impression was made, to determine whether the retraction cord medicaments had any affect on the dies before the impression was made. The dies were closely evaluated for pooling of medicament on the dies, the formation of a surface coating, and any effects of the medicament on the surface detail of the dies.

TABLE 2 Surface detail reproduction

Result	Control	Aluminum chloride	Ferric sulfate	Ferric subsulfate/ ferric sulfate	Total
Acceptable	21	0	0	0	21
Unacceptable	0	20	21	21	62
Total	21	20	21	21	83

TABLE 3 Dimensional accuracy

Group	Horizontal change (mean ± SD)
Control	0.086% ± 0.083%
Ferric sulfate	0.029% ± 0.076%
Ferric subsulfate/ ferric sulfate	0.049% ± 0.114%
Aluminum chloride	0.011% ± 0.093%

Collection of data

Twenty-one specimens were made for each of the 3 medicaments and the controls, for a total of 84 specimens. One specimen in the aluminum chloride group was eliminated from the study because of unrelated methodologic problems.

Prior to initiation of the study, sample size was statistically determined based on an α of 0.05 and power of 0.80 to detect a 0.10% change in acceptable detail reproduction. Based on calculations, it was determined that a sample of 30 impressions of each medicament would be needed. However, the presence of overwhelming trends in the data led the researchers to conduct a preliminary analysis to determine if any further specimens were needed. Based on this analysis, it was decided that no further specimens were necessary.

All data were then entered into SPSS statistical software (version 7.0 for Windows), along with the impression number, the stainless steel die number, and the group designation number. The surface detail reproduction was entered as a nominally scored variable, acceptable or unacceptable.

Statistical analysis

Fisher's exact test was used to examine the effect of medicament exposure on surface detail reproduction. The dimensional accuracy data were evaluated statistically using a 1-factor analysis of variance with Tukey's mean comparison post hoc analysis. Consistency of measurement (reliability) of the dimensional accuracy for observers was taken against the standard die. Average measurement error was found to be 0.01%, with a 95% confidence interval of ± 0.05.

RESULTS

Surface detail reproduction

The results of this study are presented in Tables 2 and 3. Medicaments had a statistically significant adverse affect ($P < 0.05$) on surface detail reproduction. All of the impressions on dies treated with the medicaments were determined to have unacceptable surface detail. In contrast, all of the control impressions (untreated dies) were acceptable with respect to surface detail; ie, the lines were clearly reproduced with distinct edges along their entire length.

When the standard dies were evaluated under the microscope prior to impression making, the dies were clean, without a surface film, and the horizontal and vertical lines were clearly visible and well defined between the cross lines. When the dies that were treated with the aluminum chloride retraction cord medicament were viewed under the microscope, there was obvious contamination of the dies. No pooling of the liquid was observed, but the medicament caused uneven changes in the color of the die. The horizontal and vertical lines remained distinct and were not obliterated.

In comparison, dies that were treated with ferric sulfate did not appear to have a surface coating, and the horizontal and vertical cross lines were distinct. Under ×10 magnification, very small pools of medicaments were, however, noted in some areas along the vertical and horizontal lines. These dies appeared dry to the naked eye. The ferric subsulfate/ferric sulfate had a similar effect on the dies.

Although all 3 medicaments adversely affected the surface detail reproduction according to the defined criteria, the manner in which aluminum chloride affected the surface detail of the PVS was quite different from the way in which the ferric sulfate and ferric subsulfate/ferric sulfate affected the specimens. The aluminum chloride medicament produced a very rough, almost "melted" appearance; whole sections of lines were destroyed on many of the specimens. This may have resulted from contamination and/or a film effect of the aluminum chloride on the die. The ferric sulfate and ferric subsulfate/ferric sulfate retraction cord medicaments had much less of an effect on surface

detail reproduction. However, the surface detail was determined to be unacceptable, because pooling of liquid did occur in some small areas around the edges of the lines, destroying their integrity according to the defined criteria.

Dimensional accuracy

There was no statistically significant difference ($P > 0.05$) in dimensional accuracy between the control and the various medicament groups or between any of the medicament groups. Shrinkage values ranged from 0.110% to 0.029% for the medicament-treated impressions compared to 0.086% for the control samples. All values fell within the ADA standards of less than 0.500% for type 1 nonaqueous elastomeric dental impression materials.

DISCUSSION

The dimensional accuracy did not appear to be affected by any of the retraction cord medicaments used in this study. Shrinkage occurred in all impressions, including the control, but these dimensional changes were within the ADA specifications for PVS material.[11]

The medicaments, however, clearly affected the quality of the impression, and this observation should be noted by all clinicians. Surface detail reproduction was adversely affected by all of the retraction cord medicaments. Aluminum chloride had an effect that was distinctly different from that of ferric sulfate and ferric subsulfate/ferric sulfate. The aluminum chloride produced an extremely rough, melted appearance; whole sections of the lines were completely obliterated. When the aluminum chloride–treated dies were viewed under the microscope, the surface of the dies was obviously contaminated. The medicament caused uneven changes in the color of the dies, but the horizontal and vertical lines were visually distinct.

In the polyvinyl siloxane impressions of the aluminum chloride–treated dies, the horizontal lines were visually indistinct in many areas. It is unclear whether the medicament had an additional affect on the PVS impression material or whether the PVS impression material accurately recorded a contaminated die. Either way, it is critical that the clinician remove all traces of aluminum chloride medicament from the preparation prior to making a PVS impression.

In comparison, the adverse effects of ferric sulfate and ferric subsulfate/ferric sulfate were associated primarily with pooling of residual medicament around the edges of the lines. Often this pooled medicament was incorporated into the edges of the line, destroying its integrity. When the dies that were treated with these medicaments were viewed under the microscope, they did not appear to have a surface coating, but very small traces of medicaments were noted along the vertical and horizontal lines. These dies appeared dry to the naked eye.

Although the impressions of these treated dies were considered unacceptable, the ferric sulfate and ferric subsulfate/ferric sulfate medicaments had a less severe adverse effect on the impressions and the dies than did aluminum chloride. The horizontal lines were distinct in most areas of the impressions, except in very small areas where remnants of the liquid were incorporated into the lines or edges of the lines. With the ferric sulfate and ferric subsulfate/ferric sulfate medicaments, it appeared as if a contaminated die was reproduced in the impression.

The results of this study do not support the conclusions presented by previous authors.[2,8-10] For example, De Camargo et al[8] concluded that the chemical medicaments aluminum chloride, epinephrine, aluminum sulfate, aluminum potassium sulfate, and ferric sulfate do not have any inhibitory affect on the polymerization of PVS impression materials. Several criteria were used to define *inhibition* in their study, including an obvious lack of detail reproduction on the surface of the impression material.[8] Others have used anecdotal clinical reports to discount the possibility of interaction between aluminum chloride and various PVS impression materials and did not investigate further.[9,10] Although it cannot be stated that these medicaments inhibit the set of PVS impression material, the manner in which they were used in the present study suggests that these materials adversely affect surface detail reproduction.

One explanation for these contradictory results is that the methodology used in this study is different. The earlier study, by De Camargo et al,[8] evaluated impression materials injected over 1-inch segments of retraction cord and 1-cm² squares of cotton. The retraction cord and cotton were impregnated with the medicament and blotted dry, and the impression was recorded and evaluated under ×10 magnification.

In contrast, the current study used impressions of standardized metal dies similar to those described in ADA specification No. 19.[11] The quantity of impression material injected was carefully controlled. Surface detail reproduction was evaluated by examination of the depth, width, and character of 160-μm lines that were recorded in the impression. Close inspection of these lines at ×10 magnification facilitated the detection of any effect the retraction cord medicament had on the polyvinyl siloxane impressions of the treated dies.

In this investigation, the medicament was not washed off the die before the impressions were made. This protocol was used to simulate the most severe clinical situation, ie, where the clinician fails to rinse the medicament off the tooth or retraction cord prior to recording the impression. In studies where gloves were found to inhibit the set of the material, the only effective method for completely removing the inhibiting particles from the tooth or die was mechanical removal of any trace of the material with a toothbrush or prophylaxis head and pumice.[12] Simple rinsing with mouthwash, hydrogen peroxide, or an air-water syringe was ineffective at removing the inhibitor particles.[9,12] A similar study on the most effective method for completely removing retraction cord medicaments from the die is required.

It is critical that impressions, particularly for fixed prosthodontics, accurately reproduce the preparation; an imperfection in the impression will result in an inaccurate die and, ultimately, an unsatisfactory restoration. The results of this study suggest that the clinician must be diligent in his or her efforts to remove retraction cord medicaments prior to recording a polyvinyl siloxane impression. Further investigations are needed to determine if rinsing with air and water is sufficient to remove retraction cord medicaments. Additional studies are required to determine the effects of other medicaments as well as the interaction of the medicaments used in this study on the wide variety of commercially available polyvinyl siloxane impression materials.

CONCLUSION

Within the limits of this study, the following conclusions were derived from the results:

1. There was a statistically significant difference in surface detail reproduction between all of the retraction cord medicament groups and the control group investigated in this study.
2. Surface detail reproduction in the polyvinyl siloxane impressions was adversely affected by all of the retraction cord medicaments.
3. There was no statistically significant difference in dimensional accuracy among any of the groups. All of the impressions exhibited shrinkage that was within the ADA's acceptable limits for type I nonaqueous elastomeric dental impression materials, ie, less than 0.5% shrinkage.

ACKNOWLEDGMENTS

This project was supported in part by the Rhinehart Foundation, University of Missouri–Kansas City, School of Dentistry.

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Smear layer instability caused by hemostatic agents

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The effect of hemostatic agents, other than a 15.5% $Fe_2(SO_4)_3$ solution, on prepared tooth structure is unknown. The purpose of this study was to (1) compare the effect of six commonly used hemostatic solutions and two nondental astringents on the dentinal smear layer and (2) determine whether different responses caused by product and/or time could be established. Standardized dentinal smear layers were exposed to eight astringent solutions for 30, 120, and 300 seconds (n = 6). A total of 144 SEM photographs at ×2400 magnification were ranked according to predetermined criteria for five categories of smear layer removal and etching of underlying tooth structure. There were significant differences ($p < 0.001$) caused by the solution, exposure time, and their interaction. Greatest smear layer removal was observed with 21.3% $AlCl_3$-6 hydrate, 8% racemic epinephrine HCl, and 15.5% $Fe_2(SO_4)_3$ solutions at longer exposures. These caused significantly more removal than did almost pH neutral tetrahydrozoline or oxymetazoline ($p < 0.05$). (J Prosthet Dent 1996;76:477-82.)

In a previous pilot study, a 15.5% $Fe_2(SO_4)_3$ solution was shown to remove the dentinal smear layer and etch the underlying dentin with partial loss of peritubular dentin.[1] The effect of other hemostatic agents on prepared tooth structure is unknown. The purpose of this study was to compare the effect of six commonly used hemostatic solutions and two nondental astringents on the dentinal smear layer and to determine whether different responses caused by product and/or time could be established. Two nondental astringents, Visine and OcuClear (Table I), used as eye drops, were included in this study because they are almost pH neutral. The possible dental application of such solutions has been suggested, and the hemostatic efficacy of tetrahydrozoline hydrochloride, the active ingredient in Visine astringent, has been tested.[2]

The use of retraction cord that has been soaked in an astringent or vasoconstrictor is a common procedure in dentistry. Its primary objective is to assist in hemostasis and tissue displacement to facilitate impression making.[3] Nemetz and Seibly[4] have reported on commonly used chemical agents in gingival retraction. Commonly used dental astringents include aluminum chloride, aluminum potassium sulfate, aluminum sulfate, and ferric sulfate, which are typically dispensed in buffered aqueous or aqueous/glycol solutions. Recently, a gel-based ferric sulfate astringent was introduced. Vasoconstrictors such as racemic epinephrine hydrochloride by itself or in combination with zinc chloride or zinc phenolsulfonate are also available as either impregnated cords or pellets to assist with hemostasis before impression making. Astringents exert weak vasoconstrictive and protein denaturing properties. They are relatively safe and almost devoid of systemic effects although they may produce local tissue irritation and transient staining.[5] A vasoconstrictor, such as epinephrine, has potent sympathomimetic and vasoconstrictive properties, and systemic absorption of the topically administered form cannot be controlled or quantified.[5] Accordingly, the advantages of its use need to be carefully weighed against the potential risks, especially in patients with significant cardiovascular histories.

The hypothesis of this study was that as the pH of routinely available astringent solutions is typically highly acidic,[1,5] smear layer removal and etching of underlying dentin would result, whereas when prepared dentin was exposed to pH-neutral astringents neither the smear layer nor underlying dentin would be affected.

MATERIAL AND METHODS

A total of 144 tooth preparation specimens were used. Recently extracted molar teeth were obtained from the Oral Surgery Department at Southern Illinois University School of Dental Medicine. Tooth selection was based on predefined criteria: intact clinical crown, no existing restorations, no excessive decalcifications, and an intact

Presented before the 24th annual meeting of the American Association for Dental Research, San Antonio, Tex., March, 1995.
This study was funded in part by Southern Illinois University Research Grant DSRA 94-2.
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Table I. Hemostatic agents tested

Hemostatic agent	Active ingredient	pH
Astringedent (AS) (Ultradent Products, Inc., Salt Lake City, Utah)	15.5% $Fe_2(SO_4)_3$	0.8
Hemogin-L (HG) (Van R. Dental Products, Inc., Oxnard, California)	25% $AlCl_3$ aqueous	0.9
Hemodent (HD) (Premier Dental Products Co.)	21.3% $AlCl_3$ aqueous/glycol	1.3
Cranberry Styptin (ST) (Van R. Dental Products, Inc.)	20% $AlCl_3$ buffered glycol	1.3
Gingi-Aid 25% (GI) (Gingi-Pak Laboratories, Camarillo, Calif.)	25% $AlCl_3$ NF	1.9
Orostat 8% (OR) (Gingi-Pak Laboratories)	8% racemic Epinephrine	2.0
Visine (VI) (Leeming Div., Pfizer, Inc., New York, N. Y.)	Tetrahydrozoline hydrochloride	6.8
Ocu Clear (OX) (Health Care Products, Inc., Memphis, Tennessee)	Oxymetazoline HCl	6.5

cementoenamel junction (CEJ). The teeth were initially stored in a glutaraldehyde solution and handled in accordance with applicable CDC guidelines. The teeth were prepared for complete ceramic crowns with heavy shoulder preparations with coarse diamonds by use of conventional high speed instrumentation and water spray. The teeth were prepared in this manner to ensure removal of all axial tooth enamel. All teeth were then instrumented for 30 seconds, each with a new 557D medium-grit diamond (Brasseler USA, Savannah, Ga.) under water spray to standardize the resulting smear layers. The teeth were sectioned with a diamond disk (model 7941M, Brasseler USA). The root portions were sectioned several millimeters below the CEJ in a direction perpendicular to the long axis of the teeth, and then all pulpal tissues were removed. Each tooth was sectioned buccolingually and mesiodistally into four individual specimens, which were stored in vials with an isotonic sodium 0.2 % azide solution.

Surface treatment

Exposure time to the various hemostatic solutions was consistent with those used in a previous pilot study.[1] The solutions, their manufacturers, and their respective pH measurements are listed in Table I. A total of 24 experimental groups (n = 6) were treated within 24 hours of tooth preparation. The teeth were dried by three short blasts of air from a dental multifunction syringe that simulates clinical drying of tooth preparations. Subsequently, each specimen was submerged in the hemostatic agent for the applicable time. Immediately after the timed exposure the specimens were removed and subjected to a three-phase irrigation cycle in water followed by a 10-second spray with the multifunction syringe. The irrigant was changed for each experimental group.

For ensuring blind conditions to prevent examiner bias, the specimens were transferred to 144 numbered individual vials before their return as numbered specimens for SEM examination and photography.

Table II. Scoring criteria for the residual dentinal smear layer

Rank	Category	Description
1	Smear layer intact	Outline of tubular pattern not visible; Amorphous mass of debris; Possible rotary instrument tracks; Possible artifact, deposit, coagulum
2	Smear layer partially removed, tubules occluded	Smear layer barely removed, some with apparent residual debris Recognizable tubular pattern with cracks across tubular opening All occluded
3	Smear layer (partially) removed, tubules largely occluded	Some smear layer residue Identifiable tubular pattern Some cracking Substantial number remain occluded
4	Smear layer removed tubules largely open	Clearly identifiable tubular pattern Substantial number of open tubules Odontoblastic processes typically not discernible
5	Smear layer removed tubules open dentin visibly etched	Tubules wide open Intertubular dentin with etch pattern Odontoblastic processes visible, may or may not protrude

Mounting

The specimens were dried for 24 hours and mounted on aluminum stubs with silver colloidal paste (Electron Microscopy Sciences, Ft. Washington, Pa.). The perimeter of each stub was notched to permit standard orientation of the tooth specimen on the stub and in the SEM chamber. The specimens were positioned so that the treated surface was located approximately 3 mm above and parallel to the top of the stub. The corresponding specimen number was engraved in the base of the stub. The specimens were then stored in plastic specimen holders and the colloidal paste was allowed to dry for 24 hours.

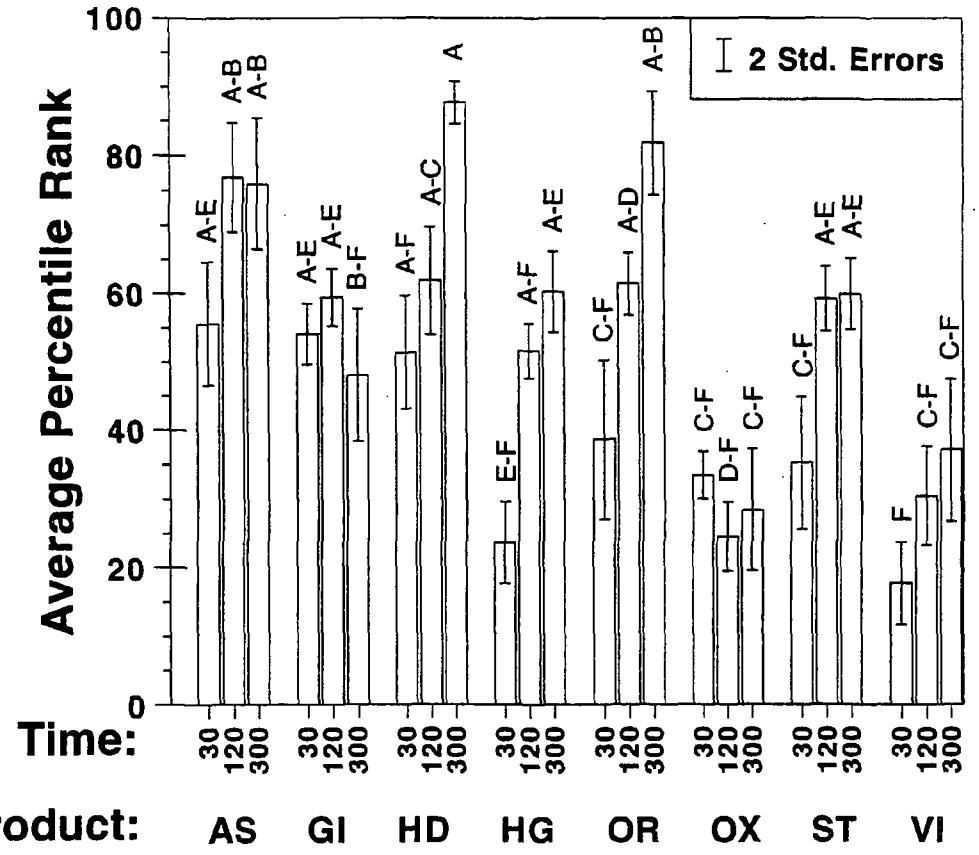

Fig. 1. Average percentile ranks by product and exposure time. Average percentile ranks that have common identifying letter over base were not statistically significant. Product abbreviations are listed in Table I.

Table III. Means and standard deviations of the average ranks for the subgroups

Product	Duration of exposure					
	30 Seconds		120 Seconds		300 Seconds	
	Mean	SD	Mean	SD	Mean	SD
Astringedent	55.60	20.10	76.86	19.19	75.95	23.07
Gingi-Aid	54.16	10.91	59.48	10.23	48.04	23.80
Hemodent	51.39	20.26	61.84	19.23	87.62	7.72
Hemogin-L	23.58	14.76	51.62	9.83	60.23	14.43
Orostat 8%	38.60	28.43	61.41	11.11	81.81	18.22
Oxymetazolone	33.39	8.42	24.44	12.40	28.28	21.74
Styptin 120	35.17	23.58	59.20	11.60	59.89	12.66
Visine 120	17.59	14.68	30.32	17.59	37.07	25.52

Sputter coating

After drying, the specimens were coated with a thin film of AuPd in an Anatec LTD Hummer VI (Anatec Ltd., Springfield, Va.) sputter system. Based on results obtained in a pilot study, a 4-minute coating cycle was used for each specimen.

SEM observation

Specimens were examined with a scanning electron microscope (model JSM 35 LF, Jeol U.S.A. Inc., Peabody, Mass.) at 25 kV, tilt 0, condenser lens 4.3, and contrast 4.6. The orientation mark on the stub was used to standardize specimen position in the chamber. The specimens

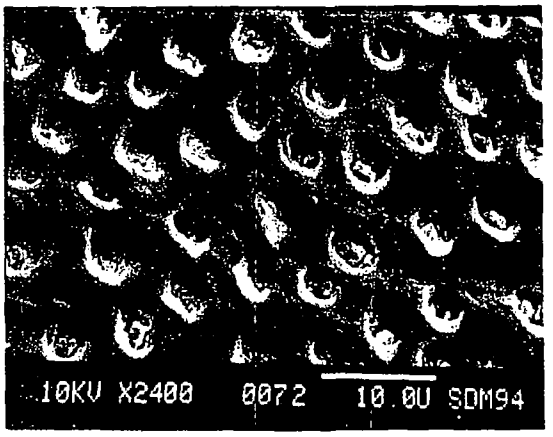

Fig. 2. After 5-minute exposure to 15.5% $Fe_2(SO_4)_3$, complete smear layer removal and severe etching results.

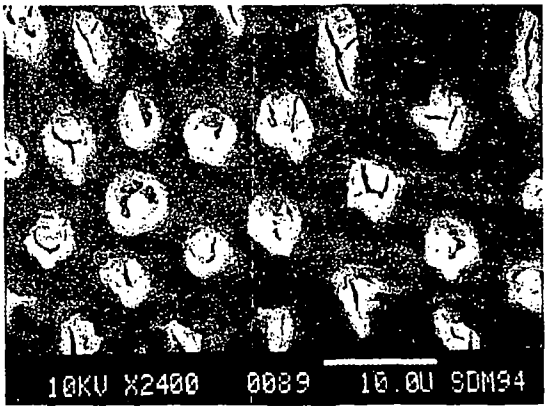

Fig. 3. Five-minute exposure to 21.3% $AlCl_3$ 6 hydrate results in complete smear layer removal and noticeable dentin etching, although some tubules remain partly occluded.

were rotated so the prepared cavosurface line angle was parallel to the bottom of the video screen. All specimens were initially examined at ×240 magnification and focus was done for all specimens at ×18000. Scanning electron micrographs (SEMs) were then made at ×2400 magnification with Polaroid 55N film. Photography location was standardized from specimen to specimen; all micrographs were taken in the center of the horizontal surface of the specimens, one video screen height (at ×2400) occlusal from the prepared cavosurface margin.

Evaluation

After all 144 micrographs were obtained, four evaluators rated each micrograph according to predetermined criteria for five ranked categories; smear layer: (1) intact; (2) partially removed, tubules occluded; (3) partially removed, tubules largely occluded; (4) removed, tubules largely open; and (5) removed, tubules open, dentin visibly etched. Table II lists the criteria for these categories in detail. SEM observation, interpretation, and ranking were completed under blind conditions.

Statistical significance was determined by first converting the ranked categories to percent ranks for each evaluator.[7] Where the repeated measure for each sample was the ranking of the four evaluators, and the between-subject factors were product and exposure time, a full repeated measures analysis of variance of these ranks was performed. Because the evaluator factor and every interaction that involved evaluator showed no statistical significance, the ranks of the four evaluators were averaged, and these average percentile ranks were subjected to the Ryan-Einot-Gabriel-Welsch multiple range (REGWQ) test.[8]

RESULTS

Before the study began, it was anticipated that the acidic hemostatic solutions would result in smear layer removal and etching of the underlying dentin, whereas the pH-neutral solutions would affect the smear layer to a lesser degree. The analysis of variance (ANOVA) of the average ranks indicated that there were statistically significant differences caused by the solution ($p < 0.001$), exposure time ($p < 0.001$), and their interaction ($p < 0.02$). Figure 1 illustrates the average percentile rank for each tested solution by exposure time.

Greatest smear layer removal was observed with 21.3% $AlCl_3$ 6 hydrate, 8% epinephrine HCl, and 15.5% $Fe_2(SO_4)_3$ solutions at longer exposures. These caused significantly more removal than tetrahydrozoline or oxymetazoline ($p < 0.05$).

Representative results are presented in Figures 2 through 5. These SEMs illustrate respectively a typical response to 15.5% $Fe_2(SO_4)_3$ and 21.3% $AlCl_3$ 6 hydrate both after a 5-minute exposure time (Figs. 2 and 3). Figure 4 represents a 5-minute exposure to tetrahydrozoline HCl, which is comparable to the responses seen with oxymetazoline. Figure 5 shows appearances after 30 seconds, 2 minutes, and 5 minutes of exposure with 8% racemic epinephrine HCl exposure.

DISCUSSION

This investigation serves as an initial step to determine and quantify the extent of surface change as a result of exposure to hemostatic agents. When prepared tooth structure is exposed to acidic solutions, the smear layer will be removed to various degrees and the underlying dentin etched. Exposure to hemostatic agents is a regular occurrence in general dentistry. Informal inquiries among general practitioners suggest that a 10-minute exposure to a hemostatic solution may be considered routine with longer exposure times not unusual as the complexity of the restorative procedures (for example, the number of tooth preparations) increases.

Although the intraoral use of tetrahydrozoline and

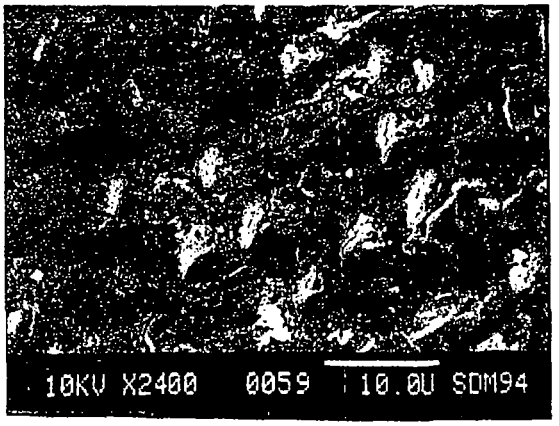

Fig. 4. After 5-minute exposure to tetrahydrozoline HCl, smear layer remains intact. This is also seen after prolonged exposure to oxymetazoline.

oxymetazoline is not commonplace, it is reasonable to assume that the vast majority of dental hemostatic agents used are highly acidic. Therefore, in clinical practice, the smear layer in proximity to the cavosurface line angle will be removed and the underlying tooth structure will be etched. Exposed tooth enamel also will be etched. The "keyhole" etching pattern typical of etched enamel was seen on many specimens during the SEM observations.

With the exception of the Gingi-Aid hemostatic agent, all acidic solutions exhibited an increased surface effect as a function of time. The active ingredient in the Hemogin-L, Hemodent, Cranberry Styptin, and Gingi-Aid agents is $AlCl_3$ in concentrations that range from 20% to 25%. At the time intervals 30 seconds and 2 minutes, the response to these materials seemed to be comparable. The difference in surface change after longer exposure (namely 5 minutes) is not readily explained on the basis of chemical composition alone.

A 2-minute exposure to 15.3% ferric sulfate results in severe etching comparable to a 5-minute exposure to Hemodent and Orostat hemostatic agents. A longer exposure (5 minutes) to ferric sulfate did not appear to increase the resulting surface effect. For Hemodent and Orostat agents, the degree of surface change appeared to be a function of time, and longer exposure had a definite effect on the residual smear layer and underlying tooth structure.

Significance of smear layer retention

The desirability of smear layer retention versus smear layer removal has been the subject of controversy.[9,10] Correlations have been suggested between postoperative pain and fluid movement through the dentinal tubules.[11] It has also been argued that maintaining the smear layer effectively diminishes fluid flow through the dentinal tubules by as much as 8%.[12] In

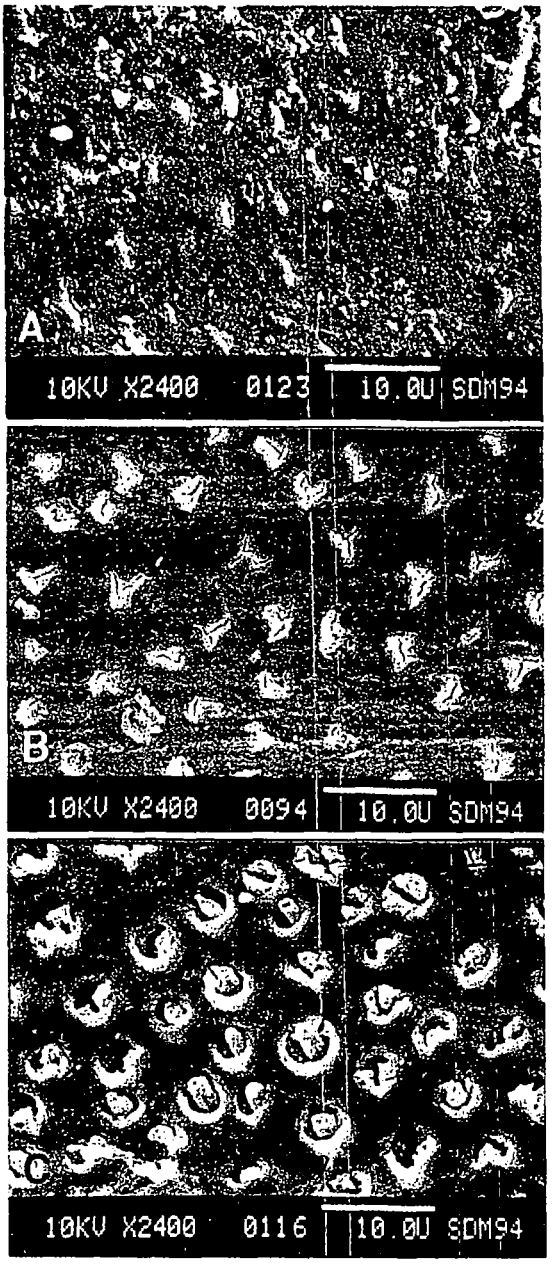

Fig. 5. Representative appearances after respectively 30 seconds (**A**), 2 minutes (**B**), and 5 minutes (**C**) of exposure to 8% racemic epinephrine HCl. Progressively increased smear layer removal and etching is noticeable as exposure time increases.

addition, increased bacterial infiltration has been demonstrated after smear layer removal.[13] These findings suggest that it may be beneficial from a biologic perspective to maintain the smear layer completely or in part because postoperative discomfort may be dimin-

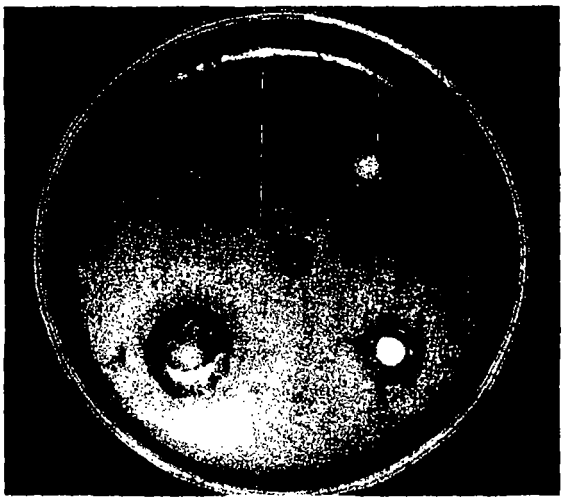

Fig. 1. Representative agar plate inoculated with *S. salivarius* contained wells of tested materials. Zones of growth inhibition after 2 days of incubation. *Top left,* Syntac; *top right,* Optibond; *center,* Heliobond; *bottom left,* Vitremer; *bottom right,* Variglass VLC.

The aim of this laboratory study was to evaluate the inhibitory effect of two dentin bonding systems on bacterial growth, one with fluoride and the other with glutaraldehyde, and two light-cured glass ionomer cements that are frequently used as liners.

MATERIAL AND METHODS

The materials used and manufacturer information are presented in Table I. All materials were prepared in accordance with manufacturers' recommendations. The glass ionomer cements, Vitremer and Variglass VLC, were prepared in the consistency of liner. Because Syntac adhesive contains no polymerization initiators, it was mixed with Heliobond bonding agent in a ratio of 1:1. In a pilot project, it was found that Heliobond bonding agent had negligible antibacterial activity; thus it was used as negative control.

Antibacterial activities of the materials were evaluated against the following bacteria: *S. mutans* (ATCC 25175), *S. sobrinus* (ATCC 27609), *Streptococcus sanguis* (ATCC 10556), *Streptococcus salivarius* (clinically isolated), *Lactobacillus casei* (ATCC 4646), *Enterococcus faecalis* (ATCC 29212), *Fusobacterium nucleatum* (ATCC 10953), and *Actinomyces viscosus* (ATCC 15987). Vitremer glass ionomer cement was not tested against *S. sanguis, F. nucleatum,* and *A. viscosus* because it was included after the study had started.

Cultures of the bacteria species used herein were reconstituted from lyophilization, grown and maintained in a brain-heart infusion broth, prereduced, and anaerobically sterilized (BHI-PRAS). All procedures were carried out under aseptic conditions in a laminar air flow cabinet. The turbidity of inoculum, prepared in BHI-PRAS, was adjusted to the optical density of a 0.5 McFarland standard (1.5×10^8 bacteria/ml).

Table I. Materials used

Name	Manufacturer
Optibond light-cured adhesive	Kerr, Romulus, Mich.
Syntac adhesive	Vivadent, Schaan, Liechtenstien
Vitremer	3M, St. Paul, Minn.
Variglass VLC	Dentsply, Petrópolis, Brazil
Heliobond (control group)	Vivadent

The agar diffusion test was used. Petri plates that contained BHI agar were inoculated with the bacteria tested by use of sterile cotton-tipped applicators that were brushed across the medium. Wells 5 mm in depth and 6 mm in diameter were punched in agar plates and filled with the materials tested. After placement, the materials were light cured according to manufacturers' recommendations. Each assay was made in duplicate for each material and bacterial strain. Positive control plates were streaked with bacteria but no material was used.

The bacteria agar plates were placed into anaerobic jars. Anaerobic conditions were produced by the evacuation-replacement procedure, in which the air in the jar is removed by use of a vacuum pump and replaced with a mixture containing 10% hydrogen and 10% carbon dioxide in nitrogen. The jars were incubated at 37° C for 2 days. Afterward, the diameters of the zones of growth inhibition were measured (Figs. 1 and 2), with the 6 mm diameter as the cutoff value.

Statistical analysis was not performed because of the different diffusibility coefficients of the tested materials in agar. Hence a semiqualitative comparison as carried out by Al-Khatib et al.[24] was made.

RESULTS

The means of the zones of bacterial inhibition for each material are presented in Table II. Vitremer glass ionomer cement exhibited the largest zones of inhibition against the bacterial strains tested. Syntac adhesive was inhibitory against all strains, but it was not more effective than Vitremer glass ionomer cement. Variglass VLC, the other light-cured glass ionomer used, exhibited antibacterial activity against most of the bacterial strains and was ineffective only against *L. casei* and *S. sobrinus*. There were no zones of growth inhibition for Optibond or Heliobond bonding agents.

DISCUSSION

The agar diffusion test has been widely used to evaluate the antibacterial activity of dental materials.[25-27] For this method the zones of growth inhibition provided by the materials depend on the toxicity of the material against the bacteria tested, and the diffusibility of the material across the culture medium used. A material that

Table II. Zones of inhibition (in millimeters)

	OPT	S/H	HEL	VIT	VAR
S. mutans	0	12	0	14	10
S. sobrinus	0	6	0	21	0
S. sanguis	0	5	0	*	14
S. salivarius	0	6	0	11	10
L. casei	0	3	0	12	0
F. nucleatum	0	6	0	*	10
E. faecalis	0	3	0	8	3
A. viscosus	0	7	0	*	32

OPT, Optibond light-cured; *S/H*, Syntac adhesive/Heliobond; *HEL*, Heliobond; *VIT*, Vitremer; *VAR*, Variglass VLC.
*Not tested.

diffuses more easily will probably provide larger zones of inhibition. Thus, in addition to direct cytotoxicity, the different diffusion rates of the different materials used in this experiment may have influenced the results. This factor may be less important when bacterial suspensions, which permit direct contact between materials and bacterial cells in an aqueous medium, are used. Thus we believe that further studies with another method such as the microdilution broth technique are necessary to compare and contrast the antibacterial activities of the materials. On the other hand, to our understanding, the great advantage of the agar diffusion test is the elimination of some variables, such as different inoculum size and medium manipulation, so long as the materials are placed in the same agar plate, and hence the allowance of an effective comparison among materials. Moreover, the method used in this study allowed measurement of the inhibitory activity against bacteria colonizing a surface, which imparts clinical relevance if in vitro data are being extrapolated to oral bacteria colonizing around or on restorative materials.

Most of the bacterial strains used in this study were ATCC isolates. The use of standard bacterial strains was preferred for the results to be reproducible. However, different bacterial susceptibilities may be observed in strains other than fresh clinical isolates.

The results of this study demonstrated adverse conditions for most of the bacterial species when glass ionomer cement was used during setting, especially for Vitremer glass ionomer, which showed the largest zones of inhibition. It has been assumed that the antibacterial effects of glass ionomer cements are the result of the release of fluoride and zinc ions from the materials.[22] In addition, dual setting, which is a characteristic of some glass ionomer cements such as Vitremer, causes a slow acid-base reaction with consequently prolonged low surface pH. Therefore these materials may promote an acidification of the medium, thereby creating a condition unsuitable to bacterial growth.

It was concluded by Woolford and Chadwick[28] that glass polyalkenoates maintain a low surface pH for the first 60 minutes of setting. Therefore a significant initial inhibitory effect on bacterial growth is observed when this material is used. On the basis of the in vivo study conducted by van Dijken et al.,[29] it is believed that a low fluoride release only is not sufficient for a significant antibacterial effect. These authors concluded that the fluoride levels in plaque adjacent to glass ionomer cement would not become high enough to inhibit the accumulation of *S. mutans*, total streptococci, and lactobacilli on sound enamel surfaces and 1-year-old glass ionomer cement.

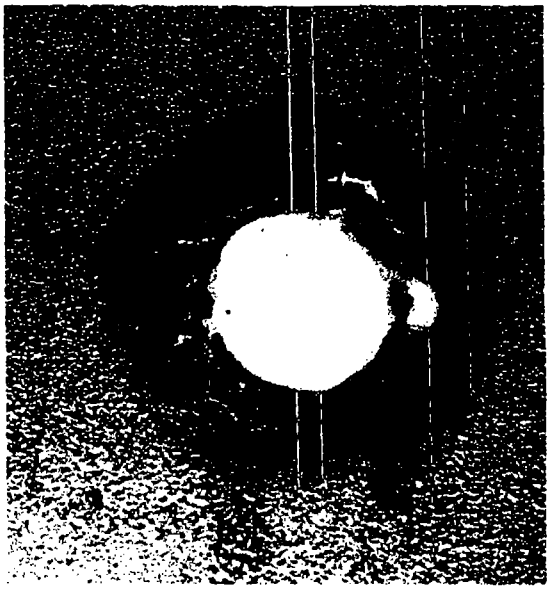

Fig. 2. Higher magnification of inhibitory effect of Veriglass VLC on *Streptococcus salivarius*.

No effect was shown by a dentin bonding agent with fluoride in its composition; however, a significant inhibition occurred when the dentin bonding agent that contained glutaraldehyde was tested. It is known that these materials are similar in composition, which suggests that the dissolution mechanism and release of their agents may also be similar. The most important difference between Optibond and Syntac/Heliobond is the incorporation of fluoride and fillers in the former and glutaraldehyde in the latter. The higher disinfectant effect of glutaraldehyde was probably the reason for the better results it provided. The substances may be released by the dissolution of materials or by some other means of matrix erosion.[30] It is possible that Optibond bonding agent does not release fluoride ions during setting. It is also possible that this release provides only a low fluoride concentration around the material, which may have been insufficient to inhibit bacterial growth.

On the basis of data from this study, it would appear that Vitremer glass ionomer cement was superior in inhibiting bacterial activity compared with the other materials tested. However, the obvious limitations of in vitro

studies indicate that direct extrapolation to a clinical situation must be done with caution.

CLINICAL IMPLICATIONS

Some studies have demonstrated inhibitory effects of dental materials on bacterial growth. The presence of bacteria in prepared cavities may cause pulpal pathosis. We believe that remaining microorganisms in dentinal tubules can be eliminated by the low surface pH of the glass ionomer liner or by glutaraldehyde released by Syntac adhesive during setting. It is possible that the inhibitory effect caused by setting materials has clinical significance. Furthermore, a low release of antibacterial compounds from liners or adhesives can occur for a long time after setting and may inhibit secondary caries.

SUMMARY

1. Vitremer, a dual-cured glass ionomer, demonstrated the largest zones of inhibition against the bacterial strains tested.

2. Variglass VLC glass ionomer cement showed antibacterial effect on six bacterial species but did not show any action on *L. casei* and *S. sobrinus*.

3. The dentin bonding with glutaraldehyde Syntac adhesive exhibited inhibitory activity on growth of the eight bacteria species used in this study.

4. Optibond light-cured or Heliobond bonding agents did not demonstrate any antibacterial effect.

We thank Mr. Fernando A.C. Magalhães for technical assistance.

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Efficacy review

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British Journal of Pharmaceutical Research
1(3): 66-87, 2011

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Pharmacological Agents in Dentistry: A Review

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Review Article

Received 3rd May 2011
Accepted 2nd June 2011
Online Ready 5th June 2011

ABSTRACT

All clinicians should be fully aware of the recent trends in their speciality to enable them to provide effective and successful treatment to their patients. One vital aspect of the treatment is that the clinician should constantly update his knowledge on the drugs being administered during the course of treatment and their interactions. The purpose of this article is to review the current pharmacological agents being used in Prosthodontics along with their interactions and indications. The paper mainly focuses on Therapeutic drugs and drugs that aid in prosthodontics treatment. Therapeutic drugs include local anesthetics, antiseptics, steroids, analgesics, antimicrobials, antifungals, antianxity drugs, centrally acting muscle relaxants. Drugs that aid in prosthodontics treatment include astringents, vasoconstrictors, hemostatic agents, sialogogues, anti-sialogogues, denture cleansers, gum paints, denture cleansers, denture adhesives, ORAL protective agents and demulcents. An odontologist should have sound knowledge of the benefits and drawbacks of all these agents. This will enable the clinician to provide a safe and predictable treatment to the patients.

Keywords: Pharmacotherapeutics; Drugs; Dentistry;

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British Journal of Pharmaceutical Research, 1(3): 66-87, 2011

1. INTRODUCTION

Rapid progress in dental pharmacotherapeutics requires that clinicians constantly update their knowledge of new drugs, drug interactions and useful therapeutic trends. The pharmacological agents aid in rapid healing and repair of the damaged tissues, relieve patients of pain and bring back the tissues to the healthy state. These drugs play a useful role in prosthodontics in the treatment of ulcerations, inflammations, xerostomia and bleeding during gingival retraction. They also help in reducing dentinal hypersensitivity during vital tooth preparation and increasing the gingival resistance against infections.

These pharmacological agents can be classified as:-

I. Therapeutic drugs.
II. Drugs that aid in prosthodontics treatment.

2. THERAPEUTIC DRUGS

2.1 Local Anesthetics

Local Anesthetics (LA) are the drugs which upon topical application or local injection cause reversible loss of sensory perception, especially of pain, in a restricted area of the body. These drugs act by excessive stimulation followed by depression (Bennett, 1984a). To work efficiently, the dental local anesthetics should have some requirements (Haas, 2002) such as:

- High intrinsic activity, which ensures complete anesthesia for all dental treatment
- Rapid onset
- Adequate duration of anesthesia (30 to 60 min for standard dental treatment)
- Low systemic toxicity
- High efficacy-toxicity ratio
- Low overall incidence of serious adverse effects

Chemically local anesthetics are classified as either Esters or Amide types. The ester based agents Procaine and Cocaine are no longer widely used as dental anesthetics due to their unwanted side effects. The commonly used injectable dental local anesthetics are explained in table 1. Anesthetic preparations for dental use differ from those for nondental use. The concentration of local anesthetics for dental use is higher, because the volume which can be injected into the oral mucosa is limited. Local anesthetics cause some degree of vasodilation, therefore, vasoconstrictor agents can be added to local anesthetic solutions to antagonize LA action, reduce bleeding at surgical site, diminish toxicity and prolong the duration of anesthesia (Table 1.1). An acidic carrier solution is added to the LA cartridge to maintain the pH of the solution. Apart from this the dental cartridge also contains a reducing agent Metabisulfite that prevents oxidation of the vasoconstrictor and Thymol that acts as a fungicide (Bahl, 2004).

Local anesthetics containing vasoconstrictor agents are to be used with caution in patients with pheochromocytoma, uncontrolled or unstable angina, cardiac arrhythmias, congestive heart failure, hyperthyroidism, or diabetes. Recommended maximum dosage of epinephrine for a healthy individual is 0.2 mg, while 0.04 mg for a patient with clinically significant cardiovascular disease. If 1:100,000 concentration of epinephrine is considered then the

amount of Lignocaine administered is 20 ml in healthy individual (Bennett, 1984b) and 4 ml in patients with cardiovascular diseases (Bennett, 1984c).

For short dental procedures a short or medium acting local anesthetic likes 2% Lidocaine+1:100,000 Epinephrine is used, whereas for long dental procedures such as implants one can use 0.5% Bupivacaine+1:200,000 Epinephrine (Bennett, 1984d). Along with these anesthetic agents, Articaine has also been widely used and it has been seen that, soft tissue anesthesia and pain experience after 4% Articaine with 1:100,000 Adrenaline, and 2% Lignocaine with 1:100,000 Adrenaline are similar (Oliveira et al., 2001). Occasionally, these local anesthetic agents may lead to local and systemic side effects, if not used carefully. The local adverse effects can be in the form of hematoma, spread of infection, temporary/permanent nerve damage (Chen, 1998), while systemic reactions fall into four categories: toxic (drug overdose, rapid absorption, intravascular injection), psychogenic, idiosyncratic, or allergic (Malamed, 1990). Theamide classes of local anesthetics are significantly less allergenic than the ester type. If allergic reactions occur, the immediate treatment is intravenous injection of 0.01 ml per kilogram body weight adrenaline, supplemented by antihistamine agents such as 10 to 20 mg chorpheniramine, or 50 mg hydroxyzine or promethazine hydrochloride (Ball, 1999). Although, allergy to lignocaine is known to be extremely rare, it continues to be suggested as a cause when adverse reactions to dental injections occur. In fact, the overwhelming majority of adverse reactions to local anesthetics is psychogenic in nature and related to fear. A smaller proportion of adverse responses can beattributed to intravascular injections that are avoidable if injections are administered carefullyand with previous suction (Rood, 2000). Apart from these injectable agents, certain topical anesthetics (Table 2) are used in the oral cavity to provide pain relief at needle insertion site and over ulcerations. Topical anesthetic agents can also provide some form of relief in patients exhibiting gagging during the impression procedure. Glycerine, lanolin, petrolatum, mineral oil, sodium carboxymethylcellulose, propylene glycol and polyethylene glycol are used as vehicles for topical anesthetics (Adriani and Zepernick, 1964).

2.2 Antiseptics

Antiseptics are drugs that are applied on the body surfaces to prevent infection by killing or inhibiting the growth of pathogenic bacteria either by oxidation of bacterial protoplasm or denaturation of bacterial proteins including enzymes (Tripathi, 2008a). Amongst the various types of antiseptics available, chlorhexidine a biguanide, is one of the most commonly used. It is found to be more effective against Gram positive micro-organisms, while less effective against Gram-negative micro-organisms, fungi, and ineffective against spores and viruses. Therefore, mouth rinses containing chlorhexidine are widely prescribed in patients with persistent areas of oral inflammation (Newman et al., 2006). Daily oral irrigation with 0.06 to 0.12% chlorhexidine has been shown to be an effective method for the treatment of chronic gingivitis and apthous ulcers (Brownstein et al., 1990). Chlorhexidinedigluconate, at concentrations of 0.12%, binds to hard tissue, soft tissue and salivary protein of oral cavity and then releases slowly, thereby reducing the formation of plaque and inflammation (Yankell et al., 1982). The patient suffering from traumatic ulcer and inflammation after denture insertion is asked to swish 10 ml of chlorhexidine mouthwash for 1 minute that will facilitate healing. Commonly available chlorhexidine containing mouthwashes include Peridex, Periochip, Perichlor, Corsodyl and Periogard oral rinse. Recently, alcohol free dentyl pH mouthwash has been introduced which has a distinctive working action.

British Journal of Pharmaceutical Research, 1(3): 66-87, 2011

Table 1. Injectable Local Anaesthetic agents used in Dentistry

Parameters	Anaesthetic agents				
	Lignocaine	Articaine	Bupivacaine	Prilocaine	Mepivacaine
Concentration	2-3%	4%	0.25-0.5%	3-4%	2-3%
Vasoconstrictor	Epinephrine 1:50,000-1:100,000	Epinephrine 1:100,000-1:200,000 or without	Without epinephrine	Felypressin 1:1,850,000	Epinephrine 1:66,000 -1:100,000 or without
Chemical class	Amide	Amide with Ester side chain	Amide	Amide	Amide
Onset	Rapid	Rapid	Slow	Slow	Rapid
Duration (with Epinephrine)	120-240 minutes	140-270 minutes	4-8 hours	90-360 minutes	120-180 minutes
Maximum dose	4.5-7 mg/kg	4-7 mg/kg	2.5-3 mg/kg	5-7.5mg/kg	5-7mg/kg
Brand name	Xylocitin/Xylestesin	Ubistesin/Ultracain /Septocaine	Carbostesin/ Marcaine	Xylonest/ Citanest	Scandonest/Mepivastesin /Carbocaine

Table 1.1. Recommended dosage of L.A.

	With vasoconstrictor	Without vasoconstrictor
Recommended dosage of L.A. (Bernett, 1984)	500mg (6.6 mg/kg body weight)	300 mg (4.4 mg/kg body weight)
Maximum syringes* administered in healthy patients	12.5 syringes	7.5 syringes

** One Syringe contains 2 ml of solution.*
(Each 2 ml contains 40 mg of Lignocaine and 0.02 mg of epinephrine)

This advanced formula consists of two phases, a water-based phase incorporating the antibacterial agent Cetylpyridinium Chloride (CPC), and an oil-based with natural essential oils that removes an adherent bacterial layer from a solid surface and exhibits a continuing inhibitory effect on bacterial activity (New addition to alcohol free mouthwash range, 2009).

Table 2. Topical local anesthetic agents

Parameters	Anaesthetic agents			
	Benzocaine	**Dyclonine**	**Lidocaine**	**Tetracaine**
Concentration	6-20%	0.5-1%	2-5%	0.2-2%
Available as	Liquid, Spray, Ointment, gel,	Solution	Gel, ointment Liquid, Solution, 10% spray	Liquid, Spray, Ointment
Chemical class	Ester	Ketone	Amide	Ester
Duration	30-60 minutes	<60 minutes	30-60 minutes	30-60 minutes
Max dose	5000mg	300 mg	200mg	20mg
Brand name	Anbesol Benzodent Gingicaine Topicale	Dyclone	Xylocaine Alphacaine Octocaine Dologel	Pontocaine Supracaine Cetacaine

2.3 Steroids

Steroids play a role in the modulation of the inflammatory reaction by inhibitory activity affecting the production of mRNA and thus protein synthesis. Application of topical steroid preparations provides temporary relief of symptoms associated with inflammation and ulcerated lesions in the oral cavity such as recurrent apthous stomatitis. These topical ointments include Triamcinolone acetonide 0.1%, Kenalog in Orabase; hydrocortisone acetate 1% and Betamethasone dipropionate 0.05%.Topical use of steroids is usually well tolerated but some patients may develop a secondary erythematous candidosis or pseudomembranous candidosis (thrush) if predisposing conditions like xerostomia, systemic and/or topical use of antibiotics, corticosteroid asthma inhalants, prostheses and cigarette smoking are present in them. Even though clinical experience and laboratory studies have shown systemic absorption of steroids to be insignificant through the oral mucosa but caution should be exercised when used in patients with diabetes, hypertension, tuberculosis and those with extensive area of coverage and unmonitored usage (Savage and McCullough, 2005).

2.4 Analgesics

Analgesic agents are used for the management of pain and can be divided into the Nonopioid (non-narcotic), Acetaminophen (Paracetamol) and the Opioid (narcotic). An important difference between the opioids and the nonopioid analgesic agents is their mechanism of action. The action of the nonopioid analgesic agents is related to their ability to inhibit prostaglandin synthesis at the peripheral nerve endings whereas the opioids affect the amount of pain by depressing the central nervous system.

British Journal of Pharmaceutical Research, 1(3): 66-87, 2011

2.4.1 Non steroidal anti-inflammatory Drugs (NSAIDs')

The NSAIDs constitute a heterogeneous group of drugs with clinically important analgesic, antipyretic and anti-inflammatory properties that rank intermediately between corticoids with anti-inflammatory properties on one hand, and major analgesics – opioids on the other (Poveda-Roda et al., 2007).These agents differ from opioid analgesics in the following ways: (1) there is a ceiling effect to the analgesia; (2) they do not product tolerance or physical dependence; (3) they are antipyretic; and (4) they possess both anti-inflammatory as well as analgesic properties (Yagiela et al., 2004a). Nonopioids are most effective in treating postprocedural pain when given before the procedure (or immediately following a short procedure), thus preventing the synthesis of prostaglandins that quickly follow the surgical insult. Table 3 lists the currently available NSAIDs.

Mechanism of action of NSAIDs

Physical, chemical or mechanical stimuli in the form of tissue damage, hypoxia, immune processes, etc. induce arachidonic acid release and metabolization. NSAIDs inhibit cyclooxygenase (COX) – the enzyme responsible for the transformation of arachidonic acid into prostaglandins and thromboxanes, which are substances generically referred to as eicosanoids. These resulting metabolites (prostaglandins and thromboxanes) exert potent vasodilating action, resulting in increased vascular permeability, with the extravasation of fluids and white blood cells therby contributing to inflammation. Consequently, the inhibition of cyclooxygenase synthesis exerts a clear anti-inflammatory effect (Poveda-Roda et al., 2007).Out of the two forms (isoenzymes) of cyclooxygenase namely cyclooxygenase-1 (COX-1) and cyclooxygenase-2 (COX-2) the latter COX-2 appears to be more involved with synthesis of prostaglandins at sites of inflammation, whereas COX-1 is more involved at sites where adverse effects of NSAIDs are expressed, such as the gastrointestinal tract. Therefore NSAIDs that have more selective inhibitory activity on COX-2 as opposed to COX-1 would be expected to have a more favorable therapeutic index (Waldman et al., 1982). Celecoxib, Rofecoxib and Parecoxib are drugs showing selective COX-2 inhibitory action but these should be avoided in patients with moderate to severe hepatic damage. Potential adverse effects of NSAIDs include peptic ulcer disease, gastrointestinal (GI) bleeding, GI perforation, impaired renal function and inhibition of platelet function. These side effects are more pronounced in drugs showing COX-1 inhibitory activity. Salicylates should be avoided in patients suffering from Ulcers, Asthma, Diabetes, Gout, Influenza and hypercoagulation states. Asprin and related salicylates are contraindicated for treatment in children and teenagers with viral infections, as it has been associated with hepatotoxicity and encephalopathy (Reye's syndrome) (Waldman et al., 1982). Ibuprofen, naproxen sodium, ketoprofen and asprin are currently approved by the food and drug administration for over the counter (OTC) use. These OTC drugs should not be used consecutively for over 10 days for pain and 3 days for fever (Yagiela et al., 2004b). A 200 to 800 mg dose of ibuprofen should be considered as the first choice for management of acute inflammatory pain (Hargreaves and Abbott, 2005).

British Journal of Pharmaceutical Research, 1(3): 66-87, 2011

Table 3. Nonsteroidal anti-inflammatory drugs

Group	Generic name	Trade name	Maximum adult dose (mg)	Dosing interval (hours)	Dosing form
Salicylic acid derivatives	Asprin	-	325-650	4	Tablets
Aryl-Acetic acid derivatives	Diclofenac	Voveran/Diclonac/ Movonac	50	8	Tablets/Suppositories/ Injection
	Aceclofenac	Aceclo/Dolokind			
Oxicams	Piroxicam	Dolonex/Pirox Piricam	40 on first day/20 on following days	12-24	Tablets/ Suppositories
	Meloxicam	Meflam Mel-OD	7.5-15		
	Lornoxicam				
Propionic acid derivatives	Ibuprofen/Ketoprofen/Flurbiprofen/ Fenoprofen/Naproxen/Oxaprozin		400/50/50/200/250/ 600-1200	4-6/6/6/4-6/6-8/24	Tablets/ Suppositories
Anthranilicacid (Fenamates)	Mefenamic acid/ Meclofenamate	Medol/Meftal/ Ponstan	250	6	Capsule/ Tablet/ Suspension
Coxibs	Celecoxib	Celact/Revibra	200	12-24	Capsules
	Etoricoxib	Etody/Etoxib	120		Tablets
	Parecoxib	Revaldo/Valto	40		Solution for injection
Pyrazolones	MetamizolPhenylbutazone Oxyphenbutazone	Analgin	500-1500		Capsules/Solution for injection/Suppositorie/ Sachets
Indole	Indomethacin	Indicin/Indoflam/ Indocap/Recticin	200-400	6-8	Capsules/ Suppository
	Etodolac				
Pyrrolo-pyrrole derivative	Ketorolac	Ketorol/Zorovon/ Torolac	10	4-6	Tablets/Solution for injection

British Journal of Pharmaceutical Research, 1(3): 66-87, 2011

2.4.2 Acetaminophen (Paracetamol)

It has analgesic and anti-pyretic effects, and it is a weak inhibitor of the cyclo-oxygenase sub-groups COX-1 and COX-2. At therapeutic doses it does not inhibit prostaglandin in the peripheral tissues so there is very little, if any, anti-inflammatory action. It is therefore not classified as an NSAID (Felpel, 1997).Tolerance and dependence have not been reported, and Paracetamol does not cause the same gastric irritation or the other complications associated with aspirin and other NSAIDs (Seymour et al., 1999).

The usual recommended adult dose of Paracetamol is 500-1000mg every four to six hours (up to a maximum of 4000mg per day) (Therapeutic guidelines, 2002).

2.4.3 Opioid Analgesics

Opioid analgesics used in dentistry for oral administration are Codeine, Hydrocodone, Oxycodone and Pentazocaine whereas Morphine, Meperidine and Fentanyl are used parenterally (Table 4). Opioids are added to nonopioids to manage pain that is moderate to severe or that does not respond to nonopioids alone. Opioids differ from the nonopioids in that they have no ceiling effect. The only dosing limitation is based on side effects (Felpel, 1997).

Mechanism of action of Opioids

Opioid-induced analgesia results from agonist action at one or more of opiate receptors namely mu (μ), kappa (κ), delta (δ), and sigma (σ) at the level of the brain and spinal cord, whereas side effects result from their activation at both central and peripheral sites. Morphine and Codeine, produce analgesia and euphoria by an agonist action at μ_1-receptors and side effects of respiratory depression and constipation by an agonist action at μ_2-receptors. Opioids, which are agonists at some receptors and antagonists at others, are called "mixed" agents or partial agonists. Pentazocine, for example, causes analgesia by an agonist action at κ-receptors and dysphoria by an agonist action at σ receptors. The third class of opioids is antagonists at opioid receptors and is therefore primarily used to treatopioid overdose (Felpel, 1997). Repeated use of opioids for control of pain can lead to analgesic tolerance (loss of analgesic effect), as well as physical and sometimes psychologic dependence. Their undesirable effects, include respiratory depression, urinary retention, sedation, nausea and vomiting, and constipation. Coadministration of Opioids with Tricyclic antidepressants and Phenothiazines is known to produce additive CNS depression and orthostatic hypotension (Yagiela et al., 2004c). Meperidine a synthetic opioid, can cause a life-threatening drug interaction with Monoamine oxidase inhibitors and in contrast to other opioids, its overdose of causes CNS stimulation.

2.4.4 Combination drug therapy

The goal of combining analgesics with different mechanisms of action is to use lower doses of the component drugs, thereby improving analgesia without increasing adverse effects (Mehlisch, 2002). Patients with acute dental pain are best treated with NSAIDs or acetaminophen as the primary analgesic and the addition of a narcotic should be reserved for situations when additional analgesia is required. Opioid and acetaminophen combination studies show that a combination is better than opioids or acetaminophen alone (Moore et al., 1997). Opioids such as codeine, hydrocodone and oxycodone combined with ibuprofen are superior to manage acute dental pain than ibuprofen alone (Po and Zhang, 1998). The

analgesic properties of aspirin, acetaminophen and ibuprofen have been seen to increase when combined with 65 to 100 mg caffeine. Table 5 lists the drugs available as a combination therapy for use in Dentistry.

Table 4. Opioid analgesics

Group	Generic name	Trade name	Therapeutic dose (mg)	Duration of action (hr)	Route of administration
Agonist analgesics	Alfentanil	Alfenta	0.5-2	0.5	Intravenous
	Codeine	-	30-60	4-6	Oral
	Fentanyl	Sublimaze	0.05-0.1	1-1.5	Intramuscular
			0.05-0.1	0.5-1	Intravenous
	Hydrocodone	Dicodid	5-10	4-6	Oral
	Levorphanol	Levodromoron	2-3	4-5	Subcutaneous Oral
	Meperidine	Demerol	50-100	2-4	Intramuscular Oral
	Methadone	Dolophine	2.5-10	3-5	Intramuscular Subcutaneous
			5-15	4-6	Oral
	Morphine	-	10-15	4-5	Intramuscular Subcutaneous
			20-60	3-5	Oral
	Oxycodone	In percodan	5-10	4-5	Oral
	Oxymorphone	Numorphan	1-1.5	4-6	Intramuscular
	Propoxyphene	Darvon	32-65	4-6	Oral
Agonist-Antagonist	Buprenorphine	Buprenex	0.4-0.8	6-8	Intramuscular Sublingual
	Butorphanol	Stadol	1-4/0.5-2	3-4/2-4	Intramuscular
			1-2	3-4	Intravenous Nasal
	Dezocine	Delgan	5-20	3-6	Intramuscular
			2.5-10	2-4	Intravenous
	Nalbuphine	Nubain	10	3-6	Intravenous Intramuscular Subcutaneous
	Pentazocine	Talwin	30	3-4	Intramuscular
		Talwin NX	50	3-4	Oral
Antagonist	Naloxone	Narcan	0.4-2	1-2	Intravenous
	Naltr	Trexan	25	1-4	Oral
Others	Tramadol	Ultram	50	5-6	Oral

2.5 Antimicrobials

Antibiotics are chemicals virtually always derived naturally with the exception of ulfonamides, fluoroquinolones and oxazolidinones. These drugs act on the microorganisms to effect their viability hence they can be either bactericidal (inducing cell death) or bacteriostatic (preventing cell growth or replication) (Yagiela et al., 2004d). Antibiotics with activity against a wide range of disease-causing bacteria are termed as broad-spectrum antibiotics. It also means that it acts against both Gram-positive and Gram-negative bacteria. This is in contrast to a narrow-spectrum antibiotic which is effective against only specific families of bacteria (Figure 1). Table 6 lists the various antimicrobial agents available for use. Of these,

British Journal of Pharmaceutical Research, 1(3): 66-87, 2011

tetracyclines and clindamycin are accepted by the Council on Dental therapeutics, American Dental Association. Other antibiotics appropriate for use in Dentistry include penicillin, erythromycin, cephalosporins and bacitracin (Felpel, 1997). Oral infections are usually caused by aerobic gram-positive cocci (*Staphylococcus aureus*) and anaerobic microorganisms (Peptostreptococcus) and the use of antibiotics in dentistry is to either treat these or as a prophylaxis to prevent bacterial endocarditis that is caused by α hemolytic streptococci.

Most acute oral infections respond well to one of the oral penicillin preparations. However Penicillin can cause few adverse side effects, and allergic reactions. A true allergic reaction usually manifests as an irritating rash. Anaphylactoid reactions though rare, occur in susceptible patients within 30 seconds of an intramuscular injection. Signs and symptoms of anaphylaxis include oral paresthesia, cold hands and feet, bronchospasm and wheezing, circulatory collapse, and unconsciousness.

Table 5. Combination analgesics used in dentistry

Trade name	Contents	Amount (mg)
Anacin	Asprin	400
	Caffeine	32
Empirin	Asprin	325
	Codeine	15/30/60
Tylenol	Acetaminophen	300
	Codeine	15/30/60
Vicodin	Acetaminophen	660/750
	Hydrocodone	10/7.5
Percodan	Asprin	325
	Oxycodone	2.44/4.88
Percocet	Acetaminophen	325/500/650
	Oxycodone	5/7.5/10
Talwin	Asprin	325
	Pentazocaine	12.5
Talacen	Acetaminophen	650
	Pentazocaine	25
Ultracet	Acetaminophen	325
	Tramadol	37.5
Synalgos	Asprin	356.4
	Caffeine	30
	Dihydrocodeine	16
Vicoprofin	Ibuprofen	200
	Hydrocodone	7.5
Combiflam/Renofen Answell	Acetaminophen	325
	Ibuprofen	400

British Journal of Pharmaceutical Research, 1(3): 66-87, 2011

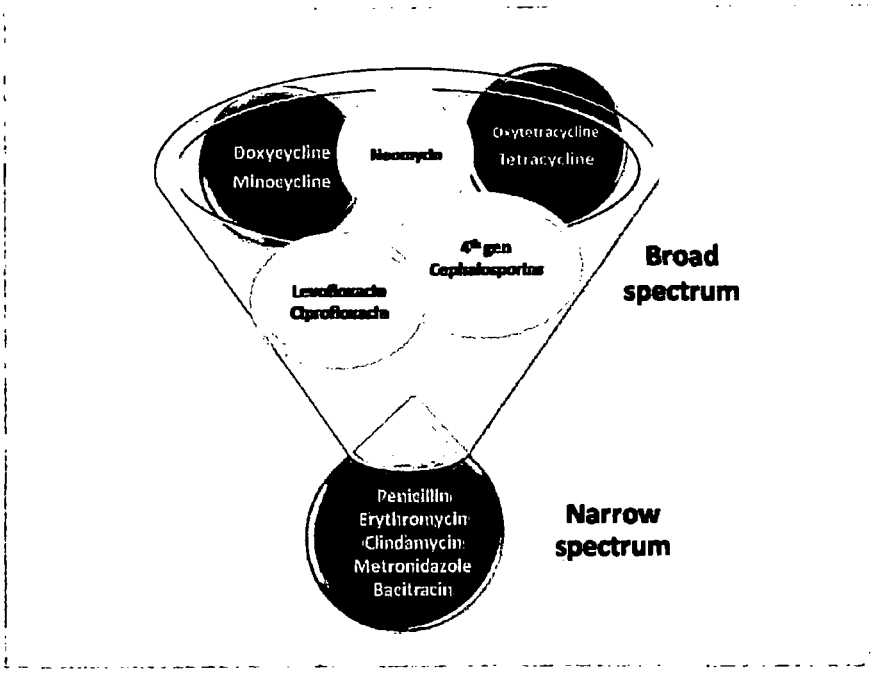

Fig. 1. Spectrum of activity of antibiotics

Alternatives to penicillin include Erythromycin, Cephalosporins, Clindamycin, and Tetracycline but Cephalosporins should not be used in a person with a history of anaphylaxis, angioedema or urticaria with penicillins or ampicillin. Erythromycin estolate and Erythromycin ethylsuccinate are contraindicated in the presence of liver dysfunction as they can cause cholestatic hepatitis. The use of Tetracyclines should be avoided during pregnancy and in children below 8 years because permanent staining of deciduous and permanent teeth and retardation of bone growth may occur. Other adverse effects include gastrointestinal upset, hepatotoxicity, nephrotoxicity, photosensitivity and impaired calcium absorption. Similarly, quinolones should be avoided in children, pregnant or nursing women, and in epileptics (Felpel, 1997). Antibiotic prophylaxis is recommended for dental procedure in patients with prosthetic cardiac valve, previous infective endocarditis, cardiac transplantation recipients who develop cardiac valvulopathyand during the first six months following any procedure to treat congenital heart disease (Prevention of infectiveendocarditis, 2007). Antibiotic coverage for invasive dental procedures is recommended in patients with poorly controlled or uncontrolled diabetes, infective endocarditis, 2007) but not in those having orthopedic prosthesis placed over 2 years prior to the dental procedure. Advisory statement, (2003) lists the dental procedures requiring antibiotic prophylaxiswhile. Figure 2 shows the current regimen of prophylactic antibiotics to be administered (Prevention of infective endocarditis, 2007; Tong and Rothwell, 2000). Prophylactic use of antibiotics in conjunction with dental treatment should be avoided unless there is a clearindication since unwarranted overuse of antibiotics can lead to development of resistant strains of microorganisms (Barker, 1999).

British Journal of Pharmaceutical Research, 1(3): 66-87, 2011

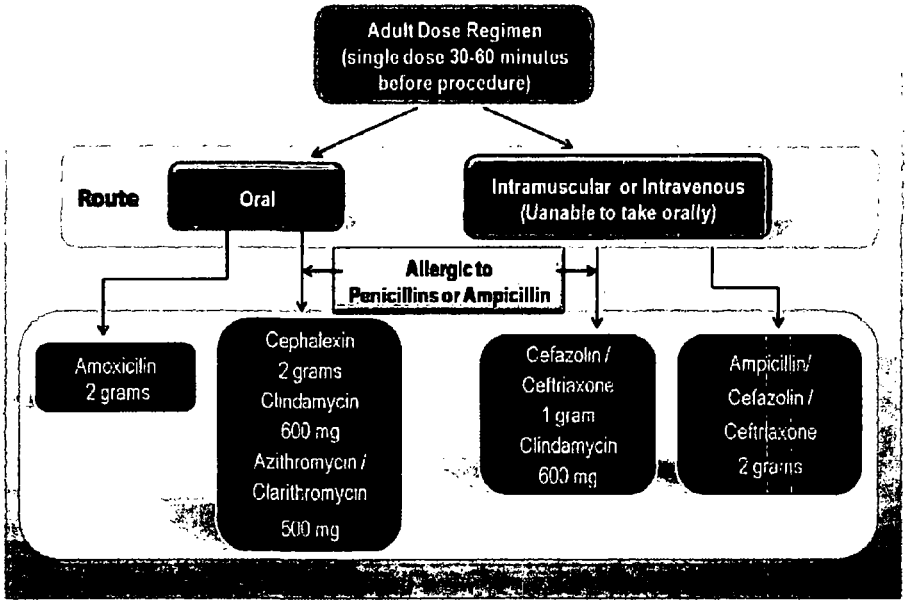

Fig. 2. Antibiotic prophylactic regimen for dental procedures in high risk patients

2.6 Antifungals

Oral moniliasis (thrush) is a fungal infection of the oral cavity caused by Candida albicans. C albicans can also colonize prosthetic devices like dentures. Atleast 2 weeks of therapy are required for treating oral candidiasis. Nystatin (Mycostatin) is the most common drug used in dentistry and it can have a fungistatic or fungicidal effect depending on its dose. A 2-3 ml (100,000 units/ ml) suspension or 1-2 lozenges (200,000 units each) may be used four to five times per day. Colonized dentures can be treated by soaking them in a nystatin solution or applying an ointment (100,000/g) of nystatin to the tissue surface. Clotrimazole (Mycelex), a fungistatic can be used in a dose of 10 mg troches dissolved in the mouth five times a day. Since Nystatin and Clotrimazole are not appreciably absorbed from the gastrointestinal tract, the topical route is preferred for their administration. Oral Fluconazole (Diflucan) in a dose of 50 to 100 mg/day and Itraconazole (Sporanox) 200mg/day are broad-spectrum antifungal agents that are effective in treating oropharyngeal and esophageal candidiasis (Yagiela et al., 2004e).

British Journal of Pharmaceutical Research, 1(3): 66-87, 2011

Table 6. List of Antimicrobial drugs

Mechanism of action	Class	Generic name	Trade name	Dose(mg)/ Interval (hours)	Effect
Inhibition of cell wall synthesis	Penicillin	Ampicillin	Penicillin	250-500/6	Bacteriocidal
		Amoxicillin	Amoxylin	250-500/8	Bacteriocidal
	Beta-lactamase inhibitors	Clavulanic acid	Augmentin	Amoxicillin 250+ Clavulanic acid 125/8	Bacteriocidal
	Cephalo-sporins	Cefadroxil	Duricef	500/12	Bacteriocidal
		Cephelexin	Keflex	250-500/6	Bacteriocidal
		Cephradine	Velosef	250-500/6	Bacteriostatic
		Cefaclor	Keflor	250-1000/8	Bacteriocidal
		Cefixime	Topcef	200/12	Bacteriocidal
Alteration of cell membrane integrity	Polypeptide	Polymyxin B	Aerosporin	Topical	Bacteriostatic
		Neomycin	Mycifradin	Topical	Bacteriostatic
		Bacitracin	Baciguent	Topical	Bacteriostatic
Inhibition of ribosomal protein synthesis	Macrolide	Erythromycin stearate	Erythrocin	250-500/ 6	Bacteriostatic
		Erythromycin estolate	Althrocin	250-500/6	Bacteriostatic
		Erythromycin ethylsuccinate	Erynate	400/6	Bacteriostatic
		Azithromycin	Azithral	500/24	Bacteriostatic
		Roxithromycin	Roxid	150-300/12	Bacteriostatic
	Tetracycline	Oxytetra-cycline	Terramycin	250-500/6-12	Bacteriostatic
		Minocycline	Minocin	100/12	Bacteriocidal
		Doxycycline	Vibramycin	100/12-24	Bacteriocidal
		Tetracycline	Achromycin	250-500/12	Bacteriocidal
	Lincosamide	Clindamycin	Cleocin	150-450/6	Bacteriostatic
Inhibition of nucleic acid synthesis	Nitroimidazole	Metronidazole	Flagyl	400/8	Bacteriocidal
	Fluoro-quinolones	Ciprofloxacin	Ciplox	250-500/12	Bacteriocidal
		Norfloxacin	Norflox	400/12	Bacteriocidal
		Levofloxacin	Tavanic	500/24	Bacteriocidal
Inhibition of folic acid synthesis	Sulphonamides	Sulfadizine	Sulfadizine	500/6	Bacteriostatic
	Cotrimoxazole	Trimethoprim+ sulfa-methoxazole	Septran	80-160+400-800/12	Bacteriocidal

British Journal of Pharmaceutical Research, 1(3): 66-87, 2011

2.7 Antianxiety Drugs

Antianxiety agents are used in clinical dentistry for premedication in an apprehensive patients pending operative procedure like Implant surgery. Antianxiety agents are known to summate with anesthetics, opioid analgesics, antidepressants, sedative-hypnotics and alcohol to cause excessive CNS depression (Yagiela et al, 2004f), hence should be prescribed with caution. Benzodiazepines such as Diazepam (Valium), Lorazepam (Ativan) and Alprazolam (Xanax) and Antihistamines such as Hydroxyzine (Vistaril) and Promethazine (Phenergan) are the preferred anxiolytics for use in dentistry. They should preferably have a rapid onset and a short duration of action. Diazepam (2-10mg), Lorazepam (2-6 mg) and Alprazolam (0.25-1.5mg) have a 12-24 hour duration of action whereas antihistamines in a dose of 25-100mg have a 4-6 hour duration of action. The use of Benzodiazepines is contraindicated in patients with psychosis, acute narrow-angle glaucoma, or liver disease.

2.8 Centrally Acting Muscle Relaxants

These are drugs that reduce skeletal muscle tone without altering consciousness. They are used in chronic spastic conditions and acute muscle spasms of the temporomandibular joint. Table 8 lists the various drugs used alone or in combination with analgesics as muscle relaxants in Dentistry. These drugs usually cause slight sedation hence caution is to be exercised regarding operation of motor vehicles. These drugs have a potential for abuse and dependence hence prolonged administration and abrupt stoppage is to be avoided (Stanko, 1990).

Table 7. Dental procedures requiring antibiotic prophylaxis

Prophylaxis recommended	Prophylaxis not recommended
Dental extractions	Postoperative suture removal
Subgingival placement of antibiotic fibers or strips	Making impressions or Taking radiographs
Intraligamentary local anesthetic injection	Local anesthetic injections
Initial placement of orthodontic bands	Placement and adjustment of removable Prosthesis and Orthodontic appliance
Prophylactic cleaning of teeth or implants with anticipated bleeding	Restorative procedures (with/without retraction cord)
Endodontic instrumentation or surgery beyond the tooth apex	Endodontic procedures, post placement and buildup
Dental Implant placement, reimplantation of teeth	Placement of rubber dams
Periodontal procedures including surgery, scaling, root planing and probing	Bleeding from trauma to lips or mucosa
	Shedding of deciduous teeth

British Journal of Pharmaceutical Research, 1(3): 66-87, 2011

Table 8. Centrally acting muscle relaxants

Generic name	Trade name	Content	Dose (mg)	Dosing interval (hours)
Casiprodol	Carisoma	Casiprodol	350	6-8
	Somaflam	Casiprodol	175	6-8
		Ibuprofen	400	
Chlorzoxazone	Mobizox	Chlorzoxazone	500	
		Diclofenac	50	8
		Paracetamol	500	
	Parafon	Chlorzoxazone	250	8
		Paracetamol	300	
Methocarbamol	Flexinol	Methocarbamol	400	6
		Paracetamol	325	
	Robiflam	Methocarbamol	750	8
		Ibuprofen	200	
Baclofen	Lioresal	Baclofen	10-25	8-12
Dantrolene	Dantrium	Dantrolene	25	4-6
Diazepam	Valium	Diazepam	2-10	12

3. DRUGS THAT AID IN PROSTHODONTIC TREATMENT

3.1 Astringents

Astringents are the substances that precipitate proteins, but do not penetrate cells, thus affecting the superficial layer of mucosa only. They toughen the surface by making it mechanically stronger and decrease exudation. Astringents may be administered by retraction cords already impregnated with the agent or by applying them to cotton pellets. Some of the examples are alum, aluminum chloride, zinc chloride (8-20%) and tannic acid (Table 9). Styptics are the concentrated form of astringents. They cause superficial and local coagulation. Some of the examples are ferric chloride and ferric sulfate. Aluminum chloride and Ferrous sulfate are preferred astringents amongst prosthodontists because they cause minimum tissue damage (Rosenstiel, 2006a).

3.2 Vasoconstrictors

Vasoconstrictors are used in dentistry either as components of the local anesthetic syringe or for application with gingival retraction cords. These agents do not produce coagulation of blood but act by constricting blood vessels. Examples of vasoconstrictors accepted by the Council on Dental Therapeutics include Epinephrine (1:200,000/1:100,000/1:50,000), Levonordefrine (1:20,000) and Norepinephrine (1:30,000). Epinephrine is the vasoconstrictor of choice for use in dentistry (Felpel, 1999). It restricts the blood supply to the area by decreasing the size of blood capillaries thereby decreasing hemorrhage and fluid seepage. It is advisable to use low concentration epinephrine (0.01%) for gingival retraction due to its superior effect in keeping the gingival sulcus relatively dry during the impression procedure (Csillag et al., 2007).

British Journal of Pharmaceutical Research, 1(3): 66-87, 2011

Table 9. List of Hemostatic agents

Brand name	Constituent	Action	Available as
Gel Cord/ Gel cord clear (Pascal)	25% Aluminum sulfate Gel	Biologic fluid coagulant	Cartridge-0.32g Syringe-0.75g Jar- 30g
Stat Gel FS (Pascal)	15.5% Ferric sulfate	Styptics	
Racelletcotton Pellets (Pascal)	Epinephrine	Vasoconstrictor	1.15mg and 0.55 mg pellets
Rastringent/ Retraxcotton Pellets (Pascal)	25 % Aluminum sulfate	Biologic fluid coagulant	Solution in bottle
Epidri pellet (Pascal)	Racemic epinephrine HCl	Vasoconstrictor	1.9mg pellet
Hemostatic gel (Pro-option)	20% Ferric sulfate	Styptics	Syringe
Hemostatic solution (Pro-option)	15.5% Ferric sulfate	Styptics	Syringe
Traxodent/ Hemodent (Premier dental products)	15% Aluminum chloride	Biologic fluid coagulant	Syringe
Hemostasyl gel (Kerr)	15% Aluminum chloride	Biologic fluid coagulant	Syringe
ViscoStat clear (Ultradent)	Aluminum chloride gel	Biologic fluid coagulant	1.2 ml syringe
Gingiaid (GingiPak)	8% dl epinephrine HCl	Vasoconstrictor	Syringe
Racestyptine (Septodent)	25 % aluminum chloride, oxyquinol, hydroalcoholic excipients.	Biologic fluid coagulant	Solution in bottle
Astringedent (Ultradent)	15.5% Ferric sulfate solution	Styptics	Bottle/ syringe
Astringedent X (Ultradent)	12.7% Iron Solution Containing Equivalent Ferric sulfate and Ferric Subsulfate	Styptics	Bottle/ syringe
ViscoStatWintermint (Ultradent)	20% Ferric sulfate gel	Styptics	Syringe
ViscoStat Clear (Ultradent)	20% Aluminum chloride gel	Biologic fluid coagulant	Syringe
QuickStat FS (Vista)	15.5% Ferric sulfate gel	Styptics	Syringe

3.3 Hemostatic Agents

Hemostatic agents are used in dentistry for hemorrhage control and wound protection (Mc Bee and Koerner, 2005). These are drugs which arrest more serious bleeding from cut or lacerated capillaries and arterioles.

British Journal of Pharmaceutical Research, 1(3): 66-87, 2011

Some of the examples are:

i. Thrombin- It is prepared from mammalian pro-thrombin, acts by accelerating the clotting of blood. It is available in powder form and mixed with saline. It should be applied locally and never injected.

ii. Gel Foam- It is also known as gelatin sponge and is available as a powder or porous sheet. The hemostatic properties of absorbable gelatin sponge can be improved by soaking it in a thrombin solution before application (Felpel, 1999).

Table 10. Salivary stimulants

Stimulants	Type	Example	Key ingredients
Mechanical (Masticatory) Stimulants	Sugarless gums	Biotene Eclipse Orbit Airwaves Trident, Xylifresh	Xylitol, Sorbitol, Mannnitol, Aspartame, Acesulfame K
	Sugarless tablets	Salix	Carboxymethylcellulose/ hydroxypropylmethylcellulose
Chemical Stimulants	Solutions	Mouth-Kote	Alcohol free Mucopolysaccaharide Sol with citric acid
		Optimoist	Citric acid
Electrical Stimulation		Salitron	Intra-oral electronic stimulator of saliva
Pharmacologic Stimulant	Drugs	Salagen (PilocarpineHCl)	Cholinergic agonist
		Evoxac (CevimelineHCl)	Cholinergic agonist
Oral moisturizers		Water	
	Solutions	Salivart Oralube Xero-Lube Moi stir Glandosane Aqwet	Carboxymethyl cellulose and hydroxyethyl cellulose
		Orex	Carboxymethylcellulose with flouride
	Gel	Plax Oral Balance	Water-glycerin agent Glycerate polymer

3.4 Sialogogues

Xerostomia may result from disease states (Sjogren's syndrome, rheumatoid arthritis, diabetes insipidus, pernicious anemia), from radiation, as a side effect of a wide variety of drugs, or from natural aging. Edentulous patients suffering from xerostomia may experience

difficulty in using dentures and an increased incidence of intraoral candidal infection (Felpel, 1999). Sialogogues are the agents which activate muscarinic cholinergic receptors of the parasympathetic nervous system to increase salivary flow in patients with xerostomia (Tripathi, 2008b).Various agents can be used as salivary stimulants (Table 10). All commercially available preparations have a limited duration of action, making frequent application necessary. Agents such as sugar free gum or candies and lozenges containing citric acid sorbitol, mannitol or xylitol may be recommended. According to Boucher, making a conscious effort of consuming at least eight glasses of water, juice or milk daily is the most important measure to relieve dry mouth (Zarb and Bolender, 2004a). Pilocarpine and Bethanechol have been reported as potentially effective sialogogues for xerostomic patients in a study on patients with dry mouth following cancer therapy (Gorsky et al., 2004). Carboxy methyl cellulose based artificial saliva demonstrated moderate effects in reducing dry mouth-related symptoms with more significant effects appearing in patients whose residual secretory potency was severely compromised (Oh et al., 2008).

3.5 Anti-sialogogues

These agents are used to decrease salivary secretion by cholinergic antagonist action. They decrease salivary secretion by inhibiting the action of myo-epithelial cells in the salivary glands thus producing a dry field. Methantheline and Propantheline (synthetic atropine derivatives) are few examples of anti-sialogouges, with Propantheline being 5 times more potent. Clonidine (0.2mg) an antihypertensive drug has been found to be as effective as methantheline (50 mg) in reducing salivary flow (Wilson et al., 1984). For thedesired reduction in salivary flow, the oral administration of atropine, scopolamine, or methantheline and propantheline should precede the clinical procedure by 1to 2 h, half to 1 h, or one-half an hour, respectively. Medications with anti sialogogic effect include (Rosenstiel et al., 2006b); probanthine (7.5 to 15 mg), robinul (1 to 2 mg), saltropine (0.4 mg) and antipasbentyl (10 to 20 mg). Anticholinergic drugs are contraindicated in patients with glaucoma, prostatic hypertrophy, severe gastrointestinal disorders (ulcerative colitis, obstructive disease, intestinal atony), and myasthenia gravis (Felpel, 1999).

3.6 Gum Paints

Gum paints are the combination of antiseptics and tanning agents which precipitate proteins but do not penetrate cells thereby affecting only the superficial layer making it mechanically stronger and decreases exudation. They have germicidal, fungicidal, anesthetic and healing properties. When applied, they provide a soothing, cooling and an astringent effect. All these preparations contain Choline salicylate, Tannic acid, Cetrimide, Thymol, Camphor, Cinnamon oil, Iodine and Alum (hydrated potassium aluminumsulfate). 'Zingisol' containing 2% Zinc Sulfate is used to control bleeding gums. The patient is advised to apply 3-4 drops on finger and massage 3-4 times a day. 'Sensoform' gum paint (Warren) contains tannic acid, glycerine and potassium iodide and is applied on affected area several times with the cotton applicator for the treatment of stomatitis, inflammation and bleeding gums. It also decreases sensitivity and increases gingival resistance against infections. 'Stolin' gum paint (dr. reddy's)15ml contains cetrimide 0.1 % w/v, tannic acid 2 % w/v, zinc chloride 1 % w/v. 'Sensorok' gum astringent with zinc sulfate is used for gum massage 2-3 times daily. Other commonly available brands include Gumex and Pyastringent, Payogum and Pyosan.

British Journal of Pharmaceutical Research, 1(3): 66-87, 2011

3.7 Denture Cleansers

It must be emphasized that improper care of dentures can have detrimental effects on the health of the denture supporting tissues. Maintenance of adequate denture hygiene is essential to minimize and eliminate adverse tissue reactions. It must be an integral component of post insertion patient care (Zarb and Bolender, 2004b). Following are the requirements of an ideal denture cleanser:

- Should be non toxic
- Easy to remove and harmless to the patient
- Be able to dissolve the denture deposits such as calculus
- Exhibit bacteriocidal and fungicidal effect
- Should have long shelf life and inexpensive
- Harmless to the denture base materials, denture teeth as well as soft liners

Commonly available denture cleansers are available in powder and tablet form and include:

a) Oxygenating cleansers- overnight immersion of dentures in alkaline peroxide solution is a safe and effective method.
b) Hypochlorite cleansers- immersion of the dentures in a solution of one part of 5% sodium hypochlorite in three parts of water followed by light brushing is advisable.
c) Dilute mineral acids.
d) Abrasive powders and pastes.
e) Enzyme containing minerals (proteases).

Commercially available denture cleansers include Kleenex, Stain Away, Polident, Triclean, Efferdent.

3.8 Denture Adhesives

Denture adhesives augment the same retentive mechanisms already operating when a denture is worn. They consist of keraya gum, tragacanth, sodium carboxyl methyl cellulose, polyethylene oxide, flavouring agents, antimicrobial agents and plasticizers. They enhance retention through optimizing interfacial forces by increasing the adhesive and cohesive properties and viscosity of the medium lying between the denture and the basal seat and eliminating voids between the denture base and the basal seat (Zarb and Bolender, 2004c).

They are supplied in powder and paste form. Method of application is as follows:

(1) The powder is sprinkled on the wetted denture base and after the excess powder is shaken off; the prosthesis is inserted and seated firmly.
(2) Placement of thin beads of adhesive is recommended in the incisor and molar regions in case of cream type. An anteroposterior bead should be placed along the midpalate in the maxillary unit.

Commercially available denture adhesives are Fixodent, Poligrip, Cushion grip, Rigident, SeaBond wafers, Secure, Effergrip and Staydent.

British Journal of Pharmaceutical Research, 1(3): 66-87, 2011

3.9 Oral Protective Agents

These agents are finely powdered, inert and insoluble. They afford physical protection to the mucous membrane thus are used for apthous ulcers and gingival inflammation. All these gel preparations should be applied 2-3 times daily. The Lignocaine based preparations contain Lignocaine hydrochloride, Benzalkonium and Choline salicylate. Examples are Dentogel, Dologel and Emergel. Dentasep, Dentonex-M, Maghex-M and Metrogyl DG gel are examples of metronidazole and chlorhexidine preparations. Oraguard B and Mucopain are gels containing Benzocaine as the active ingredient. Petroleum jelly is also used successfully as an oral protective agent.

3.10 Demulcents

These are inert substances which sooth the inflamed and denuded mucosa by preventing contact with air or irritants in the surrounding. They can be applied as thick colloidal and viscid solutions in water. Commonly used agents are Gum Acacia and Gum Tragacanth. These are used as suspending agents for indiffusible powders, emulsifying agents for oils and in lozenges. Glycerin (50-75%) in water acts as a popular vehicle for gum paint(Tripathi, 2008c).

4. CONCLUSION

All the pharmacological agents mentioned are used either before commencement of the treatment, during the treatment or at the post treatment duration. Judicious use of these agents yield good results and have a positive effect in the success of any prosthesis. Therefore, a prosthodontist should have sound knowledge of the benefits and drawbacks of these agents in achieving the desired results.

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Gary M. Radz, DDS

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The Key to the Perfect Impression

Gary M. Radz, DDS*

There appears to be universal agreement that far too many inadequate and unreadable impressions are being sent to dental laboratories.[1-3] This creates daily frustration for the technicians as they try to fabricate a clinically acceptable restoration with less-than-adequate information.

All too often, the dentist will blame the impression material. However, impression materials are among the most developed and reliable of all dental materials.[1] Currently, many excellent choices are available.

More often than not, the fault lies with us, the dentists. We may be overlooking essential details, such as the proper handling of the soft tissue during tooth preparation or management of the soft tissue immediately before taking the impression. If correct technique is used and appropriate attention paid to the management of the soft tissue, the chance of capturing a clinically acceptable impression is dramatically increased.

Many simple techniques and beneficial materials can be applied to help the dentist properly manage the soft tissue, thereby helping to obtain a more ideal impression.

SOFT-TISSUE MANAGEMENT DURING TOOTH PREPARATION

In an ideal world, excellent soft-tissue health would be a prerequisite for predictable impressions. Inflamed tissues will bleed more readily and exhibit increased crevicular fluid flow, rendering moisture control more difficult.[4] However, the reality of private practice does not always provide the opportunity to consistently have ideal soft-tissue health. Despite having less-than-ideal conditions, the capture of an excellent impression is still possible.

During tooth preparation, it is critical to minimize, if not eliminate, soft-tissue trauma. This trauma will create fluid flow, making it more difficult to manage the area when the time comes to take the final impression. There is general agreement that during tooth preparation, the soft tissue should be mechanically displaced using a gingival retraction cord.[2,3,5] A single cord of the appropriate size is placed to deflect the soft tissue from the path of the rotary instrument, thereby decreasing the opportunity to mistakenly touch the tissue. Inevitably, this is not possible 100% of the time, but this technique will certainly minimize the amount of trauma created during tooth preparation.

TISSUE MANAGEMENT FOR FINAL IMPRESSION

The use of a two-cord technique is a time-proven and effective way to properly deflect and control the soft tissue in order to capture the margin of the tooth preparation in its entirety.[1-7] During the tooth preparation, the clinician will leave in place the initial cord (or replace it if damaged during preparation), and then position a second cord on the first. Research has demonstrated that this second cord should remain for 4 minutes before the final impression is taken.[8] After this time span, the top cord is pulled and the final impression taken. Use of this technique consistently produces excellent impressions.

Another option is the use of a single-cord technique. This method can work well with tooth preparations that terminate supragingivally or at the tissue height. In today's age of all-ceramic restorations, we frequently find that the placement of subgingival margins is not always necessary.

With this technique, the cord used to displace the tissue during tooth preparation is kept in place (or replaced if damaged) for the final impression. Often, this technique will work very well, provided the clinician maintains control of the soft tissues and the related fluids in the area.

The placement of retraction cord is frequently uncomfortable for the patient. In areas of less-than-ideal soft-tissue health, it can lead to more bleeding. Recently, the introduction of gingival retraction pastes has provided dentists with a more comfortable and less traumatic option. These pastes are placed in the gingival sulcus and are stiff enough to physically displace the soft tissue and allow for better exposure of the preparation margin. Also, these products have aluminum chloride, which will provide for localized hemostasis.

These materials work best with preparations located at the height of the tissue. Another application that can function well is the use the retraction paste instead of placement of a second retraction cord. Virtually, this is the two-cord technique without the second cord.

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Clinical situations can arise in which the soft tissue is too bulky or too inflamed, hindering visualization of the preparation margin. In these situations, mechanical removal of the soft tissue may be indicated.

The use of electrosurgery or laser surgery provides the opportunity to remove excess soft tissue, which will enable the clinician to see where to place the margin of the final restoration. The tissue removal will also allow for exposure of the preparation margin when it is time to take the final impression.

Gingivectomies with either an electrosurge or laser can be practical ways of dealing with excessive and/or irritated soft tissue. However, the dentist needs to be aware of the concept of biological width.[3] Impinging on the biological width can lead to long-term failure of the final restoration.

FLUID MANAGEMENT FOR THE FINAL IMPRESSION

Crevicular fluids and blood can and will lead to an inaccurate final impression. The dentist must have the area controlled before attempting to take the impression. Several techniques are available for the management of the fluids.

The use of a retraction cord is the first line of defense to control fluid flow. When placed in the gingival sulcus, the retraction cord will physically block crevicular fluids from the preparation margin. In addition, retraction cords can be impregnated with epinephrine, which is an excellent hemostatic agent. It can minimize any bleeding that may be in the preparation area.

The use of electrosurgery or laser surgery is not only effective in eliminating excess soft tissue but also can be used to provide an area of hemostasis. A slight alteration in the settings of these devices can change from a "cutting" setting to a "coagulation" setting. These tools provide a predictable and quick option to control bleeding areas.

Most commonly, bleeding is managed chemically. Ferric sulfate, aluminum chloride, and epinephrine are the most common options. These materials will cause constriction of peripheral blood vessels, resulting in a transient shrinkage of the surrounding tissues.[4]

For years, ferric sulfate has been the most frequently used hemostatic and has been proven to be highly effective in stopping sulcular bleeding.[9] The only issue is its potential to leave an organic black residue on the tooth preparation.[2,4] This is an adverse effect if placing an all-ceramic restoration.

Aluminum chloride, while not quite as effective as ferric sulfate, is another popular option for controlling localized bleeding. Its benefit is that no dark residue remains on the restoration. This makes aluminum chloride the chemical of choice when the final restoration is made of an all-ceramic or indirect composite material.

Another option is epinephrine, which stops localized bleeding through vasoconstriction. While effective, the potential for systemic interactions[4] makes it the least desirable choice. However, when used in combination with a local anesthetic in a 1:50,000 concentration, it can be highly successful at controlling localized bleeding for a short period.

DIGITAL IMPRESSIONS

Digital impression devices have recently became commercially available and are proving to be very effective clinically. While providing a dramatic step in helping to create even better impressions through digital accuracy, these new tools require the clinician to continue applying precise soft-tissue management.

These devices work by capturing digital images of the preparation and surrounding area. If the device cannot "see" the preparation margin, it cannot capture it.

CONCLUSION

A bad impression is rarely caused by the material itself. If great care is not taken to manage the soft tissue during the preparation and in preparation of taking the final impression, inadequate impressions will continue to be sent to the dental laboratories. The good news is that we have many time-proven materials and techniques to help us create great impressions.

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Tissue Management, Gingival Retraction and Hemostasis

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COURSE OBJECTIVES

At the completion of this program, the participant will be able to:

- List the clinical situations where gingival retraction are beneficial in restorative dentistry
- List the different methods of gingival retraction and hemostasis
- List three different types of gingival retraction cord
- List different astringents used in dentistry for retraction and hemostasis

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Dentists, Dental Assistants and Dental Hygienists.

THE ORAL CAVITY IS A DIFFICULT AREA TO TREAT IN RESTORATIVE DENTISTRY because of the constraints of the lips, tongue and cheeks, challenges for access to visualize and manipulate instruments, as well as the position of the teeth that are being treated relative to the gingival tissues — which bleed if improperly managed. While for operative dentistry and single-tooth restorations, the use of the dental dam provides control of the field and access to tooth preparation and restoration, there are many times in restorative dentistry that use of the dental dam is precluded. There are times that caries or non-carious cervical lesions are at or below the free margin of the gingiva — as well as, for fixed prosthodontics, crown or inlay/onlay margins are at or below the free margin of the gingiva and access to them for preparation, impressioning and cementation is impossible without additional techniques to displace the gingival tissues and control gingival hemorrhage and sulcular fluids.

One of the most challenging aspects of crown and bridge is management of the gingival tissues when making an impression. Tissue management includes placing the gingival tissues away from the preparation margins so they can be impressed, combined with providing for hemostasis when the gingival tissues are susceptible to bleeding.[1,2] The rationale for tissue management is a critical aspect of impression making, whether the impression is made with a conventional impression material or by a digital impression technique so that all tooth preparation margins are captured in the impression to assure an excellent marginal fit of a laboratory fabricated restoration.[1,3] From this, the final restoration will be well adapted to the tooth preparation so that when cemented, the restoration will prevent recurrent caries, tooth sensitivity and gingival irritation.

Tissue management is also critical for placement of direct restorative materials, especially for the restoration of Class V lesions. In our practices we have seen a significant increase in Class V cervical lesions. Whether these lesions are carious (Fig. 1) or non-carious cervical lesions (Fig. 2), when these teeth need restoration, the cervical margin can be difficult to access due to both the extent of the lesion and the need for a dry, controlled field when placing the restoration — whether it be composite resin or glass ionomer.


FIG. 1

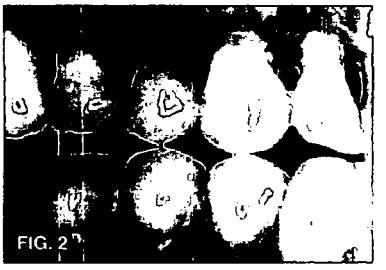


FIG. 2

FIG. 1: Class V carious lesions where gingival retraction will be necessary to prepare and restore. **Fig. 2:** Class V non-carious cervical lesions (NCCL) where gingival retraction would be useful to control the field when restoring.

Table 1
Partial listing of gingival retraction cords

NAME	TYPE	IMPREGNATED	MANUFACTURER
Fas-Tract	knitted	none	Benco
Fas-Tract	knitted	epinephrine	Benco
Crown-Pak	twisted	epinephrine	Gingi-Pak
Gel-Cord	braided	aluminum sulfate	Pascal
GingiBraid+	braided	none	DUX Dental
GingiBraid+	braided	epinephrine/alum	DUX Dental
GingiBraid+	braided	aluminum potassium sulfate	DUX Dental
GingiCord	twisted	epinephrine/alum	DUX Dental
GingiGel	braid	precoated aluminum chloride	DUX Dental
GingiKNIT	knitted	none	DUX Dental
GingiKNIT	knitted	aluminum sulfate	DUX Dental
Hemodent Cord	braided	aluminum chloride	Premier Dental
Knittrax	knitted	none	Pascal
Pascord	twisted	aluminum sulfate	Pascal
Racord	twisted	epinephrine	Pascal
Racord Two	twisted	zinc phenolsulfonate/epinephrine	Pascal
Retrax	twisted	none	Pascal
Roeko Stay-Put Retraction Cord	braided	none	Coltene/Whaledent
Sil-Trax	braided	aluminum sulfate	Pascal
Sil-Trax	braided	epinephrine/zinc phenolsulfonate	Pascal
Sil-Trax	braided	epinephrine	Pascal
Sil-Trax	braided	none	Pascal
UniBraid+	braided	aluminum potassium sulfate	DUX Dental
UniBraid+ (unit dose/precut)	braided	epinephrine	DUX Dental
UltraPak (unit dose/precut)	knitted	none	Ultradent
Z-Twist	twist	aluminum sulfate	Gingi-Pak
Z-Twist	twist	epinephrine	Gingi-Pak
Z-Twist	twist	none	Gingi-Pak

No matter what the circumstance for soft-tissue mangement for restorative dentistry, the goal for managment of gingival tissues requires that the periodontium be in a state of health. As part of any comprehensive treatment plan, especially if a restorative intervention is required and there is need for control of the gingival tissues, that the teeth be cleaned and the periodontium brought to a state of health. With this accomplished, restoration will be more easily accomplished. Management of the gingival tissues for access, visualization, maintaining a controlled field for restoration placement and cementation can be accomplished with a variety of techniques. This article will provide the clinician with an overview of the techniques available for clinical situations that are frequently encountered.

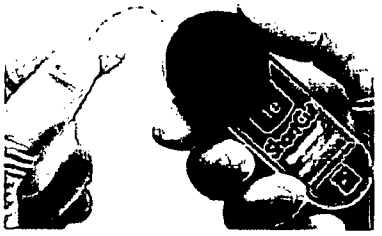
Techniques for Soft-Tissue Management, Displacement Retraction and Hemorrhage Control

Mechanical Methods

Among the first techniques developed and available to clinicians for displacement

FIG. 3

FIG. 4



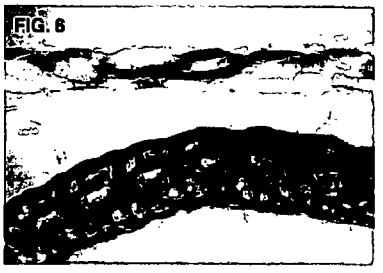


FIG. 3: Dispensing GingiBRAID+ with ShortCut (DUX Dental) click dial dispensing to length desired. **Fig. 4:** Built-in cutter on ShortCut dispenser to cut to length needed. **Fig. 5:** Placement of braided cord for retraction for a Class V carious lesion with a smooth, non-serrated cord placement instrument (Fischer UltraPak Packer, Ultradent). **Fig. 6:** Comparison of braided cord (top) and knitted cord (bottom).

of gingival tissues, especially for crown and bridge impressions, were mechanical displacement. Mechanical displacement refers to physically moving the gingival tissues aside from the tooth/tooth preparation margins to allow for visualization and access for treatment.[1, 2, 4, 5] In many cases, the materials used for gingival retraction can be used by themselves or in combination with other materials and techniques.

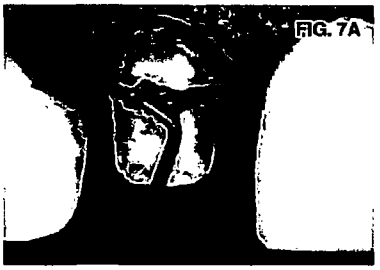
One of the earliest techniques for mechanical displacement of gingival tissues for restoration was the use of the dental dam. Specialized gingival retraction retainers (clamps), when placed, displace the gingival tissues to allow for access for tooth preparation and restoration.[6] The use of gingival retraction clamps has also been described to provide access for scaling and root planing.[7]

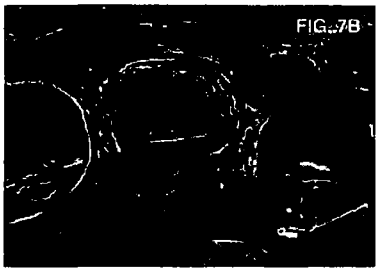
Among the most popular methods of gingival displacement is the use of gingival retraction cord.[1, 2, 4, 5, 8-10] Gingival retraction cords can be woven, braided or twisted in a variety of configurations to provide for different diameters and thicknesses (Table 1). They are typically dispensed from containers or bottles and cut to length. The cord is usually dispensed by pulling the cord from a bottle using a cotton pliers and cutting with a scissors. Hemodent Cord (Premier) has addressed this problem by dispensing its braided and twisted cords in self-cutting plastic dispensing boxes. These techniques have the risk of contamination of the retraction cord. Some recent innovations have addressed this shortcoming of cord dispensing. Unit dose dispensing of retraction cords has been introduced where the chemically treated braided cord is pre-cut and individually packaged in 2-inch lengths (Uni-Braid+, DUX Dental). Of issue is that there is the need for different lengths of cord for different clinical situations and for the various diameters of teeth. There have been no measuring tools as part of the dispensing system, so it is not uncommon to dispense too short a cord, or too long a cord, for the clinical indication. Most clinicians and their chairside dental assistant err by dispensing too long a section of retraction cord that is more difficult to manage when placing the cord into the gingival sulcus. It must then be cut intraorally to the length desired.

This shortcoming in cord dispensing and cutting has been addressed with the introduction of an all-in-one delivery system that combines convenience, efficiency and effectiveness in gingival retraction cord dispensing and cutting.[11] This system, ShortCut (DUX Dental) dispenses the braided gingival retraction cord (GingiBRAID+) by merely turning the click-stop dial of the ShortCut device the number of clicks specific to the length of cord needed. (Fig. 3) Typically 3-4 clicks provides a length of braided cord for an anterior tooth; 4-5 clicks for a premolar; and 5-6 clicks for a molar. Large molars, in this author's experience, require five clicks for the needed length. Once dispensed, the built-in cutter is activated and pushed in with firm pressure, dispensing to the length needed for your clinical procedure. (Fig. 4) The ShortCut device has proven itself to be both durable and easily disinfected. ShortCut is available in braided cord diameters sizes 0, 1 and 2. It is provided as non-impregnated, allowing the clinician to choose the astringent-hemostatic agent, or the GingiBraid+ can be used impregnated with 8% racemic epinephrine/7% aluminum potassium sulfate or impregnated with 10% aluminum potassium sulfate and still allow for soaking in an astringent-hemostatic agent.

The choice of gingival retraction cord has proven itself to be one of personal preference by the clinician. Keep in mind that different cord types offer a variety of properties that to some make them more desirable. Also, as will be reviewed later in this article, many manufacturers have a range of options of non-impregnated and chemically impregnated cords. Some clinicians prefer twisted cords so they can hand-twist the cord to be tighter when placed in the sulcus — and, as the cords untwist, they expand, creating a physical effect of expanding the sulcus for access.

The preference for braided cords relates to their tight and consistent weave. They provide two benefits: First, braided cords for many clinicians are easier to place in the gingival sulcus with packing-placement instruments, both serrated and smooth, non-serrated, because they are solid and can be pushed into place. (Fig. 5) Some braided cords are not only impregnated with astringent-hemostatic agents but are covered with a gel of that reagent (Gel-cord, Pascal; GingiGel Coated Braid, DUX Dental). A braided cord wrapped around an ultrathin copper wire (Roeko Stay-Put Retraction Cord, Coltene-Whaledent) is described as being more stable in the sulcus once placed. Some recent improvements in braided cords (e.g., GingiBraid+) have a modified weave with a unique cotton yarn to allow the cord to have less memory. In this author's hands, this braided cord has offered more precise placement with minimal soft-tissue damage. Also, the change in the yarn used for the braided weave allows the cord to be significantly more absorbent and not split or tear during placement. This superior absorbency contributes to increase absorption of gingival fluids in the sulcus, as well as a swelling effect in the sulcus which contributes to improved retraction for better visualization of margins when making an impression.





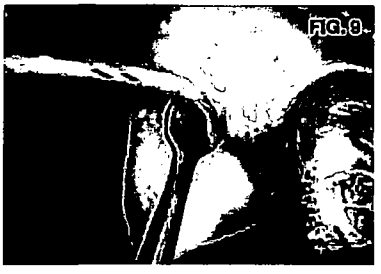


FIG. 7A: Placement of knitted cord (Ultra-Pak, Ultradent) for central incisor crown preparation using a double-cord technique. **Fig. 7B:** Impression demonstrates excellent gingival retraction for making an impression of the subgingival crown margins. **Fig. 8:** Dual-packing blade of TN010 Double Cord Packer (Garrison Dental Solutions). **Fig. 9:** Placement of braided cord (GingiBraid+) for crown preparation.

Knitted cords have increased in popularity. Among the major benefits of knitted cords is their unique knitted weave (Fig. 6), which minimizes unraveling and fraying after cutting and during cord placement. Knitted cords offer easy placement, and they expand when wet, opening up the sulcus greater than the original diameter of the cord.[1,2] The knitting and yarn selection allows for a greater range of knitted cotton cord diameters/sizes. In this author's experience, when using knitted cord, a smooth, non-serrated placement instrument allows for precise placement without pulling the cord out of a gingival sulcus. Also, the range of sizes/diameters allow for placement in both the easy-to-access gingival sulcus and the tighter, healthier gingival sulcus. (Fig. 7)

When describing mechanical displacement of gingival tissues with gingival retraction cords, one would be remiss if there were no mention of retraction cord placement packing instruments. There are many different instruments that have been described.[1] Key to placement of cord with instruments is that the end of the cord packer be thin enough to be placed in the gingival sulcus without damaging the gingival tissue and potentially causing bleeding; and that the angle of the instrument allow for orientation so that cord placement can be accomplished around all surfaces of the tooth. In this author's experience, the use of standard off-angle plastic filling instruments (PFI) is inappropriate due to the thickness of the blade. Also, there is variation in the size, length and shape of the end of the blade of the cord-packing instrument. Most commonly, the clinician will use double-ended instruments. Recently a novel double-ended instrument with multiple orientations of a dual-packing blade (TN010 Double Cord Packer, Garrison Dental Solutions) has been introduced so that the instrument does not need to be twirled to get the end orientation needed (Fig. 8). A good friend, Dr. Bob Margeas, designed this instrument because when using magnification, he found that this design maintains the instrument in the field of view while packing cord around the tooth.

Which are better, serrated or smooth cord-packer blades? For braided and twisted cords, both serrated and smooth cord packers work well (Fig. 9); for knitted cords, smooth cord-packing instruments are less likely to pull the cord from the sulcus during placement (Fig. 10). If you are satisfied with your cord-packing instrument, there is no need to change. If you desire an instrument to manage shortcomings with your current instrument, it would be worthwhile, at the next dental meeting you attend, to seek out manufacturers that provide excellent cord-packing instruments (Table 2).

Recommendations for improved gingival retraction with cord include use of a double-cord technique where a thin-diameter cord is placed to the base of the gingival sulcus without overlap, and cut to be flush within the sulcus. This cord is maintained during the impression to control any bleeding from the base of the sulcus. A second, wider-diameter cord is placed on top of the first cord to achieve tissue displacement. Immediately before making the impression, the cord should be wetted with water so as not to grab and tear the gingival tissues, which can create bleeding. The cord is removed and the impression is made immediately while leaving the first cord in place. Once the cord is removed, the retraction is maintained for only 30 seconds.[1]

Table 2
Partial listing of manufacturers that provide cord-packing instruments

MANUFACTURER	WEB SITE
Garrison Dental Solutions	garrisondental.com
Gingi-Pak	gingi-pak.com
Hu-Friedy	hu-friedy.com
Miltex	miltex.com
Pascal	pascaldental.com
Premier Dental Products	premusa.com
Ultradent Products	ultradent.com

Helpful hint: From this author's experience, if bleeding is persistent when the first cord is removed, continue with the impression, making certain to syringe the impression material within the sulcus. Even with the expectation that the impression will be unsuccessful, this impression will maintain the retraction while allowing for hemostasis. Remove the first impression and *do not* look at it. Immediately make a second impression. The sulcus will still be open and will not be bleeding.

One other method of mechanical displacement for gingival retraction includes making the impression at the same time. The use of copper tubes or copper bands to displace soft tissue for impressions for crown preparations requires that a fitted copper band be cut to shape, contoured and fitted to beyond the crown preparation margins.[4,5,12] The fitted band is filled with an elasomeric impression material, compound or a combination of acrylic resin and then relined with rubber base to simultaneously displace the gingival tissue and make the impression.

Mechanicochemical Methods

A variety of chemical solutions and gels have been recommended for use with gin-

gival retraction cords because of the properties as drugs to act as an astringent or hemostatic agent.[1, 2, 4] In most cases, these drugs are both astringent, causing contraction-retraction of the gingival tissues, and hemostasis, constricting blood flow through coagulation. When these reagents are placed on a retraction cord, they cause a transient ischemia, shrinking the gingival tissue and blood vessel coagulation. Common astringent-hemostatic agents include ferric sulfate, aluminum chloride and racemic epinephrine. As previously stated, gingival retraction cords are available unimpregnated or impregnated with the aforementioned astringent-hemostatic agents, as well as aluminum potassium sulfate, aluminum sulfate, racemic epinephrine and zinc phenolsulfonate/racemic epinephrine, among others. Chemically impregnated cords offer greater sulcus displacement with the combined physical and chemical effect.[1] Also, cord diameter, astringent-hemostatic agent and cord type have a direct effect on the physical properties of the cord.[13] In some cases, both solutions and gel formulations are recommended for direct placement into the gingival sulcus with specialized tips (Astringedent, Ultradent; ViscoStat, Ultradent; Racecord, Septodont) to achieve a hemostatic effect with some ischemic effect before cord placement.

A 20–25% aluminum chloride and 15.5–20% ferric sulfate are among the most popularly used chemical reagents.When used for durations within the gingival sulcus of less than 10 minutes, they cause minimal tissue damage.[1, 2, 14] There has been concern over the use of an 8% racemic epinephrine impregnated cord.[4, 15-18] It has been reported that epinephrine-impregnated cords should be used with care. It has been reported that an 8% racemic epinephrine cord can cause elevation in blood pressure and tachycardia, especially if the gingival tissue is bleeding due to laceration.[16] In fact, it has been demonstrated that no clinical benefit in gingival retraction could be recognized between an epinephrine-containing cord and other cords.[17] A systematic review of the dental literature of cardiovascular effects of epinephrine-containing anesthetic agents and epinephrine-impregnated cords was done to identify any additional risks of adverse cardiovascular outcomes to hypertensive individuals.[18] Although the increased risk for adverse events among uncontrolled hypertensive patients was found to be low, and the reported occurrences of adverse events in hypertensive patients associated with the use of epinephrine in local anesthetics minimal, the quantity and quality of the pertinent literature is problematic.[18]

Table 3
Cordless gingival retraction

PRODUCT	MANUFACTURER
Expasyl	Kerr
GingiTrac	Centrix
Magic Foam Cord	Coltene/Whaledent
Racegel	Septodont
Traxodent	Premier Dental

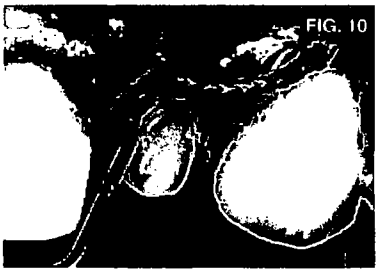


FIG. 10

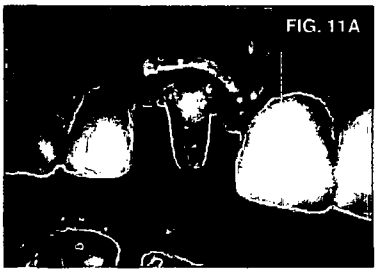


FIG. 11A

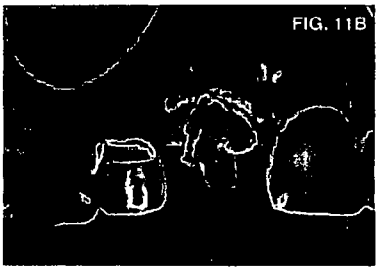


FIG. 11B


FIG. 11C


FIG. 12A

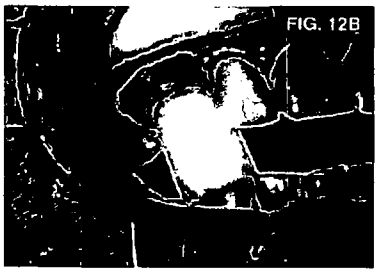


FIG. 12B

FIG. 10: Placement of knitted cord (UltraPak) for crown preparation. **FIG. 11A:** Crown preparation maxillary central incisor. **FIG. 11B:** Placement of GingiTrac paste (Centrix) into gingival sulcus before reseating putty matrix to force paste into sulcus for retraction. **FIG. 11C:** Impression for crown demonstrating the retraction accomplished by the GingiTrac cordless retraction system. **FIG. 12A:** Syringing the retraction paste into the sulcus prior to inserting the compression cap. **FIG. 12B:** GingiCap compression cap placed over the crown preparation to push the paste into the sulcus.

Of special note, the solutions that are used as astringents and for hemostasis are acidic. There has been evidence demonstrating that the use of these products removes the smear layer.[19, 20] There is concern that if the root surfaces beyond the crown preparation margins are exposed to these solutions, there may be an increase in postoperative sensitivity. If, as a clinician, you have this problem, it is recommended that after making the impression and before cementation of the provsisional restoration, the preparations be treated with a desensitizing agent such as Gluma (Heraeus-Kulzer) or Calm-It (Dentsply Caulk).

Cordless Retraction

In most cases, gingival retraction cord is the most effective method for retracting tissue to the depth of the sulcus. Unfortunately, many times on the day of the tooth preparation, gingival bleeding is difficult to control — or, when packing a cord into the sulcus, the tissues start to bleed, making impression difficult or impossible. For this reason, a new class of gingival retraction materials have been introduced (Table 3).

These cordless retraction materials provide for excellent hemostasis and some gingival retraction. Some of the materials incorporate the use of a compression cap to enhance the retraction effects of the material.

GingiTrac (Centrix) was an improvement over the first-generation cordless retraction and tissue-management material, Retrac (Centrix).[21] The technique for GingiTrac is the use of a heavy-viscosity matrix combined with a light-body retraction/hemostatsis paste for single and multiple tooth preparations (Fig. 11) or for single teeth with a compressible closed foam cap (GingiCap, Centrix)[22] (Fig.12). In this author's experience, another paste-like material, Expasyl (Kerr) provides for excellent hemostasis but minimal retraction even when syringed into the sulcus. A poly vinyl siloxane material (Magic Foam Cord, Coltene-Whaledent) not only pro-vides for hemostasis but also, when used with its compression cap, expands the sulcus to allow for easy access for impression making. GingiTrac and Magic Foam Cord are more easily used for impression techniques; Expasyl can be used for impression techniques and for hemostasis during routine restorative procedures. Clinical studies evaluating Magic Foam Cord and Expasyl demonstrated their effectiveness in cordless retraction and control of bleeding during and after the retraction.[23,24] Expasyl was found to cause slightly more inflammation than Magic Foam Cord and UltraPak knitted cord, and Expasyl had a higher rate of postoperative dentin hypersensitivity.[23] Also, both products caused less histologic damage than a retraction cord technique.[25]

Using these cordless retraction techniques provide for a non-traumatic, non-invasive tissue management of the sulcus for fixed prosthodontic impressions. Expasyl offers the additional advantage of hemostasis for routine restorative procedures. For the Retrac and Magic Foam Cord, control of the soft tissue for exposing the margins of the tooth preparation using pressure, astringency and time allows the clinician to get predictable gingival retraction and hemorrhage control. These materials and techniques can be used by themselves or in combination with the use of gingival retraction cord, electrosurgery or laser tissue sculpting when bleeding is difficult to control.

Surgical Methods of Gingival Retraction

The use of specialized devices to reshape and remove gingival tissue to control bleeding and to create access to preparation margins has been shown to be successful.[26-28] The surgical method for gingival retraction and exposure of the margins of the tooth preparation has been referred to as "troughing" or "tissue dilation."[26, 27] The first use of this technique was with electrosurgery.[26, 27, 29] In recent years, the use of laser tissue sculpting for gingival retraction has been described.[28] The trough, soft tissue excision, extends from the height of the free margin of the gingiva to a point 0.3–0.4mm apical to the finish line margin of the tooth preparation. The displacement of the soft tissue is accompanied by hemostasis. Unlike other techniques that provide retraction without removal of the gingival tissue, this technique removes gingival tissue and requires soft-tissue healing. It may be problematic in the esthetic zone where the healing and height of the gingival margin has a direct impact on the esthetics of the gingival tissue. Most manufacturers of lasers have specialized tips and settings for this technique. This author has limited experience with these techniques and would recommend that a clinician interested in the use of lasers for soft tissue management review with manufacturers' representatives and colleagues familar with the use of lasers.

Conclusion

There are a variety of techniques and materials that allow the clinician to manage the gingival tissues during restoration and when making an impression. These include gingival retraction cords, chemical reagents, electrosurgery, laser tissue sculpting, copper tube impressions, hydraulic impressions and non-invasive, atraumatic displacement/hemostatic materials. In most cases, gingival retraction cord is the most effective method for retracting tissue to the depth of the sulcus. The other methods have their advantages and indications. In any case, the control of the soft tissue for exposing the margins of the tooth preparation for restoration and impressioning is critical. It would be worthwhile for the clinician to understand all the choices available.

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1. **Displacement of gingival tissues in restorative dentistry may be necessary for**

a. restoring Class V carious lesions below the free margin of the gingiva.
b. restoring Class V non-carious cervical lesions (NCCL) below the free margin of the gingiva.
c. for fixed prosthodontic impressions where the margin of the crown preparation is below the free margin of the gingiva.
d. all the above.

2. **In this article, the description of tissue management when making impressions for fixed prosthodontics includes:**

a. placing the gingival tissue away from the preparation margins.
b. providing soft-tissue hemostasis when the gingival tissues are susceptible to bleeding.
c. surgically creating a soft-tissue flap to reflect the gingiva from the crown margin to visualize the presence of calculus.
d. a and b.

3. **The rationale for tissue management is a critical aspect of impression making. The rationale includes both conventional impressions with impression materials and using a digital impression technique.**

a. Both statements are true.
b. The first statement is true; the second statement is false.
c. The first statement is false; the second statement is true.
d. Both statements are false.

4. **Tissue management is critical for placement of direct restorative materials, especially for Class V lesions. When teeth with Class V lesions need restoration, the cervical margin can be difficult to access due to the extent of the lesion and the need for a dry, controlled field when placing the restoration.**

a. Both statements are true.
b. The first statement is true; the second statement is false.
c. The first statement is false; the second statement is true.
d. Both statements are false.

5. **The goal of tissue management for restorative dentistry requires that the gingival tissue be in a state of health.**

a. True.
b. False.

6. **Mechanical methods for gingival retraction when restoring Class V carious lesions that are subgingival include all the following EXCEPT:**

a. dental dam (rubber dam) using gingival retraction clamps.
b. gingival retraction cord.
c. wooden wedges.

7. **Gingival retraction cord can be woven, braided or twisted. There is only one diameter of cord available to dentists to use.**

a. Both statements are true.
b. The first statement is true; the second statement is false.
c. The first statement is false; the second statement is true.
d. Both statements are false.

8. **Easy methods of dispensing cord include all of the following EXCEPT:**

a. cord dispensed in self-cutting dispensing boxes (Hemodent Cord).
b. precut, individually packaged cord (UniBraid+).
c. 100-inch-long cords dispensed like thread in a sewing machine (The Long and Short of It).
d. all-in-one delivery with a dispensing device that dispeneses and cuts the cord (ShortCut).

9. **Gingival retraction cord is a very popular method for gingival retraction.**

a. True.
b. False.

10. **Gingival retraction cords are available both chemically treated/impregnated with astringents and hemostatic agents and not impregnated. The benefit of a non-impregnated cord is that clinicians can choose their own hemostatic/astringent to use.**

a. Both statements are true.
b. The first statement is true; the second statement is false.
c. The first statement is false; the second statement is true.
d. Both statements are false.

11. **According to this article, the choice of gingival retraction cord is**

a. because one type is much better than other types.
b. personal preference by the clinician.
c. to save money.
d. to save time.

12. Braided gingival retraction cord can be easily used with what type(s) of cord-packing instruments?

a. Smooth, non-serrated cord-packing instruments.
b. Serrated cord-packing instruments
c. Porous, notched, cardboard single-use flexible cord-packing instruments.
d. a and b.

13. In this article, the type of cord-packing instrument recommended for knitted cords is

a. smooth, non-serrated cord-packing instruments.
b. serrated cord-packing instruments.
c. porous, notched, cardboard single-use flexible cord-packing instruments.
d. b and c.

14. Chemical solutions and gels have been recommended for use with gingival retraction cords. These solutions and gels are drugs that

a. act as an astringent causing contraction-retraction of gingival tissue.
b. are anticoagulents to promote gingival bleeding to flush the gingival sulcus of any bacteria before doing the restorative procedure.
c. are hemostatic to control bleeding when doing the restorative procedure.
d. a and c.

15. All of the following drugs are listed in the article for use either as a hemostatic agent or astringent or both EXCEPT:

a. aluminum chloride.
b. ferric sulfate.
c. racemic epinephrine.
d. citric acid.

16. Chemically impregnated cords offer greater sulcus displacement with a combined physical and chemical effect. Also, cord diameter, astringent-hemostatic agent and cord type have no effect on the physical properties of the cord; you need only one large diameter to accomplish the task.

a. Both statements are true.
b. The first statement is true; the second statement is false.
c. The first statement is false; the second statement is true.
d. Both statements are false.

17. The acidity of astringents and hemostatic agents can remove the dental smear layer. There has been concern that using these agents can cause an increase in dentin hypersensitivity of crown margins and the root surfaces beyond the crown margins and an increase in postoperative pain.

a. Both statements are true.
b. The first statement is true; the second statement is false.
c. The first statement is false; the second statement is true.
d. Both statements are false.

18. Cordless retraction refers to the atraumatic placement of hemostatic and astringent pastes into the gingival sulcus to control bleeding and retract the gingival tissues. There have been clinical studies that demonstrate that these techniques are not effective and should be discarded from our practice of dentistry.

a. Both statements are true.
b. The first statement is true; the second statement is false.
c. The first statement is false; the second statement is true.
d. Both statements are false.

19. The use of lasers and electrosurgery for gingival retraction and hemostasis is a surgical method for controlling the soft tissue. The exposure of margins using these devices is referred to as

a. air abrasion.
b. tissue resorption.
c. troughing.
d. tissue redaction.

20. The use of lasers for gingival retraction is effective in creating a space by tissue excision from the height of the gingival margin to a point 0.2–0.4mm apical to the finish line of the tooth preparation. This tissue displacment is accompanied by hemostasis.

a. Both statements are true.
b. The first statement is true; the second statement is false.
c. The first statement is false; the second statement is true.
d. Both statements are false.

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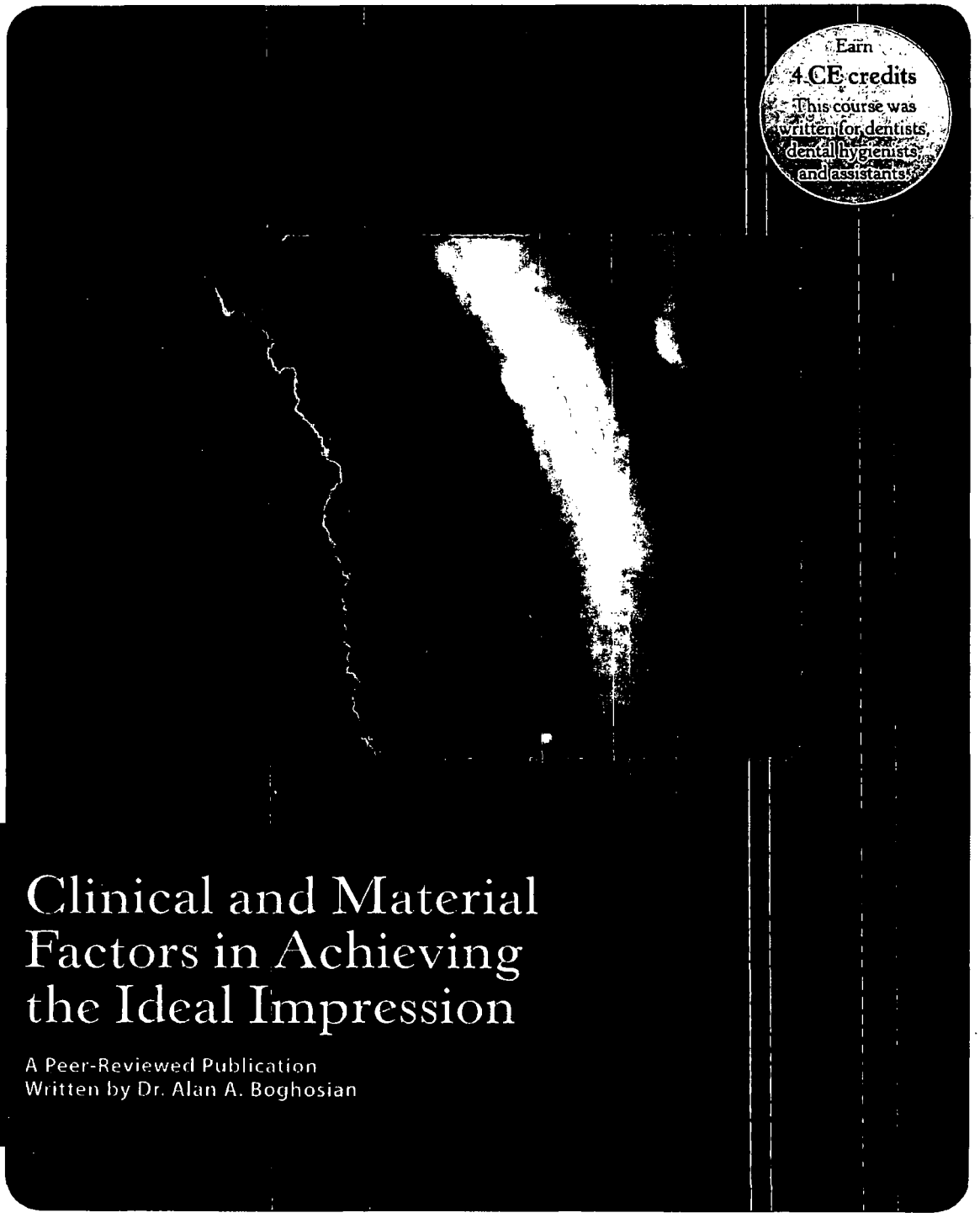

Clinical and Material Factors in Achieving the Ideal Impression

A Peer-Reviewed Publication
Written by Dr. Alan A. Boghosian

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Educational Objectives

Upon completing this course, the reader should be able to do the following:

1. Understand the key factors involved in achieving an ideal impression
2. Be knowledgeable about techniques available for soft tissue retraction and hemostasis
3. Understand the factors involved in tray and impression material selection
4. Be knowledgeable about techniques and materials available that will enhance impression material flow

Abstract

Clinicians report that the impression-taking process is the most stressful restorative procedure. Key factors involved in producing clinically acceptable impressions include managing soft tissue, appropriately selecting tray and impression material, and enabling impression material to flow predictably. Managing soft tissue is the most critical step in obtaining a perfect impression. Tray selection also plays a significant role with tray choice depending on the clinical situation and on the impression material and technique used. The most commonly used elastomeric impression materials are polyether (PE) and vinyl polysiloxane (VPS) chemistries. Appropriate use of either will produce a clinically accurate impression. The material must have an adequate working time and flowability, and have sufficient tear strength to prevent tearing at thin areas at the margin. Using a hydrophilic impression material and a surface modifier will permit enhanced flow and result in a more accurate and detailed impression. In addition, the impression must be dimensionally stable for a reasonable time until it is cast. Achieving clinically acceptable impressions requires clinical expertise and appropriate materials, trays, and techniques.

Introduction

Successful indirect restorations depend on many factors, but chief among them is taking a good impression. An impression that does not precisely duplicate the prepared teeth will produce an inaccurate working model and result in poorly fitting restorations. Clinicians report that the impression-taking process is the most stressful restorative procedure, because of clinical technique and the impression material's inherent properties.

This article will present key factors involved in producing clinically acceptable impressions, including managing soft tissue, selecting tray and impression material, and enabling impression material to flow predictably.

Soft-Tissue Management

Managing soft tissue is the most critical step in obtaining a perfect impression. When surveyed, 48% of key opinion leaders and researchers considered soft-tissue management the single most critical factor in accurate impression-taking.[1] With clinical cases involving deep decay, margin placement is an important consideration. Before any preparation, consider the biologic width.[2] Avoid placing margins too close to bone level, to prevent violating the biologic width.[3,4] Extending restoration margins beyond the biologic width can cause inflammation and, eventually, anatomic changes.[5]

Consider pre-prosthetic crown lengthening if the biologic width has been violated.[6] Also, capturing a preparation's margins is significantly easier if they are not deeply subgingival. Two criteria are critical when taking an impression of equigingival and subgingival preparations: hemostasis and gingival retraction (see Figures 1, 2).

Figure 1. Poor hemostasis resulting in inadequate impression

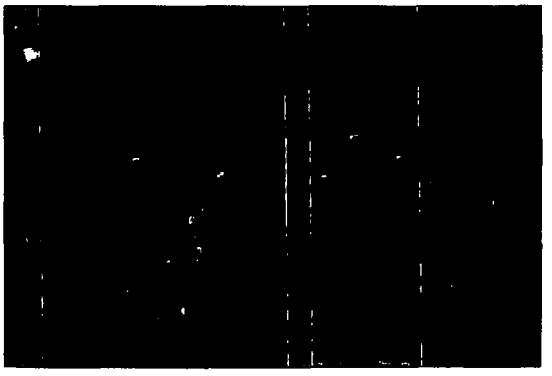
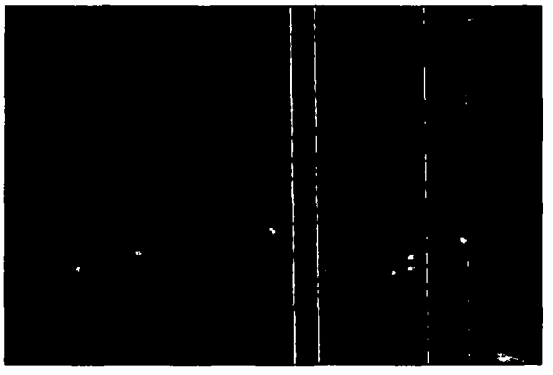


Figure 2. Poor impression with undefined margins



Hemostasis

Several hemostatic agents containing aluminum chloride and aluminum sulfate can arrest and prevent bleeding before an impression is taken. Products containing aluminum chloride include Hemogin-L (Van R), Hemodent™ Liquid (Premier Dental), and ViscoStat Clear (Ultradent). Products

containing aluminum sulfate include Gel Cord® (Pascal) and Tissue Goo™ (Clinician's Choice Dental).

To control slight-to-moderate bleeding, I have found that aluminum chloride and aluminum sulfate are suitable. To control moderate-to-severe bleeding, ferric sulfate and ferric chloride are more effective. Products containing ferric sulfate include FS Hemostatic™ (Premier Dental), and ViscoStat and ViscoStat Wintergreen (Ultradent). An ideal hemostatic agent is ferric chloride (ViscoStat Plus). It can be more effective than ferric sulfate and is potentially less irritating to dentin and pulpal tissues because of its higher pH (2.3 compared to 1.0). However, ferric chloride can tarnish stainless steel.

Gingival retraction

Gingival retraction enables accurate recording of preparation margins and the gingival sulcular area. The most common way to retract the gingiva is with retraction cord.

In addition to classical methods of gingival retraction, newer chemical systems are now available. Silicone polymer retraction materials and materials composed of high-viscosity clay include Magic FoamCord (Coltene Whaledent) and Expasyl ™(Kerr Corporation).

Magic FoamCord is a vinyl polysiloxane material that is syringed around the prepared tooth margins. The material generates hydrogen gas, which expands the sulcus. However, when preparation areas are fairly subgingival, the material may not provide enough retraction force, and it lacks a hemostatic agent.

Expasyl™ contains aluminum chloride for hemostasis. Its putty-like consistency provides sufficient retraction for conservative subgingival preparations, and it can effectively control slight-to-moderate bleeding. However, its viscosity may not provide enough retraction for deeper subgingival preparations.

Although other methods are available — such as rotary curettage, electrosurgery, and lasers — they remove tissue rather than retracting it, and all alternatives but lasers have other drawbacks.

Rotary curettage can be difficult to control and is not recommended for thin, friable gingival tissue. Electrosurgery is similarly contraindicated with friable tissue and in patients with pacemakers. Lasers have produced good results with management of gingival tissue and in postoperative healing. They not only produce an excellent visible path to the margin but also provide outstanding hemostasis.

Gingival retraction using retraction cord is the most widely accepted method. To avoid trauma, as a rule of thumb, use the thinnest cord that adequately retracts tissue. Using a nonimpregnated cord lets you select the hemostatic medicament. If using preimpregnated cord, first soak with a hemostatic agent to improve hemostasis.[7] Before removing cords, soak them with water to help prevent tissue damage and ease placement. Of prosthodontists who responded to a 1999 national survey, 98% said they used gingival retraction cord and 48% said they used double cords.[8]

Single-cord technique

This technique involves a single retraction cord placed in the sulcus and removed just before taking the impression. The single-cord technique is effective if the margins are supragingival or equigingival. It may not be as effective if the margins are subgingival, because the gingival tissue rapidly collapses back over the margins when the cord is removed (see Figure 3). This prevents the flow of impression materials apical to the margin.

Figure 3a. Placement of single retraction cord

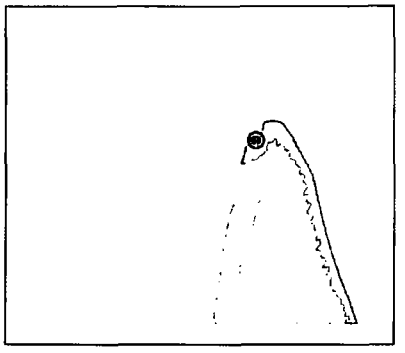
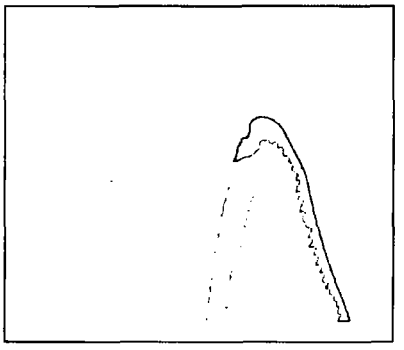


Figure 3b. Tissue collapse following removal of single-cord



Double-cord technique

This technique uses two layers of cord of differing thicknesses. It can prevent tissue collapse and bleeding, helping to achieve perfect impressions. However, careful technique is required to avoid tissue damage. In the case of a shallow sulcus or friable tissue, use only one cord.

Figure 4a. Preparation and adjacent gingiva

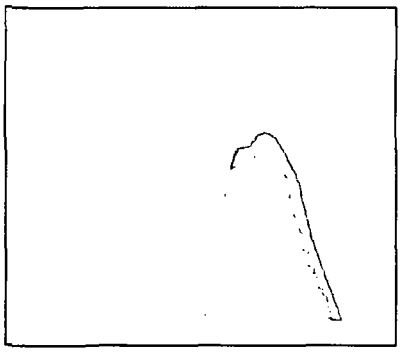


Figure 4b. Placement of first retraction cord

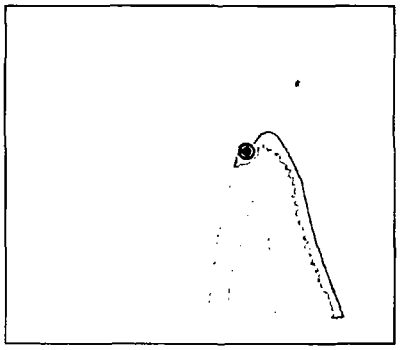


Figure 4c. Placement of thicker second retraction cord

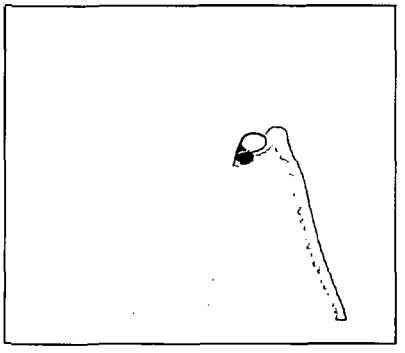
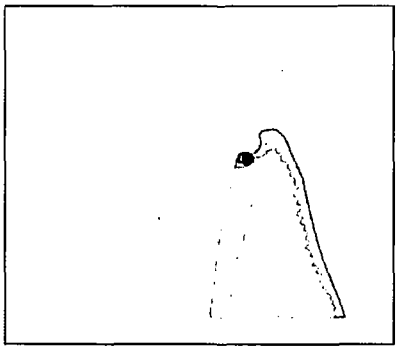


Figure 4d.Soft tissue after removal of the thicker retraction cord prior to impression taking



The following steps describe the use of the double-cord technique:

Step 1. Using a microbrush, apply a small amount of ViscoStat Plus around the entire margin to arrest slight bleeding or to prophylactically prevent bleeding during cord placement.

Step 2. Soak a thin-diameter retraction cord (Ultrapak, Ultradent; GingiBraid, Van R) in an appropriate hemostatic agent. Then place the cord subgingivally around the tooth to obtain apical retraction. The first cord acts as a gingival seal and prevents tissue-adhesion bleeding when the second cord is removed before taking the impression. Completing final margination after placing the first retraction cord protects the gingiva from potential damage by rotary instruments.

Step 3. After finalizing the margins, soak a second, larger-diameter (No. 2) retraction cord in the hemostatic agent. Place this around the preparation to create further lateral and apical retraction.

Step 4. Allow the cords to remain in place long enough for full retraction to occur and to prevent relapse when you remove the second cord (usually after four to five minutes).[9] Then remove the second cord and take the impression, keeping the first cord in place to prevent crevicular seepage and bleeding (see Figure 4). If the first cord does not come out with the impression, be sure to retrieve it from the sulcus before dismissing the patient.

Tray Selection and Impression Technique

Tray selection plays a significant role in taking accurate, detailed impressions. Base your tray choice on the clinical situation and on the impression material and technique used. Choose from stock plastic and metal trays (perforated and unperforated) and custom-fabricated trays.

Custom trays are the most reliably accurate. They also produce consistently accurate impressions of implant-fixture sites,[10] use less impression material, and are more comfortable for patients. But regardless of the clinical case or the impression technique and tray used, prevent prepared teeth from touching the tray to avoid ill-fitting crowns.

Complete-arch (full-arch) technique

When taking an impression on fewer than four teeth, you can use a stock (metal or plastic) or custom tray. But to ensure successful impressions when preparing more than four to six teeth, strongly consider using a custom tray. A properly constructed custom tray will enable optimal impression–material flow (see Figure 5).

Figure 5a. Custom tray

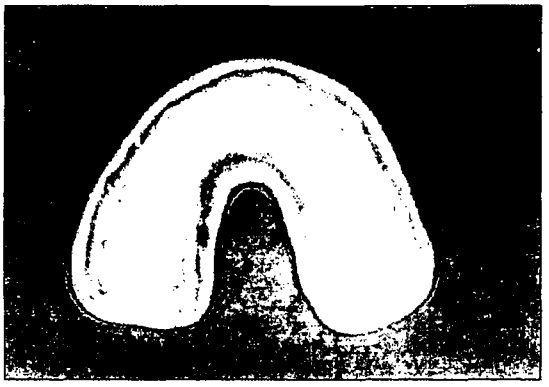


Figure 5b. Accurate impression for implant case

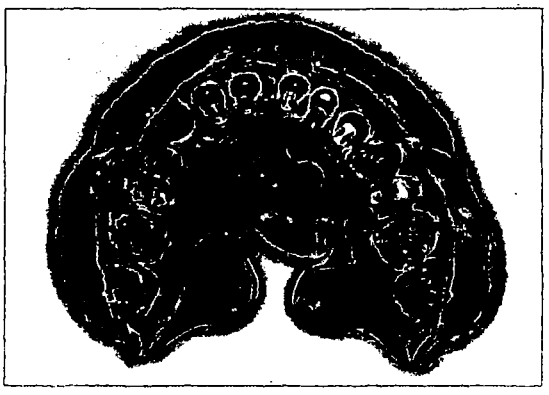
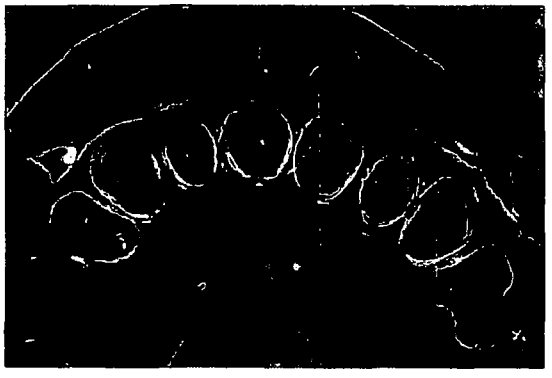


Figure 5c. Accurate multi-preparation impression



Closed-bite (double-arch) technique

The closed-bite impression is the most technique-sensitive of all impression techniques. If used correctly, it can save time and reduce occlusal adjustments on crowns. It is ideally suited for one or two prepared posterior teeth that are adjacent to unprepared teeth. These impressions, when appropriately taken, can provide dimensional and marginal accuracy[11,12] (see Figures 6, 7, 8).

Figure 6. Quad tray (Clinician's Choice Dental)

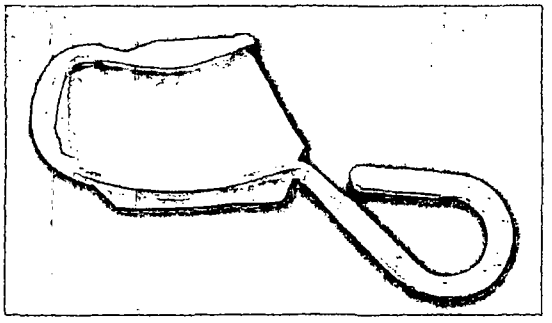


Figure 7. Incorrect impression using closed-bite technique

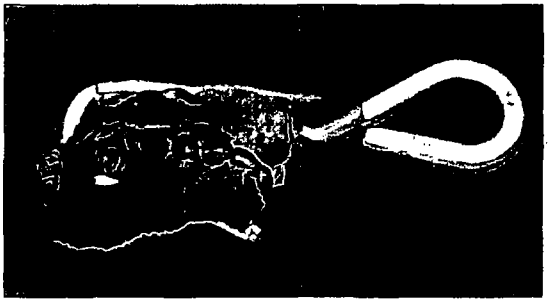
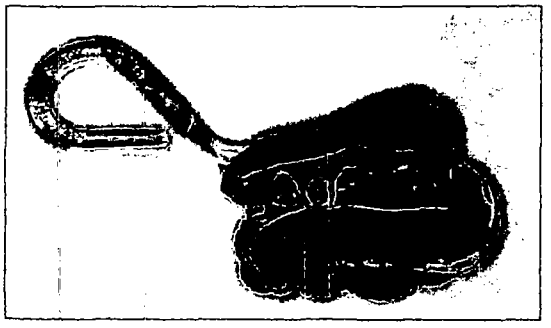


Figure 8. Correct impression using closed-bite technique



Use a rigid metal closed-bite tray with low sidewalls and a wide buccal-lingual distance. If the patient has a narrow palate, a tray with higher sidewalls could impinge and flex, causing improperly fitting restorations. Use fast-set impression material only if you can syringe and seat the tray in 20 seconds or less. Otherwise, use regular-set impression material. Use a tray material with a low strain-in-compression.

Impression Material Properties

Requirements for Impression Materials

The most commonly used elastomeric impression materials are polyether (PE) and vinyl polysiloxane (VPS) chemistries. Appropriate use of either will produce a clinically accurate impression. However, be aware of several physical-property and clinical-handling requirements.

A precision elastomeric impression material must accurately replicate the details of the prepared teeth. The detail reproduction test in International Standards Organization (ISO) document 4823 and American Dental Association (ADA) specifications requires a light body impression material to replicate a 20-micron line. The material must have an adequate working time and flowability. The impression must be dimensionally stable for a reasonable time until it is cast. In addition, the material must have sufficient tear strength to prevent tearing at thin areas at the margin.

An impression material's set hardness is measured by the strain-in-compression test. The tray material's strain-in-compression properties should correspond to the selected tray type. Full-arch impressions can be more easily retrieved from the mouth when using less rigid setting-tray materials, whereas exceedingly rigid setting-tray materials are ideal for use with the closed-bite impression technique.

When selecting an impression material, consider patient comfort. Choose materials that have as short a setting time as clinically appropriate, are easy to remove, and smell and taste pleasant. I will discuss these properties in the next section.

Working time

An impression material's working time critically depends on temperature. Addition silicones (VPS) are more sensitive to temperature changes than PE. Intraorally, VPS impressions have 66% less working time, and PE impressions 50% less working time than at the lower room temperature used as the ISO standard for testing.[13] This reduced working time affects how long the material can flow to capture all clinical details and margins (see Table 1).

Table 1. Working time and temperature

Adapted from ADA Professional Product Review Vol. 2 Issue 3.

Use fast-set material when preparing only one or two teeth. Use regular-set impression material when preparing more than two teeth, to increase working time, or if working in a warmer environment. When using a double-mix impression technique, syringe the wash material around the teeth and then immediately seat the tray. If the wash material starts to set before the tray is placed, the tray material could drag the wash and create voids.

If a putty material is selected as the tray material and is mixed too long, it will set before the tray is seated, causing recoil and resulting in inaccurate dies and tight-fitting crowns.

To lengthen working time for large restorations, refrigerate the impression material. Lowering its temperature will significantly increase working time without jeopardizing its physical properties.

Mix putty quickly, using fingertips as much as possible to avoid heat transfer from the palms. While you are syringing the prepared teeth, your assistant can simultaneously dispense impression material into the tray to provide maximum working time for the viscosity of both materials.

Strain-in-compression

Strain-in-compression measures how hard an impression material sets up, and ranges from 0.8% to 20%. Strain-in-compression is an important consideration in tray selection and impression technique. When taking a full-arch impression, use a tray material with a strain-in-compression above 3.5%. This improves patient comfort during retrieval, especially when undercuts and pontics are present. When using the closed-bite impression technique, use a stiffer setting-tray material with a strain-in-compression below 2%, because the impression material becomes the extension of the tray.

Elastic Recovery (Compression Set)

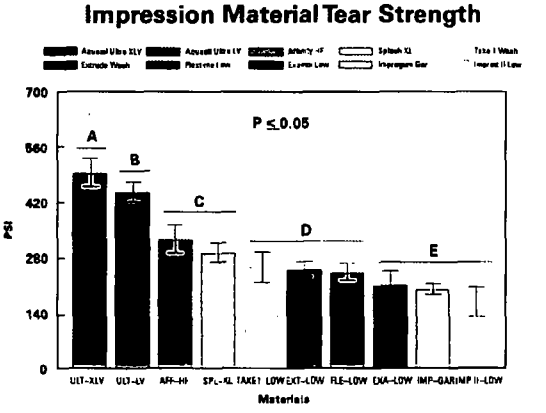
The ability of an impression material to recover to the same shape and dimension after being deformed is tested in elastic recovery. When a set impression is removed from the mouth, the material is stretched and compressed from undercuts. Vinyl polysiloxane materials with values greater than 99% have the greatest elastic recovery. Tests of polyether elastomers show that they average around 97% recovery. The higher the value, the better, but note that polysulfide materials having the lowest elastic recovery at 95% can perform well clinically. Differences in clinical performance might be seen with implant transfer type impressions, where a high degree of elastic recovery may perform better.

Tear Strength

A measurement of tear strength is not included in the suite of physical property tests in the American National Standards Institute/American Dental Association (ANSI/ADA) specification No. 19[14] or ISO 4823 specifications.[15] Lautenschlager and Boghosian investigated the tear strength of low-viscosity impression materials using specimens with notches the size of the average thickness of impressions (220 microns). We found Aquasil Ultra XLV to have the highest tear strength in this study.[16] Tear strength alone should not be the only criteria when choos-

ing a product for clinical use. However, if you experience frequent tearing, selecting a material with higher tear strength could be very helpful providing all other properties are satisfied (see Table 2).

Table 2. Tear strength



Hydrophilicity and wettability

The degree of hydrophilicity of a material is tested using a contact angle goiniometer. A small droplet of water or other liquid is placed on a surface, and the angle formed between the liquid-solid interface is referred to as the contact angle. A material with a lower contact angle is more wettable and hydrophilic. Modern vinyl polysiloxane impression materials have significantly increased hydrophilic properties over their predecessors, with measured contact angles as low as 7 degrees measured in 10 seconds.

While contemporary impression materials demonstrate highly hydrophilic behavior, the dentin on which these materials are syringed lack the same degree of hydrophilicity. Contact angles of more than 70 degrees have been reported on dehydrated dentin surfaces[17] (see Figure 9). The flow of the impression material, especially subgingivally, is limited because of the disparity between the dentin and the impression material contact angles.

Surface modifiers

In the same survey mentioned above, 57% of key opinion leaders and researchers stated that their greatest need was for an impression material that could predictably flow subgingivally, thus eliminating voids in the sulcus and at the margins.[18] Predictable flow of impression material can be attained by applying a surface modifier to dentin and other intraoral surfaces to increase the wettability. Surfactants used as surface modifiers (surface treating agents) or as topical agents on impression materials also improve wettability and reduce voids in impressions.[19]

B4™ Pre-Impression surface optimizer (DENTSPLY Caulk) is a surface modifier that has been found to wet out dentin and improve contact angles of dentin to hydrophilic VPS (Aquasil Ultra Smart Wetting® impression material). To decrease the contact angle of dentin as shown in Figure 9a, first apply B4™ surface optimizer to the surface (see Figure 9b).

Figure 9a. Contact angle of water on dentin

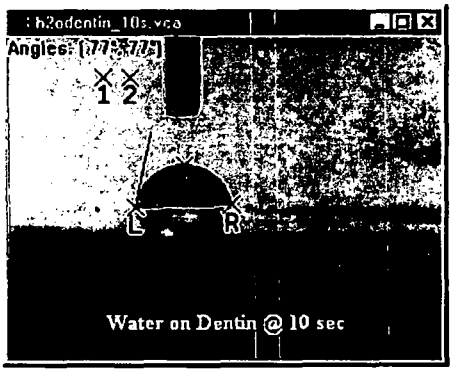
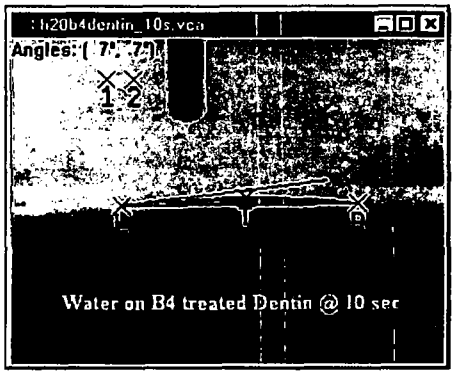


Figure 9b. Contact angle of water on B4™ surface optimizer treated dentin



Lowering the surface tension by applying B4™ surface optimizer helps the impression material flow better (see Figure 10). Figure 11 compares the application of 1.0cc of Aquasil Ultra XLV impression material syringed onto a surface with and without B4™ surface optimizer. Note the enhanced flow achieved on the right side. Enhanced impression material flow is seen on dentin with B4™ surface optimizer pretreatment (see Figure 12).

Figure 10a. Preparation with dry dentin

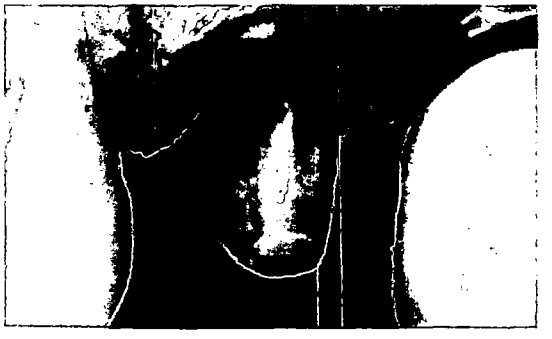


Figure 10b. Preparation after application of B4™ surface optimizer

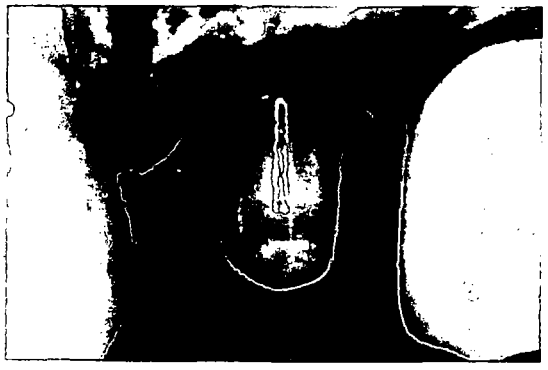


Figure 11. Surface flow with and without B4™ surface optimizer

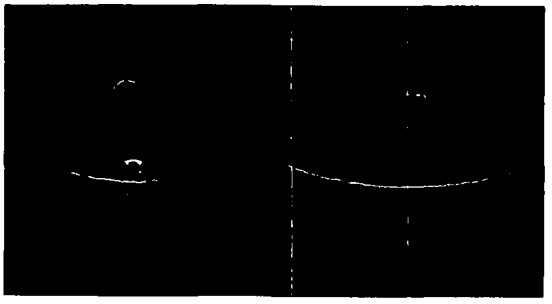
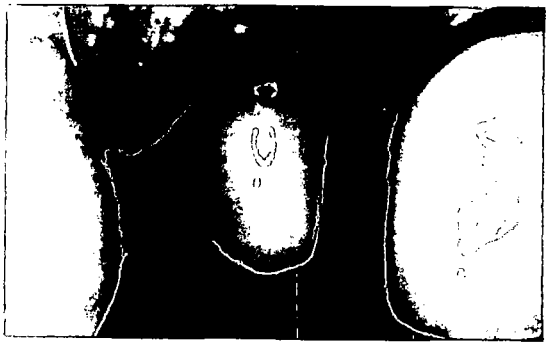


Figure 12a. Impression material flow without B4™ surface optimizer

Figure 12b. Impression flow following application of B4™ surface optimizer



The use of B4™ surface optimizer with Aquasil Ultra impression material does not interfere with the replication of the 20-micron line, as described in ADA and ISO detail reproduction testing. Higher-detail reproduction resolution was tested using 1,200 grooves/mm holographic gratings. Prior to taking an impression, a film of B4™ surface optimizer was applied to the grating surface. The impression was cast in epoxy and examined with a scanning electron microscope. The ruled lines in most areas throughout the surface showed equivalent detail compared to a replication without the B4™ surface optimizer pretreatment (see Figure 13). In conclusion, application of B4™ surface optimizer will substantially increase the flow of impression material on dentin and other intraoral surfaces, while not affecting on surface detail reproduction.

Figure 13a.
SEM of diffraction grating at 10,000x

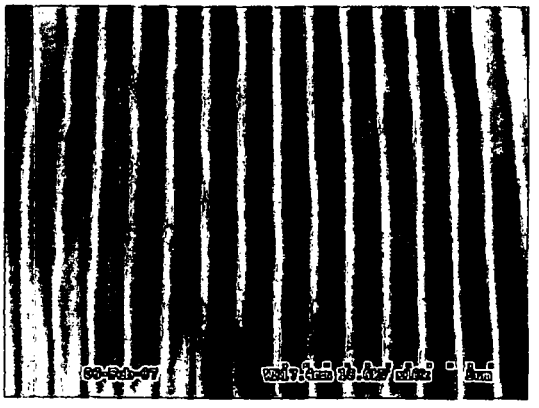
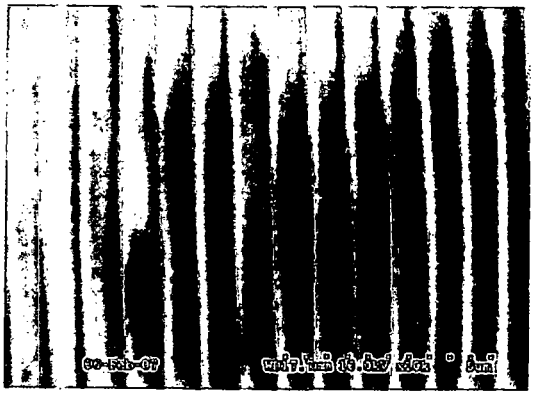


Figure 13b.
SEM of diffraction grating 10,000x after B4™ surface optimizer application



Summary

Achieving clinically acceptable impressions requires clinical expertise and appropriate materials, trays, and techniques. Several considerations are essential: properly managing

tissues before taking the impression, not exceeding the impression material's working time, and following proper protocols. Using a hydrophilic impression material and a surface modifier such as B4 will permit enhanced flow, allow time-efficient syringing of wash material, and result in a more accurate and detailed impression.

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Author Profile

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The author of this course was involved in the development of B4, in which he has a commercial interest.

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Questions

1. Clinicians report that the impression-taking process is _____.
   a. the simplest part of a prosthetic procedure
   b. the most stressful restorative procedure
   c. not critical to results
   d. none of the above

2. The most critical step in obtaining a perfect impression is _____.
   a. creating a bevel in the preparation
   b. preparing the tray
   c. using an etchant first
   d. managing soft tissue

3. The biologic width should be considered _____.
   a. after the preparation is completed
   b. before any preparation has begun
   c. only in patients with periodontal disease
   d. none of the above

4. If the biologic width has been violated, _____.
   a. inflammation can occur
   b. anatomic changes can occur
   c. pre-prosthetic crown lengthening should be considered
   d. all of the above

5. Hemostasis and gingival retraction are critical in taking an impression of _____.
   a. a subgingival or equigingival preparation
   b. any preparation
   c. a subgingival or supragingival preparation
   d. none of the above

6. Hemostatic agents used include _____.
   a. aluminum sulfate
   b. ferric sulfate and ferric chloride
   c. aluminum chloride
   d. all of the above

7. Ferric chloride _____.
   a. can be more effective than ferric sulfate
   b. is potentially less irritating to dentin than ferric sulfate
   c. has a higher pH than ferric sulfate
   d. all of the above

8. Methods for gingival retraction include the use of _____.
   a. retraction cord
   b. polymers and pastes such as Expasyl™
   c. lasers and rotary curettage
   d. all of the above

9. According to the article, the most common method of gingival retraction is the use of retraction cord, and many clinicians use the double-cord technique.
   a. True
   b. False

10. Using the thinnest retraction cord that will adequately retract tissue will _____.
    a. help avoid trauma to the tissue
    b. not be satisfactory
    c. avoid the use of too much material
    d. result in a poor impression

11. The single-cord technique for gingival retraction may not be as effective if the margins are subgingival, because the gingival tissue can rapidly collapse back over the margins when the cord is removed.
    a. True
    b. False

12. Using a double-cord technique for gingival retraction _____.
    a. can help achieve a perfect impression
    b. can prevent bleeding
    c. can prevent tissue collapse
    d. all of the above

13. The choice of tray material should be based on the _____.
    a. impression material
    b. technique used
    c. clinical situation
    d. all of the above

14. Custom trays _____.
    a. are the most reliably accurate
    b. are an unnecessary extra step
    c. are more comfortable for patients
    d. a and c

15. According to the article, a stock tray should be strongly considered if more than four to six teeth are being prepared.
    a. True
    b. False

16. The most technique-sensitive impression method for preparations is the _____.
    a. open-bite technique
    b. closed-bite technique
    c. plaster of paris technique
    d. a and c

17. The most commonly used impression materials are _____.
    a. polyethers
    b. vinyl polysiloxanes
    c. polysulfides
    d. a and b

18. ISO testing and ADA specifications require a light body impression material to replicate _____.
    a. a 20-micron line
    b. a 30-micron line
    c. a 40-micron line
    d. a 60-micron line

19. An impression material must have _____.
    a. adequate working time
    b. adequate flowability
    c. dimensional stability after setting
    d. all of the above

20. The strain-in-compression test measures _____.
    a. an impression material's flowability
    b. an impression material's set hardness
    c. an impression material's reproducibility
    d. none of the above

21. Full-arch impressions can be more easily retrieved from the mouth when using less rigid setting-tray materials.
    a. True
    b. False

22. Intraorally, VPS impressions have _____ less working time and PE impressions _____ less working time than at the lower room temperature used as the ISO standard for testing.
    a. 36%; 45%
    b. 66%; 50%
    c. 66%; 55%
    d. 75%; 60%

23. A regular set impression material is recommended _____.
    a. when preparing more than two teeth
    b. to increase working time
    c. when working in a warmer environment
    d. all of the above

24. The ability of an impression material to recover to the same shape and dimension after being deformed is tested in _____.
    a. elastic deformity
    b. elastic recovery
    c. plastic recovery
    d. none of the above

25. A material with a lower contact angle is more wettable and hydrophilic.
    a. True
    b. False

26. Modern vinyl polysiloxane impression materials have significantly increased hydrophilic properties when compared to their predecessors, with measured contact angles as low as _____ measured in _____.
    a. 3 degrees; 5 seconds
    b. 5 degrees; 10 seconds
    c. 7 degrees; 10 seconds
    d. 7 degrees; 15 seconds

27. Applying a surface modifier to dentin and other intraoral surfaces to increase wettability _____.
    a. can lead to attainment of predictable flow of impression material
    b. improves contact angles of dentin to hydrophilic impression materials (VPS)
    c. has no effect on the end result
    d. a and b

28. Using B4™ surface optimizer will_____.
    a. substantially increase the flow of impression material on dentin
    b. substantially increase the flow of impression material on other intraoral surfaces in addition to dentin
    c. not affect surface detail reproduction
    d. all of the above

29. Using a hydrophilic impression material and a surface modifier will allow time-efficient syringing of wash material and will result in a more accurate and detailed impression.
    a. True
    b. False

30. Considerations essential for achieving clinically acceptable impressions include _____.
    a. following proper protocols
    b. not exceeding the impression material's working time
    c. properly managing tissues prior to impression taking
    d. all of the above

ANSWER SHEET

Clinical and Material Factors in Achieving the Ideal Impression

Name: Title: Specialty:

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Requirements for successful completion of the course and to obtain dental continuing education credits: 1) Read the entire course. 2) Complete all information above. 3) Complete answer sheets in either pen or pencil. 4) Mark only one answer for each question. 5) A score of 70% on this test will earn you 4 CE credits. 6) Complete the Course Evaluation below. 7) Make check payable to PennWell Corp.

Educational Objectives

1. Understand the key factors involved in achieving an ideal impression
2. Be knowledgeable about techniques available for soft tissue retraction and hemostasis
3. Understand the factors involved in tray and impression material selection
4. Be knowledgeable about techniques and materials available that will enhance impression material flow

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Please evaluate this course by responding to the following statements, using a scale of Excellent = 5 to Poor = 0.

1. Were the individual course objectives met? Objective #1: Yes No Objective #3: Yes No
   Objective #2: Yes No Objective #4: Yes No
2. To what extent were the course objectives accomplished overall? 5 4 3 2 1 0
3. Please rate your personal mastery of the course objectives 5 4 3 2 1 0
4. How would you rate the objectives and educational methods? 5 4 3 2 1 0
5. How do you rate the author's grasp of the topic? 5 4 3 2 1 0
6. Please rate the instructor's effectiveness 5 4 3 2 1 0
7. Was the overall administration of the course effective? 5 4 3 2 1 0
8. Do you feel that the references were adequate? Yes No
9. Would you participate in a similar program on a different topic? Yes No
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3.	Ⓐ	Ⓑ	Ⓒ	Ⓓ		18.	Ⓐ	Ⓑ	Ⓒ	Ⓓ
4.	Ⓐ	Ⓑ	Ⓒ	Ⓓ		19.	Ⓐ	Ⓑ	Ⓒ	Ⓓ
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6.	Ⓐ	Ⓑ	Ⓒ	Ⓓ		21.	Ⓐ	Ⓑ	Ⓒ	Ⓓ
7.	Ⓐ	Ⓑ	Ⓒ	Ⓓ		22.	Ⓐ	Ⓑ	Ⓒ	Ⓓ
8.	Ⓐ	Ⓑ	Ⓒ	Ⓓ		23.	Ⓐ	Ⓑ	Ⓒ	Ⓓ
9.	Ⓐ	Ⓑ	Ⓒ	Ⓓ		24.	Ⓐ	Ⓑ	Ⓒ	Ⓓ
10.	Ⓐ	Ⓑ	Ⓒ	Ⓓ		25.	Ⓐ	Ⓑ	Ⓒ	Ⓓ
11.	Ⓐ	Ⓑ	Ⓒ	Ⓓ		26.	Ⓐ	Ⓑ	Ⓒ	Ⓓ
12.	Ⓐ	Ⓑ	Ⓒ	Ⓓ		27.	Ⓐ	Ⓑ	Ⓒ	Ⓓ
13.	Ⓐ	Ⓑ	Ⓒ	Ⓓ		28.	Ⓐ	Ⓑ	Ⓒ	Ⓓ
14.	Ⓐ	Ⓑ	Ⓒ	Ⓓ		29.	Ⓐ	Ⓑ	Ⓒ	Ⓓ
15.	Ⓐ	Ⓑ	Ⓒ	Ⓓ		30.	Ⓐ	Ⓑ	Ⓒ	Ⓓ

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Minimally Invasive Tissue Management for Restorative Procedures

A Peer-Reviewed Publication
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Educational Objectives

1. Know the factors and considerations in the placement of direct and indirect restorations.
2. Understand the reasons and pre-requisites for the successful sub-gingival placement of restoration margins.
3. Be knowledgeable concerning the various methods of gingival retraction that are available, and factors in selecting a method.

Abstract

The clinical success and longevity of restorations depend on a number of factors, including the initial accuracy of the restoration. Factors attributed to restoration accuracy have included the degree of clinical expertise; properties of impression, stone and die, and restorative materials; and the conditions under which impressions are taken and restorations completed. When restorations are placed with sub-gingival margins, it is essential that the operative site is clear of debris, dry and that the margins are accessible. This requires gingival retraction, which can be carried out using a number of methods, including retraction cord, copper bands, rubber dams, electrosurgery, and lasers, as well as polymers and pastes. Selection of the appropriate method depends on clinical demands and preferences, the individual patient, and consideration of the potential advantages and disadvantages. Ideally, gingival retraction should be quick, user-friendly, patient-friendly, painless, and inexpensive. The use of modern techniques and materials has made possible minimally-invasive and tissue-friendly gingival retraction that preserves periodontal health while enabling clear, dry access to sub-gingival margins.

Introduction

The clinical success and longevity of restorations depend on a number of factors. Although recurrent or secondary caries has been found to be a major reason for the replacement of existing restorations,[1] the materials and techniques employed at the time of restoration are key considerations in determining longevity and clinical success for both direct and indirect restorations. Factors attributed to restoration accuracy, depending on the type of restoration (direct or indirect), have included the degree of clinical expertise; properties of impression, stone and die, and restorative materials; and the conditions under which impressions are taken and restorations completed.

Restoration accuracy and longevity

Indirect restorations

Indirect restoration accuracy is influenced by a number of material and technique considerations. Impression material, setting accuracy, flow, temperature and humidity, mixing, disinfection, and time-to-pour following impression-taking have all been investigated. Polyether impressions have been shown to absorb water; their post-impression dimensional stabilities – and therefore the accuracy of the model – were found in an in vitro study to decrease with increasing humidity and higher temperatures.[2] Other studies, however, have found that the presence of water does not adversely affect dimensional accuracy of either polyether or polyvinylsiloxane impression materials, but found that polyether has a greater likelihood of producing superior impressions when water is present.[3] Studies have also found that use of appropriate agents for disinfection immersion results in polyether, polyvinylsiloxane, and addition-cured silicone impressions that have a clinically-acceptable accuracy post-immersion.[4,5] Hand-mixing and cartridge-mixing have been shown to affect shrinkage of set impressions over time, with more shrinkage occurring at extended time intervals prior to model and die-pouring.[6] Another investigation found that the investment material and number of sprues used influences the dimensional accuracy of cast restorations.[7] In addition to these considerations, the selection of restorative material must take into account occlusal forces, any paranormal habits, and the space available for the restoration vis-à-vis material strength and depth/volume. (Table 1)

Table 1. Considerations – direct and indirect restorations

Direct
- Biologic width
- Esthetics
- Restorative material(s)
- Occlusal forces and paranormal habits
- Dry, clean and accessible field for restoration placement
  - — Gingival retraction for detailed impression
  - — Hemostasis
- Technique

Indirect
- Biologic width
- Esthetics
- Restorative material(s)
- Occlusal forces and paranormal habits
- Impression material properties
- Temperature, humidity
- Disinfection of impressions
- Mixing method
- Elapsed time prior to model-pouring
- Dry, clean and accessible field for impression-taking and restoration placement
  - — Gingival retraction for detailed impression
  - — Hemostasis
- Technique
- Investment material, number of sprues

Supra-gingival restoration margins may be considered preferable for periodontal health but are frequently esthetically unacceptable and/or may be impossible due to pre-existing hard-tissue loss. As a result, restorations are placed with margins sub-gingivally in the gingival sulcus – the objectives are to achieve a long-lasting restoration that

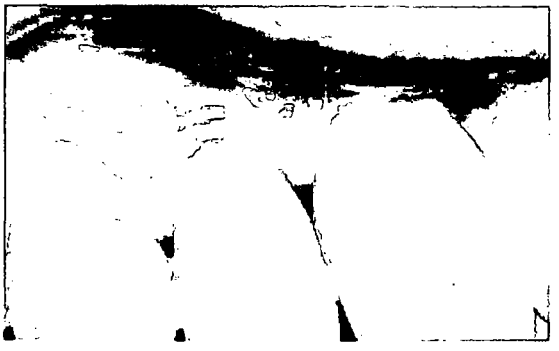
optimizes esthetics, has good marginal accuracy, maintains biologic width, and preserves periodontal health.

While the properties and selection of materials are important, margins that are free of debris, are accessible, and which impression materials can flow over and around, are a pre-requisite for detailed and accurate impressions and, ultimately, clinically-acceptable indirect restorations. Investigators have also found that the width of the gingival sulcus influences impression accuracy, with a sulcus width of more than 0.15 mm resulting in accurate impressions, and those less than 0.10 mm resulting in variable outcomes.[8]

Direct restorations

Similar considerations exist for direct class V restorations with respect to restorative material selection and technique, as well as esthetics and hard-tissue loss pre-determining sub-gingival placement of restorative margins. These, too, should respect biologic width, periodontal health, esthetics, and marginal accuracy.

Figure 1. Sub-gingival Class V carious lesion



It is critical when placing composite restorations that the field is dry to enable placement of the restoration and curing of composites. Successful placement of direct composite restorations is not possible without adequate curing. Furthermore, the degree of cure of the composite material is a determinant for leakage and marginal breakdown; one in vitro study has shown that enhanced curing reduces marginal breakdown and increases resistance to wear.[9] Gingival retraction and isolation of the operative site are essential for sub-gingival direct restoration placement and a biologically and esthetically compatible form.[10]

Gingival retraction and soft-tissue management

Regardless of all other considerations, accurate recording and restoration of sub-gingival margins is imperative for direct and indirect restorations. Optimal gingival retraction is essential.[11] Appropriate retraction enables clear visualization of the prepared tooth's sub-gingival margin; allows for accurate impression-taking apical to the margin with adequate impression material bulk between the sulcular wall and the tooth; controls crevicular seepage and bleeding; and, depending upon the preparation design, may help provide access to sub-gingival hard-tissue that must be treated due to caries or retentive/esthetic considerations.[12]

A number of retraction methods have been used, including retraction cords with and without medicaments, rotary curettage, copper bands, rubber dams, electrosurgery, lasers, and, recently, polymers and pastes. Each method offers the clinician the ability to perform gingival retraction, with selection of the appropriate method depending on clinical demands and preferences, the individual patient, and consideration of the potential advantages and disadvantages. Ideally, gingival retraction should be quick, user-friendly, patient-friendly, painless, and inexpensive – and importantly, tissue-friendly to preserve periodontal health.

Retraction cord

Retraction cords have been used for several decades and have traditionally been the most popular method. As recently as 1999, a survey of prosthodontists found that 98 percent of respondents used gingival retraction cords, with 44 percent of them using a double-cord technique.[13]

When used appropriately, retraction cord offers a quick, familiar, and inexpensive retraction method. It can be carried out with or without the addition of hemostatic agents, using either a single-cord or a double-cord technique. The double-cord technique uses two cords packed successively, with the first cord remaining in place while the impression is taken, prior to being removed. This technique is used for troughing around the preparation, to help ensure a detailed impression as well as an adequate biologic width of the final restoration.[14] It employs two knitted cords of different diameters and is considered safe and effective, provided periodontal health is good. However, it has also been recommended that where possible, the finish lines should be placed supra-gingivally when using this method.[15] With the single-cord technique, a single retraction cord is placed in the sulcus and if an impression is being taken, the cord is removed prior to this occurring. A disadvantage of the single-cord technique is that if preparation margins are in a deep sulcular area, the gingival soft-tissue can collapse over the margins making accurate restoration placement or impression-taking impossible.

The use of gingival retraction cord is technique-sensitive and requires expertise. Problems encountered include the parting of cord fibers, shredding, and cord damage or displacement when using the packing instrument or while using a bur at the margin.[16] Tissue damage may also occur, with friable thin gingival tissue particularly susceptible and subject to tearing. While packing the cord, there is a risk of damaging the epithelial attachment and/or exacerbating gingival recession and bleeding. Retraction cord use can result in tissue recession, and the double-cord technique may cause unpredictable tissue recession and patient

discomfort.[17] A 2007 investigation has found that acute, gingival tissue damage occurs with use of retraction cords, with demonstrable increases in the levels of tumor necrosis factor (alpha) (TNF-alpha) in the gingival crevicular fluid. Nonetheless, the same study also found that the damage healed clinically within two weeks.[18]

The use of hemostatic agents with retraction cords helps prevent gingival bleeding that may occur during packing or removal of the cord[19] and helps maintain a clear, dry operative site for cord-packing and impression-taking. Hemostatic agents in retraction cords include epinephrine, aluminum chloride, and ferric sulfate and, depending upon the particular cord, it may have been pre-treated or soaked at the time of placement.[20,21] Aluminum chloride has been found to be more commonly used than epinephrine: 33 percent of respondents in one survey reported side effects associated with epinephrine use, the most common being an increased pulse rate, with 24 percent reporting side effects from other medicaments used with retraction cords.[22] Use of epinephrine provides prolonged gingival vasoconstriction, but the use of aluminum chloride and ferric sulfate has been associated with hyperemia and bleeding upon cord removal.[23] However, epinephrine use is problematic in patients with cardiovascular disease and may interact with cardiovascular medications used to control the disease.[24]

Copper bands and impression copings

The use of copper bands, as well as impression copings for cast restorations, results in isolation of the site and obviates the need for gingival retraction using retraction cord or other techniques. As with retraction cords, copper bands have been used for a number of decades. Their use requires selection of copper band size, and careful trimming and fitting of the copper band prior to impression-taking. (Figure 2) Copper bands are inexpensive, readily-available, and with appropriate use are unlikely to result in tissue damage and recession. However, this method is technique sensitive, and the sharp margins of the copper band may exacerbate gingival bleeding; the bands do not incorporate a hemostatic agent and can cause patient discomfort without the use of local anesthesia.

Figure 2. Copper band

Cast impression copings function similarly to copper bands, fitting over the preparation finish line. They do not require trimming, nor do they have the sharp margins associated with copper-band use; they can capture margins and provide accurate, detailed impressions without using gingival retraction. However, they must be individually fabricated, involving an extra step.[25] By their very nature, cast impression copings are only used for indirect restorations, and both these and copper bands are unsuitable for direct restorations.

Rubber dams

Rubber dams help prevent operative-site exposure to oral micro-organisms and intraoral fluids. By using modified retention and a modified technique with placement of the rubber dam apical to the retainer after the retainer has been positioned on the tooth, rubber dams have been found to be effective in providing gingival retraction and thorough isolation of Class V restorative sites with sub-gingival margins, and help avoid damage to periodontal tissues.[26,27] This technique is intended for class V restorations and is unsuitable for impression-taking and indirect restorations.

Rotary curettage

Rotary curettage uses burs to create a trough in the sulcus around the finish line. It can result in bleeding at the site, requires local anesthesia to prevent patients from experiencing discomfort, and can be used for both direct and indirect restorations.

Electrosurgery

Electrosurgery is a modified cautery technique, utilizing an electric current passed to fine wire contacts that removes soft-tissue and creates a trough in the gingival sulcus adjacent to the finish line. One study found no difference in tissue response at four, eight, and twelve weeks between electrosurgery and bur (rotary curettage) methods.[28] A separate study found both electrosurgery and rotary curettage produced unpredictable results.[29] With clinical expertise, this method offers predictable troughing and tissue responses, with good exposure of margins for impression-taking and restorative techniques. It has also been shown to provide for more impression material bulk in the sulcus than a bur method.[30] Electrosurgery requires local anesthesia, and in addition to exposing the finish line and creating a trough, it also helps prevent bleeding at the site (Figures 3 and 4).

Figure 3. Gingival bleeding, sub-gingival preparation margin

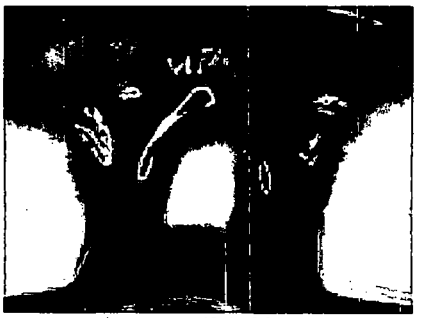


Image courtesy of Dr. Ian E. Shuman

Figure 4. Use of an electrosurgery tip (Bident) to expose margins, stop bleeding

Image courtesy of Dr. Ian E. Shuman

Lasers

The introduction of dental lasers has offered dental professionals many options in operative techniques, including their use as a gingival retraction method. Lasers produce a high-energy, collimated beam of light that is converted into thermal energy. They predictably vaporize tissue at 100 to 150 degrees Celsius, create an adequate trough and retraction that permits detailed and accurate impressions, and preserve biologic width. (Figures 5, 6, and 7) Erbium-based lasers are absorbed on the surface and the Nd:YAG series energy is absorbed deeper in the tissues.[31] A third type of laser, the diode laser (Odyssey, Vivadent), is also utilized for soft-tissue procedures. Their use results in minimal or no intra-operative and post-operative discomfort, and is not associated with tissue recession seen with the use of the double-cord gingival retraction method. In addition, lasers offer hemostasis and can be used in many patients without anesthesia.[32,33] In comparing the use of a pulsed Nd:YAG laser with retraction cord soaked in either aluminum chloride or ferric sulfate, it has also been found that the laser's use resulted in less bleeding, less tissue inflammation, faster healing than either retraction cord, and was painless, simple, and convenient. Laser use is suitable for both indirect and direct restorations in offices that have laser units.[34] In a survey of laser users, 79 percent of respondents indicated that they used lasers for gingival retraction/troughing.[35] Lasers, such as the Waterlase™ YSGG Laser (Biolase), also offer the potential to complete the hard-tissue preparation and soft-tissue management with one instrument and in some cases without the use of anesthesia.[36]

Figure 5. Crown preparation with bleeding, sub-gingival margins prior to impression-taking

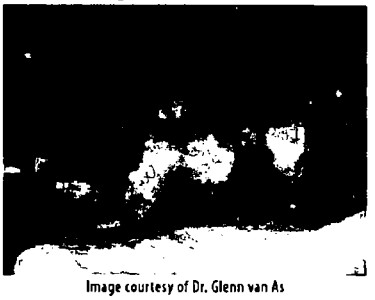


Image courtesy of Dr. Glenn van As

Figure 6. Use of a diode laser (Odyssey, Vivadent)

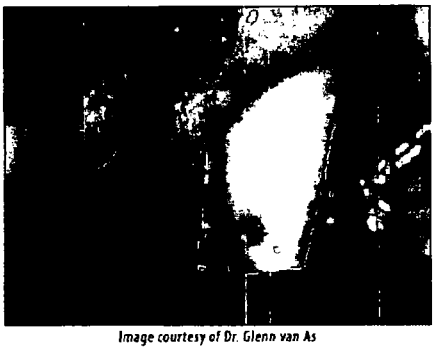


Image courtesy of Dr. Glenn van As

Figure 7. Final impression showing clear margin details

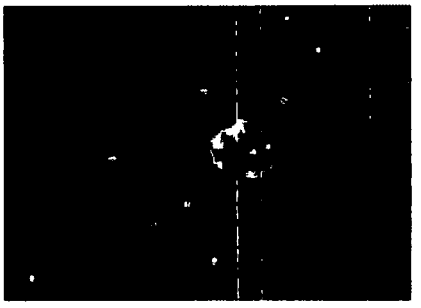


Image courtesy of Dr. Glenn van As

Polymers and pastes

Polymers and pastes have also been recently introduced as gingival retraction methods. Studies have shown that the use of polymers with a sponge-like texture cut into 2-mm strips is an effective method. The polymer swells when exposed to moisture and gently pushes the gingival tissue away from the finish line, enabling detailed impression-taking. In addition, it was found that the gingivae returned to a normal position within twenty-four hours. [37] Merocyl strips were found to be effective at expanding gingival tissue and exposing the margins of preparations for impression-taking.[38]

A recent technique uses a paste (Expasyl™) that provides for gingival retraction and hemostasis. Expasyl™ consists of an organic, clay material (kaolin), mixed with aluminum chloride as a hemostatic agent. The paste is thick, firm, and viscous to enable easy and quick tissue displacement, and the aluminum chloride controls bleeding simultaneously. It is injected directly into the sulcus from a pre-loaded syringe at a recommended rate of 2 mm per second, using even pressure. (Figure 8) If necessary, this can be followed by gently tamping on the paste with a plastic instrument or cotton pellet to ensure the paste is fully in the sulcus. The paste is left in the sulcus for one to two minutes if the tissue is thin, or three to four minutes if the soft-tissue is thicker. After this time, the sulcus will be expanded, and the paste should be removed by gently rinsing and then drying the site prior to impression-taking or restoration placement. (Figure 9a and b)

Figure 8. Expasyl™ injected into the gingival sulcus

Figure 9a. After Expasyl™ removal

Figure 9b. After Expasyl™ removal

Once the material has been applied and absorbs moisture, there is no chemical reaction, material expansion, or trauma to the tissue; hemostasis is achieved, and the material should be isolated from additional moisture, such as saliva. If necessary, the process can be repeated without traumatizing the tissue.

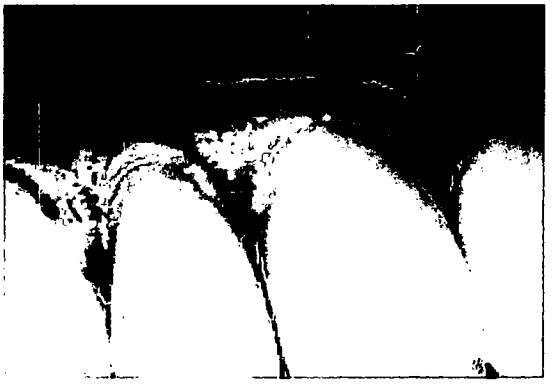
This paste system is suitable for gingival retraction prior to impression-taking (Figure 10) and final indirect restoration placement. Gingival retraction will last for four minutes after the Expasyl™ has been rinsed and removed from the site.

Figure 10. Final impression with clear margin details

It can also be used prior to direct Class V restoration to prevent gingival seepage and bleeding, and to widen the sulcus, enabling a composite of the appropriate dimension to be placed and cured. (Figures 11 and 12)

Figure 11. Expasyl™ placement

Figure 12. Final direct composite restorations



Gingival retraction cord, electrosurgery, and laser surgery are more-traditional options. However, these result in varying degrees of tissue trauma, depending on clinical experience. The risk of gingival recession and bone resorption, linked to damage to the epithelial attachment, is eliminated using the minimally-invasive tissue management offered by the paste retraction method.[39] It has been found to reduce chairside time required for retraction prior to impression-taking and restoration placement, and reduces soft-tissue trauma as well.[40,41] Time savings of up to 50 percent have been reported with its use.

A polyvinylsiloxane expandable gingival retraction paste is available (Magic FoamCord Gingival Retraction System). This is also applied around the preparation margins using a pre-loaded syringe. After syringing the material around the margins, a cap (Comprecap) is used over the material and tooth – this is used to apply pressure for 5 minutes to obtain gingival retraction. The impression is

Table 2. Comparison of gingival retraction methods

	Application method	Traumatic to tissue	Requires pressure	Requires tray or cap	Provides hemostasis	Time taken
Retraction cord	Packing into sulcus	Yes	No	No	Yes/No	Up to 5 minutes
Copper band	Trim and apply band	Yes	No	No	Yes, by isolating site	Up to 5 minutes
Rubber dam	With clamp/floss	No	No	No	Yes, by isolating site	Up to 5 minutes
Rotary Curettage	Direct	Yes	No	No	No	Up to 5 minutes
Electrosurgery	Direct	Yes	No	No	Yes	3 to 5 minutes
Laser surgery	Direct	Yes	No	No	Yes	3 to 5 minutes
Gingival retraction paste						
Expasyl™	Syringe	No	No	No	Yes	2 to 4 minutes
Magic FoamCord	Syringe	No	Yes	Yes	No	5 minutes
GingiTrac™	Syringe	No	Yes	Yes	Yes/No	5 minutes

taken after the paste has been removed. This paste does not contain a hemostatic agent, and hemostasis must be obtained prior to applying the paste and cap.

A third gingival retraction paste system (GingiTrac™) also uses a pre-loaded syringe to apply the paste around the margins. The paste contains an astringent, and if necessary a hemostatic agent can be applied prior to the application of GingiTrac™. For single tooth use, a cap (GingiCap™) is used to apply pressure for up to 5 minutes after the paste has been applied. The cap is first filled with the paste, then placed over the tooth and paste syringed around the margins. (Figures 13 and 14) For multiple tooth preparations, a plastic tray is first used with a firm paste matrix over which the GingiTrac™ paste is syringed before the tray is placed over the arch and held in position for 3-5 minutes. For both single tooth and multiple tooth preparations, gingival retraction is achieved through the application of pressure prior. The paste is removed prior to impression-taking.

Figure 13. Application of retraction paste and cap

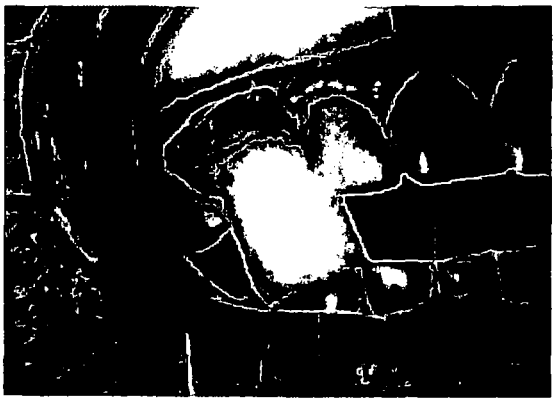
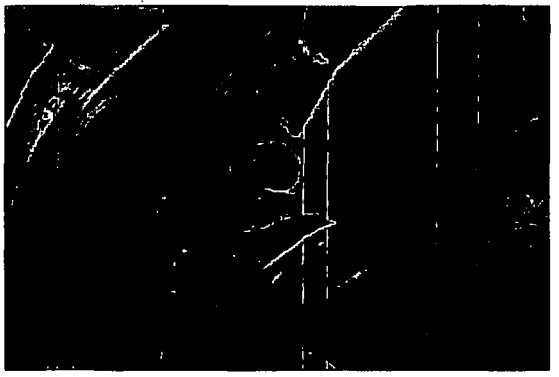


Figure 14. Preparation margins after removal of paste and cap.



Summary

The multi-faceted benefits and indications of tissue management render it an important process in assessing clinical success. Traditional gingival retraction methods include retraction cords, copper bands, electrosurgery and more recently laser surgery. In addition, pastes have been introduced that function as gingival retractors. Depending upon the paste system used, the time taken is typically 2 minutes for paste not requiring use of caps or a tray matrix (Expasyl™) and up to 5 minutes for paste systems using caps or trays to apply pressure (Magic FoamCord; GingiTrac™) In selecting a method for tissue management during restorative procedures, it is incumbent upon clinicians to consider the advantages and disadvantages of each method, the individual case and patient, and to strive for minimally-invasive methods that optimize the procedural site for impression-taking and restoration placement, while at the same time preserving periodontal health. Recent innovations have made minimally-invasive soft-tissue management an achievable reality during restorative procedures.

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Author Profile

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Questions

1. Considerations in the longevity and clinical success of restorations include _____.
   a. the materials employed
   b. the techniques employed
   c. the presence of a HEPA filter
   d. a and b

2. _____ is a factor in determining post-impression dimensional stability of impressions.
   a. Humidity
   b. Impression flow
   c. Mixing of impression material components
   d. All of the above.

3. Supra-gingival restoration margins _____.
   a. are preferable to sub-gingival restoration margins under all circumstances
   b. may be esthetically unacceptable
   c. may be impossible due to pre-existing hard-tissue loss
   d. b and c

4. Margins that are accessible and free of debris are a pre-requisite for detailed and accurate impressions.
   a. True
   b. False

5. Both direct and indirect restorations should respect _____.
   a. biologic width
   b. periodontal health
   c. esthetics
   d. All of the above.

6. _____ is a determinant for leakage and breakdown of composite margins.
   a. The choice of cavity liner
   b. The degree of cure of the composite material
   c. Using an impression material
   d. None of the above.

7. Appropriate gingival retraction _____.
   a. enables clear visualization of sub-gingival margins
   b. allows for accurate impression-taking
   c. controls crevicular seepage
   d. All of the above.

8. Gingival retraction methods include the use of _____.
   a. gingival retraction cord
   b. polymers and pastes
   c. lasers
   d. All of the above.

9. A 1999 survey found that _____ of prosthodontists use gingival retraction cord.
   a. 35 percent
   b. 63 percent
   c. 98 percent
   d. 100 percent

10. Retraction using gingival retraction cord can be carried out _____.
    a. with or without the addition of hemostatic agents
    b. using a double-cord or single-cord technique
    c. more quickly than any other gingival retraction method
    d. a and b

11. The double-cord gingival retraction technique _____.
    a. is considered safe and effective provided periodontal health is good
    b. is clinically-proven to be the least time-consuming method of gingival retraction
    c. involves the use of two retraction cords placed into the gingival sulcus, one after the other
    d. a and c

12. The use of copper bands is _____.
    a. expensive, redundant and still always requires the use of retraction cord
    b. inexpensive, technique sensitive, and with appropriate use unlikely to result in tissue damage or recession
    c. the most popular method, used routinely in the dental office
    d. a and c

13. A modified rubber dam technique that involves placing the rubber dam apical to clamps after these are placed, is suitable for _____.
    a. crown and bridge preparation margins
    b. crown and bridge, and Class V restoration, preparations
    c. only Class V restorations
    d. None of the above.

14. With clinical expertise, electrosurgery offers _____.
    a. predictable troughing
    b. a predictable tissue response
    c. good exposure of margins
    d. All of the above.

15. Electrosurgery _____.
    a. exposes the preparation margins
    b. helps prevent bleeding at the site
    c. never requires anesthesia
    d. a and b

16. Lasers expose gingival margins by _____.
    a. abrading tissue
    b. vaporizing tissue
    c. eroding tissue
    d. None of the above.

17. At 150° Celsius, gingival soft-tissue is _____.
    a. molten
    b. calcified
    c. vaporized
    d. All of the above.

18. Lasers used for gingival retraction _____.
    a. offer hemostasis
    b. may be able to be used without anesthesia
    c. are suitable for both direct and indirect restorations
    d. All of the above.

19. A recently introduced paste (Expasyl™), used for gingival retraction, _____.
    a. is applied using a pre-loaded syringe
    b. provides hemostasis
    c. contains epinephrine
    d. a and b

20. The use of hemostatic agents in gingival retraction paste containing kaolin (Expasyl™) _____.
    a. is contraindicated
    b. controls bleeding
    c. ensures that pressure and hemostatic agents will be used to control bleeding
    d. b and c

21. Expasyl™ should remain in the sulcus while an impression is being taken.
    a. True
    b. False

22. Kaolin-containing gingival retraction paste _____.
    a. absorbs moisture after application and reacts chemically until it is removed
    b. does not react chemically after being applied
    c. absorbs moisture after application, and after this there is no chemical reaction
    d. is contraindicated if moisture is present

23. Polyvinylsiloxane gingival retraction paste _____.
    a. is applied using a pre-loaded syringe
    b. requires the application of a cap over the paste and pressure for gingival retraction
    c. does not contain a hemostatic agent
    d. All of the above.

24. Some of the gingival retraction pastes discussed in the article should remain in place while an impression is taken.
    a. True
    b. False

25. GingiTrac™ gingival retraction paste _____.
    a. is applied using a pre-loaded syringe
    b. requires the application of pressure for gingival retraction
    c. can only be used for single tooth preparations
    d. a and b

26. If using GingiTrac™, a tray loaded with a heavy matrix _____.
    a. is used with multiple-tooth preparations
    b. is never necessary
    c. involves the use of composition that must be heated prior to use
    d. a and c

27. Concerning the three paste methods for gingival retraction discussed in the article, _____.
    a. all contain a hemostatic agent
    b. all are equally quick to use
    c. all use pre-loaded syringes
    d. All of the above.

28. Expasyl™ has been found to be minimally-invasive, as have Magic FoamCord and GingiTrac™, and to eliminate the risk of damage to the epithelial attachment.
    a. True
    b. False

29. In assessing the various methods of gingival retraction, it is incumbent upon clinicians to _____.
    a. consider the advantages and disadvantages of each method
    b. consider the individual case and patient
    c. use a slow method to ensure adequate gingival retraction
    d. a and b

30. Recent innovations have made minimally-invasive tissue management during restorative procedures _____.
    a. achievable
    b. no longer a consideration
    c. take more time
    d. None of the above.

ANSWER SHEET

Minimally Invasive Tissue Management for Restorative Procedures

Name:			
Title:	Specialty:		
Address:		E-mail:	
City:		State:	ZIP:
Telephone: Home ( )		Office ( )	

Instructions to obtain dental continuing education credits: 1) Complete all information above. 2) Complete answer sheets in either pen or pencil. 3) Mark only one answer for each question. 4) Successful completion of this course will earn you 4 CEUs. 5) A blank duplicate answer sheet may be copied for additional course participants.

Mail completed answer sheet to
Academy of Dental Therapeutics and Stomatology
P.O. Box 116, Chesterland, OH 44026
(216) 398-7822

For IMMEDIATE results, go to www.ineedce.com and click on the button "ENTER Answers Online." Answer sheets can be faxed with credit card payment to (216) 255-6619, (440) 845-3447, or (216) 398-7922.

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1. How would you rate the objectives and educational methods?
   5 4 3 2 1 0
2. To what extent were the course objectives accomplished?
   5 4 3 2 1 0
3. Please rate the course content.
   5 4 3 2 1 0
4. Please rate the instructor's effectiveness
   5 4 3 2 1 0
5. Was the overall administration of the course effective?
   5 4 3 2 1 0
6. How do you rate the author's grasp of the topic?
   5 4 3 2 1 0
7. Do you feel that the references were adequate?
   Yes No
8. Do you feel that the educational objectives were met?
   Yes No
9. If any of the continuing education questions were unclear or ambiguous, please list them.

   _____

10. Was there any subject matter you found confusing? Please describe.

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11. Would you participate in a program similar to this one in the future on a different topic? Yes No
12. What additional continuing dental education topics would you like to see?

    _____

1.	Ⓐ	Ⓑ	Ⓒ	Ⓓ		16.	Ⓐ	Ⓑ	Ⓒ	Ⓓ
2.	Ⓐ	Ⓑ	Ⓒ	Ⓓ		17.	Ⓐ	Ⓑ	Ⓒ	Ⓓ
3.	Ⓐ	Ⓑ	Ⓒ	Ⓓ		18.	Ⓐ	Ⓑ	Ⓒ	Ⓓ
4.	Ⓐ	Ⓑ	Ⓒ	Ⓓ		19.	Ⓐ	Ⓑ	Ⓒ	Ⓓ
5.	Ⓐ	Ⓑ	Ⓒ	Ⓓ		20.	Ⓐ	Ⓑ	Ⓒ	Ⓓ
6.	Ⓐ	Ⓑ	Ⓒ	Ⓓ		21.	Ⓐ	Ⓑ	Ⓒ	Ⓓ
7.	Ⓐ	Ⓑ	Ⓒ	Ⓓ		22.	Ⓐ	Ⓑ	Ⓒ	Ⓓ
8.	Ⓐ	Ⓑ	Ⓒ	Ⓓ		23.	Ⓐ	Ⓑ	Ⓒ	Ⓓ
9.	Ⓐ	Ⓑ	Ⓒ	Ⓓ		24.	Ⓐ	Ⓑ	Ⓒ	Ⓓ
10.	Ⓐ	Ⓑ	Ⓒ	Ⓓ		25.	Ⓐ	Ⓑ	Ⓒ	Ⓓ
11.	Ⓐ	Ⓑ	Ⓒ	Ⓓ		26.	Ⓐ	Ⓑ	Ⓒ	Ⓓ
12.	Ⓐ	Ⓑ	Ⓒ	Ⓓ		27.	Ⓐ	Ⓑ	Ⓒ	Ⓓ
13.	Ⓐ	Ⓑ	Ⓒ	Ⓓ		28.	Ⓐ	Ⓑ	Ⓒ	Ⓓ
14.	Ⓐ	Ⓑ	Ⓒ	Ⓓ		29.	Ⓐ	Ⓑ	Ⓒ	Ⓓ
15.	Ⓐ	Ⓑ	Ⓒ	Ⓓ		30.	Ⓐ	Ⓑ	Ⓒ	Ⓓ

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TISMGT0705PAT

Pharmaceutical Chemistry Journal *Vol. 40, No. 7, 2006*

SEARCH FOR NEW DRUGS

LOCAL HEMOSTATICS (A REVIEW)

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Translated from Khimiko-Farmatsevticheskii Zhurnal, Vol. 40, No. 7, pp. 9 – 15, July, 2006.

Original article submitted March 9, 2006.

Information on the hemostatic agents of local action, which are most widely used in leading countries of the world, is summarized. The mechanisms of action of various local hemostatics are considered and possible variants of their combinations in particular ready-to-use drugs are presented.

This review is intended to generalize data concerning the use of drugs with various structures and mechanisms of action, as well as their combinations for the arrest of local bleeding. Local hemostatics can be, albeit quite conditionally, classified into the following groups:

(1) Agents producing vasoconstrictive and proaggregant effects;

(2) Compounds inducing the transition of blood proteins into solid state and reducing vessel permeability by means of protein denaturation;

(3) Compounds stimulating the aggregation and adhesion of formed elements and accelerating fibrin formation;

(4) Plasma coagulation factors;

(5) Fibrinolysis inhibitors;

(6) Combined preparations.

A close classification was proposed by Krylov et al. [1]. Drugs of the first group decrease the blood flow via collateral ways (bypass channels, which provide blood flow in cases of thrombosis). This group is represented by adrenaline (epinephrine), vasopressin, desmopressin, terlipressin, and pituitrin.

Epinephrine finds rather limited use as a hemostatic, predominantly in dentistry. The hemostatic properties of this compound are related to the action upon α_1 adrenoreceptors of vessel walls, which produces vasoconstriction and stimulates blood platelet (thrombocyte) aggregation that leads to a decrease in hemorrhage [2]. Epinephrine is mostly used as a component in various solutions, pastes, gels, etc., and is rarely use in pure form. Disadvantages of this drug are the short time of action (5 – 10 min) and restricted field of possible applications (several manipulations in dentistry, skin transplantation, endoscopic arrest of bleeding from veins in the gastrointestinal tract (in combination with cyanoacrylates) [3], and low specific activity.

Vasopressin has been used as a vasoconstrictor for the treatment of portal hypertension and related complications, beginning from the 1970s. However, it was soon established that the use of this hemostatic in about half of cases is accompanied by side effects, including serious heart rhythm violations, myocardial infarction, and acute disturbances in cerebral circulation [4]. The interest in this group of hemostatics was restored due to the implementation of terlipressin – a synthetic vasopressin analog, which has increased half-elimination time that makes unnecessary continuous intravenous infusion.

Another important feature in the drug pharmacokinetics is the slow biotransformation of terlipressin into vasopressin in tissues, which facilitates the creation of its high local concentration (at a low concentration in the overall blood flow, which reduces the risk of undesired systemic effects) [5].

Desmopressin is a derivative of vasopressin, which (i) stimulates the release of endogenous factor VII, Willebrand's factor and tissue plasminogen activator, (ii) increases platelet adhesion, and (iii) reduces hemorrhage duration [6]. This compound is effective in patients suffering from hemophilia A, Willebrand's disease, and inherited or acquired platelet dysfunction, as well as in cases of acetylsalicylic acid (or some other antiaggregant) overdose [7]. Desmopressin is available in the form of spray for the arrest of nasal bleeding.

Pituitrin, comprising a mixture of oxytocin and vasopressin, is used for the treatment of hemorrhage accom-

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0091-150X/06/4007-0353

panying esophageal varicose vein dilatation [8, 9]. A close hemostatic action is produced by serotonin [10 – 12]. In addition to the vasoconstrictive action, epinephrine, vasopressin, and serotonin stimulate platelet aggregation. A common disadvantage of drugs representing this group is a relatively short hemostatic action and low specific activity.

The group of local hemostatics reducing vessel permeability by means of blood protein denaturation, which is accompanied by their transition into the solid state, contains a large subgroup of inorganic metal compounds. Among these, the most interesting agents are the salts of lead (acetate), bismuth (basic nitrate and subgallate), zinc (oxide and sulfate), copper (sulfate), silver (nitrate), and iron (feracryl). The drug kataluhem, containing aluminum chloride hexahydrate and katamin AB (alkyldimethylbenzylammonium chloride), exhibits hemostatic and antibacterial effects and is used in dentistry [13].

The international pharmaceutical market offers a number of mineral hemostatics, which are widely used in dentistry for the arrest of bleeding, including rascstiptin or septodont (containing aluminum chloride and hydroxyquinoline sulfate), imodent (containing 21.3 % aluminum chloride), rastrigent (25 % aluminum sulfate solution), and stasis (aqueous iron sulfate solution). These drugs are rather expensive and did not find wide use in Russia. Pastes containing zinc chloride and 5 – 10 % copper sulfate solutions were used for the arrest of bleeding accompanying trophic gingivitis [14]. Another widely used hemostatic preparation is the Moncel solution (containing 20 % iron sulfate). The presence of subsulfate groups and the low pH of this solution induce protein denaturation and favor the occlusion of blood vessels [15].

The aforementioned hemostatic feracryl is an incomplete iron salt of polyacrylic acid, which contains 0.05 – 0.5 % of iron. Being an acid polyelectrolyte, feracryl forms insoluble polycomplexes with various proteins (including blood proteins) at pH 2.9 – 4.0. A method has been developed and successfully used for the endoscopic introduction of this compound in cases of esophageal gastroduodenal hemorrhage of various genesis. Feracryl is used as aqueous and alcohol solutions with concentrations from 1 to 10 %, as well as in the form of a hemostatic plaster. This plaster exhibits stable activity and does not produce local irritation and autoallergic action. It was reported that feracryl also possesses antibacterial properties [16]. Iron-containing polyacrylic acid was also used as a basis for a hemostatic glue composition (hemocompact), which is used in the clinic [17].

A special position among protein hemostatic agents belongs to collagen, which is one of the main structural proteins in the organism. In cases of vessel damage, subendothelial collagen interacts with its principal receptors on thrombocytes. This interaction leads to thrombocyte activating and spreading over subendothelium. The adhesion stage is followed by the aggregation of activated thrombocytes and the creation of an active surface for the stimulation of plasma hemostasis that leads to fibrin formation [18 – 21].

Hemostatic collagen preparations are available in the form of powders (aviten), solutions (collost), fibrous mass (collastipt), and fibrin-collagen pastes and sponges (collastat, tachotop, conbutec-2, digispon, super-4, androxon, bcriplast, hemostatic collagen sponge, stimul-oss, gentacol, collagresorb) [22 – 29]. Collagen preparations are an indispensable hemostatic aid in various surgical operations, treatment of postoperation and traumatic wounds, and arrest of bleeding.

In order to stimulate the phospholipid-dependent blood coagulation process and increase the adhesion of formed blood elements, a hemostatic composition (thrombocol) has been developed on the basis of a collagen plate impregnated with thrombocytes. Thrombocol showed high hemostatic activity and was successfully used for hemorrhage arrest in surgery and dentistry [30]. Another complex preparation, based on collagen and hydroxyapatite (representing a mixture of powder, granules, and ceramic fragments) was proposed for hemorrhage arrest and the treatment of wounds of various etiology (in particular, in bones) [31]. Much interest was also attracted to the creation of hemostatic preparations based on gelatin (a product of partial hydrolysis of collagen, contained in cartilage and bone tissues of animals). Homeostatic gelatin preparations can be in the form of powder, pastes, gels, pads, and sponges.

Considerable research effort was devoted to the development of hemostatic preparations based on polysaccharides, in particular, cellulose. A highly oxidized cellulose patented in [32] can be used as a nontoxic hemostatic agent possessing antimicrobial and wound-healing properties. Cellulose and its derivatives have been used for a long time in the form of sponges (sterispan, spongostan, gelfoam, spongipost, spongel, surgical) [33 – 35]. Cellulose sponge was successfully used for the treatment of moderate uterine bleeding during cesarian section and tooth extraction operations [36]. Oxycellodex is a mixed hemostatic preparation comprising oxidized glucose powder with 20% of polyglucin, which is intended for the treatment of bleeding from small blood vessels and capillaries. The film of oxycellodex applied onto the surface of an organ dissolves within one to two weeks, not increasing the wound healing time. The mechanism of its hemostatic action is related to the stimulation of platelet aggregation, followed by the formation of an erythrocyte – hydroxycellulose thrombus possessing adhesive properties [37]. A mixture of viscose with crystalline mirabilite was used to obtain a cellulose-based sponge, which exhibited high adsorption capacity, good mechanical strength, and the ability to retain shape [38 – 40].

The use of cellulose-based hemostatic preparations has certain limitations. They cannot be used for drying and swabbing purposes after bleeding arrest. Once this goal is achieved, such hemostatics have to be removed from the regions surrounding damaged bones, bone marrow, optic nerves, and chiasm. Otherwise, the swelling of cellulose can lead to dangerous compression of these structures. Such preparations are not intended for the arrest of bleeding from large vessels [41, 42].

Extensive investigations into the hemostatic properties of chitin and chitosan began more than three decades ago [43]. A mechanism of the hemostatic action of chitosan is related to the ability of its positively charged molecules to attach to negatively charged membranes of blood cells, which leads to cell aggregation and plasma homeostasis activation. It was found that chitosan from shrimps adheres well to wounds and induces rapid blood coagulation even in patients suffering from hemophilia. A series of wound dressings based on collagen – chitosan complexes with various antiseptic drugs has been developed (collachit, collachit FA, collachit Sh, etc.), which are now widely used for hemostatic and wound healing purposes [44].

A promising direction of research is the development of polymeric materials based on algic acids. It was shown that pronounced hemostatic properties are inherent in zinc alginates [45]. The hemostatic properties of alginates are related to their ability to accelerate the polymerization of fibrin monomers — the final stage of blood coagulation — due to the carboxy groups in algic acid molecules [46]. The mechanisms of the hemostatic action of alginates include, in addition to gel formation upon contact with blood, the ability to favor the aggregation of blood formed elements (in particular, erythrocytes). The most widely used alginate based hemostatics are sorbsan, caltostat, sorbalgon, salgitex, and xamalgan [47]. Successful applications of alginate-based hemostatics were reported in otorhinolaringology [48], dentistry [49], proctology [50], and skin transplantology [51].

Hemostatic preparations may also contain the aforementioned hydroxyapatite cyanoacrylate, as well as synthetic polymers. To the present, various hemostatic compositions involving synthetic polymers have been created, a typical example being offered by gelevin — a powder adsorbent based on poly(vinyl alcohol (PVA) [52]. Gels with hydroxyapatite can be used for the treatment of bleeding from bone tissues [53]. Good hemostatic properties with minimum side reactions were reported for the polysaccharide polymer N-acetylglucosamine, which was recommended for wide use in various fields of surgery [54]. The results of experiments on pigs [55] showed that a synthetic polyethylene-based hydrogel can be used as an effective local hemostatic in laparoscopic nephrectomy.

Local hemostatics belonging to the group of cyanoacrylate glues have been developed in the USA (sitman), Germany (histacryl), Japan (aronalf), and Russia (M-1 – M-3, MK-2, M-6. etc.) [56, 57]. These preparations are based on monomer esters of cyanoacrylic acid. Since the polymerization of cyanoacrylates proceeds without volume changes, these hemostatics can be used as fillers of tissue defects. The mechanism of their action consists in creating a mechanical barrier for blood flow, which is related to the high adhesive properties. The polymer is not decomposed and the film is retained on the organism. Cyanoacrylate preparations were recommended for use in vascular and thoracic surgery [58]. Good hemostatic properties were also reported for a hydroxyacrylic glue containing cyanacrylate [59], which was recommended for use in dentistry – in particular, in patients receiving warfarin [59]. Recently, a glue composition created on the basis of acrylate latex was reported to be effective in abdominal operations [60]. Attempts to use poly(tetrafluoroethylenes) as hemostatics in surgical operations involving small vessel showed that the hemostatic effect is less pronounced compared to that of powdered gelatin, oxidized cellulose, and microcrystalline collagen [61].

Historically, the concept of using a blood clot for blocking hemorrhage from parenchymatous organs was formulated at the beginning of the 20th century. Blood preparations possess pronounced hemostatic properties, are readily sterilized, retain this activity for a long time, and exhibits fully decomposition (resorption) in tissues of the organism. In attempts to achieve local hemorrhage arrest by introducing various blood coagulation factors into wounds, numerous experiments were performed using thrombin-containing preparations [62]. In addition to the conversion of fibrinogen into fibrin, thrombin is a powerful activator of platelet aggregation and adhesion [63]. Because of the intense prothrombogenic action, thrombin is used only as a local hemostatic, in particular, to arrest hemorrhage from small vessels, capillaries, and parenchymatous organs (in patients with cerebrocranial traumas, after operations on the liver, kidneys, and other parenchymatous organs, and in cases of bleeding from the bone cavity, gum, etc.). Thrombin solutions prepared from donor blood is used in ophthalmology, in particular, during vitrectomy operations in the prophylaxis and treatment of intraoperative hemorrhage [64]. Local introduction of thrombin, as an alternative to surgical operation, can be used for the treatment of pseudoaneurism [65]. Thrombin powder can be used in dentistry for the treatment of local hemorrhage in patients with inherited and/or acquired defects in the blood coagulation system [66].

Thrombin is effective for the treatment of various hemostasis disorders except for the cases of acute hypo- and afibrinogenemia (in cases of blood coagulation dysfunction, solutions are less effective than powdered forms). Patented thrombin-containing hydrogel [67] was proposed for hemorrhage arrest. In order to prevent rapid thrombin leaching by the bloodstream, it was suggested to introduce thrombin into collagen and gelatin pastes and sponges [68 – 72] and to impregnate textile carriers [73]. In recent years, an original system was developed in which a thrombin layer is sandwiched between fibrinogen films [74 – 76]. It was reported that a hemostatic system for rapid arrest of mixed hemorrhage cases was created by thrombin and fibrinogen immobilization on a bioadsorbable unwoven material [75].

A hemostatic effect with a mechanism close to that of thrombin action is produced by the poisons of some snakes (*Botrops atrox*, *Notechs csutaius*, *Oxuranus scutellatus*) and by filtrates of *St. aureus* cultures used a basis for the preparations of botropase, reptilase, hemocoagulase, stipven, crotolase, batroxobin, and staphyllocoagulase [77], representing nonphysiological thrombin activators. Botropase only splits fibrinopeptide A from fibrinogen molecule, which

leads to the appearance of a fibrin monomer and the development of a weak thromboplastin activity. Reptilase converts fibrinogen into fibrin and, in addition, activates factors II, VII, X, and XIII.

The addition of thrombin to fibrin led to various effective local hemostatic preparations such as fibrin cotton, fibrin sponge, fibrin paper, fibrin foams, and fibrin films [78]. Also widely used in medicine are fibrin glues (biocol, besiplastP, bosil, hemasil, APR, quicksil, tissel, and tissucol) [79 – 81]. The typical fibrin glue consists of two components delivered in separate flasks, one containing thrombin with a source of calcium ions and the other containing fibrinogen, fibrinolysis inhibitor, and factor XIII [82]. The contents of two flasks are dissolved and immediately mixed on a wound. Under the action of thrombin and calcium, fibrinogen converts into fibrin, the fibrin clot is stabilized by factor XIII, and the fibrinolysis inhibitor prevents decomposition of the clot by plasmin.

Local hemostatic preparations can make use of natural factors of the blood coagulation system [83]. It was established that factor VIIA is capable of effectively arresting hemorrhage [84]. An effective hemostatic preparation was obtained by applying fibrinogen, thrombin, and factor XIII onto the surface of cellulose fibers [85]. There are local hemostatics (not widely used) based on the tissue factor thromboplastin; this group includes hemostazin, pulmin, and clauden, which are obtained by extraction from thromboplastin-rich tissues such as lung, liver, and brain [86, 87]. With allowance for the role of thrombocytes in primary thrombus formation, it was suggested to use dry thrombocytes as a hemostatic agent [88].

A hemostatic effect can be achieved both by using activators of fibrin formation and by introducing fibrinolysis inhibitors such as ε-aminocaproic acid and aprotinin [21, 89]. It was demonstrated that ε-aminocaproic acid preparations can be successfully used in patients suffering from hemophilia [90]. Capramin — a hemostatic fluid preparation based on ε-aminocaproic acid — is used in dentistry in the course of manipulations such as tooth extraction, mineral deposit removal, and cavity preparation. Aprotinin-based hemostatics are used in thoracic, cardiovascular [91], and spinal surgery [92]. Local application of aprotinin can be used to arrest postoperative hemorrhage in neurosurgery [93].

Tranexamic acid produces hemostatic action close to that of ε-aminocaproic acid. In particular, tranexamic acid was more effective than ε-aminocaproic acid in liver transplantation [94]. Mouthwash with a tranexamic acid solution provides effective hemorrhage arrest upon tooth extraction, even in patients receiving warfarin [95]. A hemostatic collagen sponge proposed in [23] contained donor blood plasma, amben, and calcium chloride.

There is a large group of combined preparations that contains either mixtures of hemostatics from different groups or mixtures of hemostatics with some other drugs, usually antibiotics [96]. For example, the introduction of amicacin (antibiotic) into a fibrin glue composition provides effective prophylaxis against local infection development, while retaining good hemostatic properties [97]. A collagen sponge impregnated with epinephrine increases the hemostatic properties of the initial preparation without increasing the risk of side effects. A fibrin glue composition modified by adding taurolidine (cytostatic) is used for the treatment of malignant cerebral tumors (glyomas) in nonoperable patients [98]. Collagen plates impregnated with fibrinogen and rifampicin (antibiotic) were successfully used for healing spleen traumas [99].

Another representative of combined preparations is tachocomb, representing a collagen plate with lyophilized fibrin glue components (fibrinogen, thrombin, aprotinin, riboflavin). Tachocomb was originally intended to arrest hemorrhage parenchymatous organs [100, 101] during operations on liver [42, 102, 103], pancreas [104], and spleen [105] and in neurosurgery [106, 107] and cardiology [108]. However, now this preparation is also successfully used for the plastic reinforcement of surgical sutures [109] and the reduction of comissure processes [110. It was reported that tachocomb plates could be used in operations on lung tumors [111], during kidney transplantation [112], and in the treatment of hemorrhoidal veins. A unique property of tachocomb is the ability to stimulate angiogenesis in underlying tissues, which significantly accelerates regenerative processes.

Algic acid salts are used in the production of materials employed for the arrest of local capillary-parenchymatous hemorrhage. These preparations have the form of a cotton with immobilized calcium ions or thrombin and fibrinogen (Gram I and II, respectively) [113]. It was also proposed to use films based on alginate and PVA with hemostatic additives (AlCl3, capralin AV, CDC) [114].

The hemostatic caprofer represents a carbonyl complex of iron(III) with ε-aminocaproic acid in physiological solution [115, 116]. The interaction of this complex with blood leads to the formation of a clot that tightly adheres to the wound surface [117]. In addition, caprofer accelerates the regeneration and epithelization processes, favors the formation of granulation tissues, and produces antiedemation and antiinflammatory effects. This preparation was also used in otorhinolaringology [118], dentistry [119], and surgery (operation on lungs) [120], and it was effective in arresting hemorrhage from parenchymatous organs [121, 122]. In recent years, caprofer was successfully used under battlefield conditions for the arrest of hemorrhage from gunshot wounds and during abdominal operations [124].

Under the conditions of violated blood coagulation system function, an effective local hemostatic action is provided by polycapran [125], which represents a cellulose N-oxide modified with ε-aminocaproic acid.

It was suggested to use gelatin in combinations with dry plasma, glucose, and antibiotics. This preparation (gelplastan) exhibits procoagulant and adhesive properties [126]. Gelatin sponge preparations spongostan, gelform, gelaspon, and hemoscpt are prepared from dry purified gela-

tin foam and possess a homogeneous porous structure [127]. Experiments demonstrated effective combined use of gelform and fibrin glue for local hemostasis in laparoscopic nephrectomy [128]. The same operation was performed using a gelatin sponge impregnated with thrombin [129]. Gelatin sponges were also successfully used in vascular [130] and general surgery [131]. A gelatin sponge with thrombin effectively arrested hemorrhage, exhibited good adhesion to a wound surface, and did not cause side reactions; in order to increase the antimicrobial effect it was proposed to additionally modify the gelatin sponge with furacilin and gentamicin [132]. A hemostatic gelatin sponge containing formalin, calcium chloride, and an antiseptic component was described in [133].

A new cellulose-based fiber containing fibrinogen, thrombin, and factor XIII, which is capable of rapidly absorbing blood plasma and activating thrombus formation in wounds, was proposed in [134].

A promising direction of development is related to the fabrication and use of hemostatic preparations based on textile carriers [20, 135], in particular, tricots of textured polymer and cotton fibers, mixed cotton – viscose, and polyester fibers. Domestic hemostatic dressings on textile carriers include coletex, activtex, and hemotex. For example, a hemotex pad consists of two layers: the first, protective (atraumatic) and hemostatic layer comprises a perforated circular-weaving tricot with immobilized iron(II) salts; the second layer is made of an unwoven cotton – viscose canvas [30]. The hemostatic pad of activex represents a textile carrier with immobilized ε-aminocaproic acid. Activex AKF contains ε-aminocaproic acid and furagin, which are immobilized on a textile base impregnated with a special biocompatible polymer. Being wetted, the polymer forms a gel from which the drug components are gradually and uniformly delivered to the wound. This preparation possesses both hemostatic and antimicrobial properties. Analogous structure and properties were reported for activex Fhem, which contains feracryl and furagin [136].

To summarize, there are many single-component and combined preparations possessing hemostatic activity and intended for local application. All such products have certain limitations and are intended for use in various clinical conditions. The specific pharmacological activity was tested under various conditions (in patients with different diagnoses, in different experimental models, and in various organs and tissues). We believe that, along with the development of new products, it would be expedient to perform comparative evaluation of various local hemostatics under identical experimental model conditions. Such comparative tests would provide useful information concerning the character of action of the existing preparations and indicate the promising directions of further search for effective local hemostatics.

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Dominic Stewardson

Trends in Indirect Dentistry: 5. Impression Materials and Techniques

Abstract: A fundamental pre-requisite for the construction of satisfactory indirect restorations is the ability to record an accurate and detailed impression of the dental structures. Knowledge of the key properties of the available impression materials and their handling behaviour is necessary if they are to be used effectively. A variety of techniques can be employed in different situations, each of which can be highly successful, but only if attention is paid to the detail of their execution and the clinician is aware of their individual limitations and pitfalls. Where imperfections occur, an appreciation of how they have been caused, and the strategies to take to prevent them will lead to greater success in impression taking.

Clinical Relevance: Current materials exceed our needs in terms of accuracy and stability, and yet the impressions produced are frequently flawed. By realizing why faults occur, being aware of the range of techniques available and having an understanding of the behaviour of materials, clinicians can achieve the quality in their impressions that is possible and necessary to provide excellence in indirect restorations.

Dent Update 2005; 32: 374-393

Until the advent of intra-oral scanning and computer-aided manufacturing techniques, the construction of indirect restorations required a model or cast to be made, this being an accurate three-dimensional facsimile of the mouth and teeth. To create a cast, a mould or impression of the oral structures is obtained. The quality of the subsequently produced restoration depends first on having an accurately fabricated cast, which in turn depends on the ability of the impression to record the dimensions of the target objects faithfully. Dimensional accuracy is therefore the most fundamental property needed in an impression material. While there are many further steps in the manufacture of an indirect restoration at which errors and inaccuracies can occur, it is the dentist's responsibility to provide the technician with high quality impressions and records with which to work and, should returned restorations be ill-fitting or have defects, the clinician should first examine his or her own technique for flaws before looking elsewhere for possible culprits.

	Polysulphide	Condensation Silicone	Polyether	Addition Silicone
Polymerization shrinkage (%)	0.4–0.45	0.4-0.6	0.2-0.25	0.14-0.17
Percentage recovery	97-95	98-97	98.5-98	99.9-99.6
Tear strengths (MPa)	0.5	1.6	2.0	2.4

Table 1. Properties of elastic impression materials. Low viscosity formulations quoted first.

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Key properties

Which is the best impression material for indirect restorations? The choice is between:

- The inaccurately termed hydrocolloids (reversible – Agar, and irreversible – Alginate) and
- The elastomers: polysulphide, polyether and the silicones (type 1 condensation-cured; type 2 addition-cured).

Dimensional accuracy is dependent on the changes occurring as the material sets. Shrinkage occurs as the molecules move together to form polymer chains, and form cross linkages. There is also some

shrinkage as the material cools on removal from the warm mouth (Table 1). Although the polyethers and addition silicones achieve the highest dimensional accuracy, all of these materials (even alginate with a specific technique) are capable of *sufficient* dimensional accuracy for use in making indirect restorations.

Dimensional stability

As well as being able to record accurately, it is clearly desirable for the material to maintain that accuracy for a convenient length of time, ie the material should have good dimensional stability, or at least one should know for how long the impression will be sufficiently accurate so that it can be used intelligently, and how storage conditions may affect its stability. Polysulphide and type-1 silicones produce water and ethanol, respectively, during their polymerization. This results in their shrinkage, with over half of the total shrinkage occurring in the first hour after removal. Although the distortion occurring is not as severe as in the hydrocolloids, it is advisable to pour these materials quickly – within 48 hours in the case of polysulphides.[1] For type-1 silicones the recommended times range from 30 minutes[2] to within 6 hours.[1] The polymerization of polyethers and type-2 silicones involves an addition reaction with no volatile by-products being created, and their polymerization shrinkage is very small. The chemistry of the polyethers, however, encourages water absorption and swelling, and so they must be stored dry until casting. They should also be shielded from strong sunlight during storage. Reversible hydrocolloid, when set, is composed mainly of water (85%) and will swell or shrink as it absorbs or releases water, according to its environment. Even when stored in 100% humidity, it must be poured within one hour to prevent clinically unacceptable distortion occurring.[3] Alginate is similarly affected but to a lesser degree; comparable storage for up to two hours is advised before pouring. However, disinfection by immersion will affect dimensional stability.

Hydrophilicity

As the mouth is a wet environment, a moisture-loving material would be expected to work better in the presence of blood and saliva. The hydrocolloids are truly hydrophilic and can produce detailed impressions in a wet field. The polyethers are hydrophilic in that they will absorb moisture, but still require an essentially dry field to capture detail. The other elastomers are hydrophobic and do not readily wet surfaces, ie they have no natural tendency to flow across prepared teeth. This makes it difficult for the casting material to wet and flow into the set impression material, and may give rise to voids or loss of detail in the produced casts. To combat this, manufacturers of the addition silicones have added surfactants to lower surface tension, creating the *so-called hydrophilic silicones*.[4,5] It is important for clinicians to understand what this means in terms of the use of such materials. The degree of hydrophilicity is often quoted in terms of contact angle measurements. This refers to a test which essentially involves placing a drop of water on to the set surface of the material, and examining the shape formed after a fixed time period. On materials which are difficult to wet, the drop will be well rounded, and a high contact angle is created (Figure 1). Conventionally, angles greater than 90° define a hydrophobic material; less than 90° indicates hydrophilicity. Unfortunately for the clinician, test results from different manufacturers are rarely comparable as there are many test variables which are not standardized between different test laboratories. Also, testing the set material is only an indication as to which impressions are easiest to cast. Testing the unset material, which has been less frequently undertaken (because it is a more difficult test to perform) gives a better assessment of the likely wetting behaviour in the mouth.[6] The only practical benefit of increasing the hydrophilicity, however, is likely to be an improvement in the quality of casts, as studies suggest that the quality of impressions obtained clinically is unrelated to the surface activation of the material; the other material characteristics exert a greater influence on quality.[7,8] Despite their name, hydrophilic impression materials will not compensate for poor moisture control!

Figure 1. Contact angles of a water droplet on a hydrophobic and a hydrophilic surface.

Detail capture

Elastomeric impression materials are required to record detail down to 20µ.[9] Such discriminatory ability is probably more than is required for indirect restorations, especially when it is considered that die-stones are only required to reproduce detail down to 50µ. However, these materials are successfully used to create replicas for microscopic examination of tissues and biological samples where there is a need to see structures considerably smaller than 20µ in size.

Permanent deformation

Impressions of the mouth will need to be withdrawn from tooth and tissue undercuts, and therefore must be sufficiently elastic to deform as they exit undercuts but then return to their original shape. Although international standards define the maximum permissible permanent deformation, manufacturers frequently refer to the converse, ie percentage recovery. Not surprisingly, highly-filled materials have slightly less elastic recovery than lower viscosity formulations. The addition silicones achieve over 99% recovery, and the type 1 silicones and polyethers reach between 98% and 99%. Flexibility is measured by strain in

	Polysulphide	Condensation silicone	Polyether	Addition silicone
Handling	Very sticky	Easy removal Protect hands while mixing	Sticky	Easy removal Reaction affected by some latex gloves. Protect hands while mixing
Taste	None	None	Bitter	None/some flavoured
Smell	Sulphurous odour	None	None	None/some scented
Colour	Usually brown	Wide variety	Limited	Wide variety
Setting time	Long – 10 minutes	4-6 minutes. Variable set times available	Fast	4-6 minutes Variable set times available Sensitive to temperature
Die plating	Silver	Usually not possible	Silver	Silver or Copper
Toxicity	Low	Very low	Some reactions reported in past[10,11]	Very low
Cost	Least expensive	Moderately expensive	Moderately expensive	Most expensive

Table 2. Additional impression material characteristics.

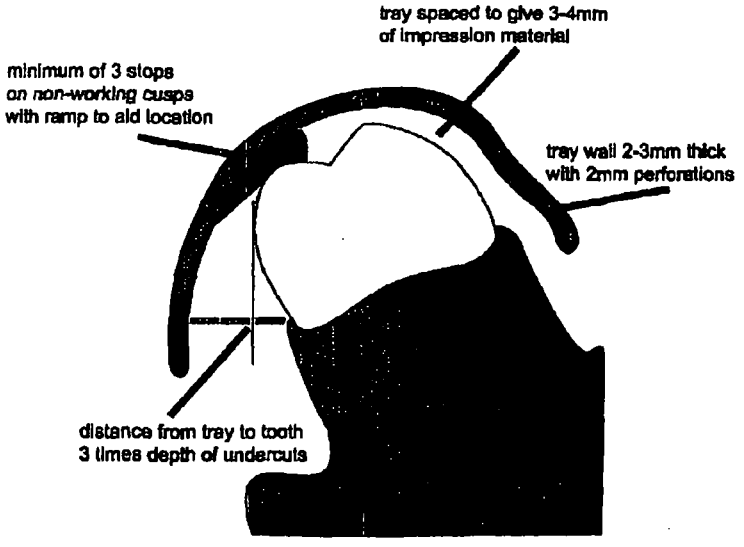

Figure 2. Features of a good individual tray, with particular reference to inclined teeth.

compression, the percentage change in length of a sample under a specific load. The polysulphides are more flexible than the other elastomers, among whom the condensation silicones are slightly more flexible than the type 2 silicones or polyethers of similar consistency. Where significant undercuts exist which need to be recorded, for example on tilted teeth, an addition silicone is less likely to distort on removal than the other materials. However, as it is also a stiff material when set, it could be difficult to disengage physically. To overcome this, a tray should be selected which allows an adequate bulk of material in the area – three times the depth of the undercut (Figure 2). A very rigid material may be indicated when it is crucial to prevent distortion of the relative positions of dies, as is the situation with implant restoration, but it may prove difficult to remove where moderate tissue undercuts are present. It may also be impossible to remove such an impression from a cast

with the same undercuts without dies and/or teeth breaking off in the process. The dentist should be alert to these potential problems and consider blocking out such undercuts clinically with cotton wool or waxes. Retrieved impressions should be cut back to remove material which reproduces these undercuts, prior to sending to the laboratory.

Tear strength

An impression should be able to record detail in narrow spaces such as the gingival crevice and preparation features like slots and grooves. It therefore needs to be strong in thin section if it is to be withdrawn intact from these sites. Polysulphides have recorded the highest tear strengths but, because they also have poor permanent deformation characteristics, they are not very reliable for recording areas of thin section. The type 2 silicones and the polyethers both have high tear strengths but there is little difference between them and the type 1 silicones. The hydrocolloids have much lower tear strengths. There are several other desirable characteristics to be considered when choosing an impression material as listed in Table 2.

Impression technique

As implied above, any of these materials has sufficient inherent accuracy for them to produce high quality restorations. Realizing their potential depends on the clinician understanding the material's properties and behaviour, and handling it so that any deficiencies are minimized. With the high quality of materials available to dentists over the past 40 years, technique is a much bigger factor in determining success or failure in indirect work than are material differences.

Irreversible hydrocolloid and polysulphides will not be considered in this section. Most UK dentists are now using silicones or polyether, as they are more user and patient friendly than polysulphide. Those who are using reversible hydrocolloid are most likely to be specialist practitioners well versed in its use.

Figure 3. A poorly executed two-stage putty wash impression. Only a section of the putty has been covered by the wash, and the tray has not been fully seated, which resulted in a stepped cast.

Putty/wash technique

Two-stage

Since elastomers shrink on polymerization, it follows that using a small volume of material will reduce the net effect of the shrinkage on the accuracy of the impression. Only a closely adapted custom tray would allow a small volume to be used. An alternative approach was proposed for the condensation silicones which allowed cheaper, time-saving stock trays to be used. A heavily filled 'putty' version, which therefore has reduced shrinkage, is effectively used to convert the stock tray into a close-fitting custom tray. As a second step, a lightly filled (higher shrinkage) material (the wash) is placed inside this 'tray' and re-seated. Very little of this low viscosity material is needed, hence little net shrinkage occurs, while good detail is recorded by its ability to flow more readily than the high viscosity putty. However, there are some problems with this technique. With such a close adaptation of the putty to the teeth, there is little space in which the wash material can flow, and the trapped material makes it difficult to reseat the tray (Figure 3). This leads to an uneven thickness in the wash, and uneven shrinkage. More importantly, the build-up of hydrostatic pressure acts to push the set putty and the walls of the tray outwards. When the impression is removed, the putty recoils and the resulting dies, which may appear flawless, will be narrower than the preparations, and the crowns made on these dies are unlikely to seat easily on the teeth.[12]

The use of more rigid (specifically metal) trays reduces the recoil from the tray but, to reduce the recoil which will occur in the set putty, modification of the putty must be made to allow release of the pressure. The putty should be generously cut back in the depths of the sulci (and palate in the upper arch), and several buccal and lingual sluices cut to

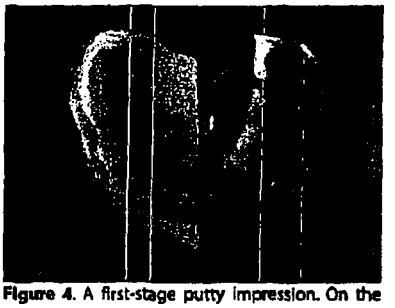

Figure 4. A first-stage putty impression. On the right side the impression has been marked to show where trimming has been carried out to remove the sulcus depths, and create several sluices. The interdental collets will also be removed to allow easy, positive re-seating.

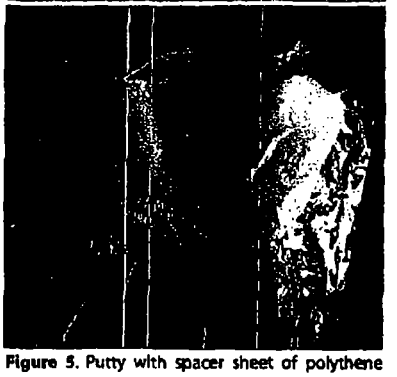

Figure 5. Putty with spacer sheet of polythene prior to taking first-stage of two-stage impression.

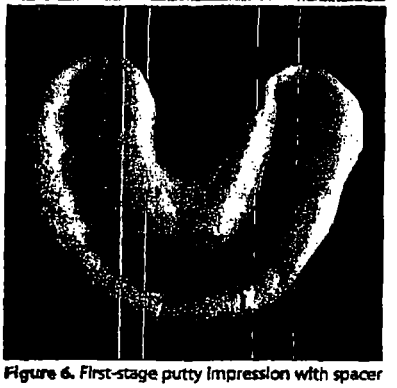

Figure 6. First-stage putty impression with spacer removed.

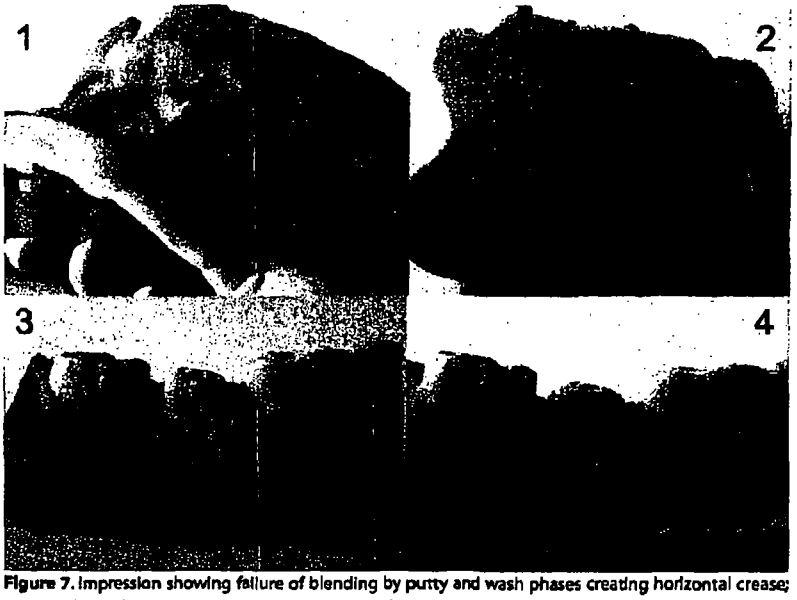

Figure 7. Impression showing failure of blending by putty and wash phases creating horizontal crease; arrowed (1) and in cross-section (2). Resulting die shows corresponding ridge on preparation surface (3, 4), with similar drag defects on adjacent teeth.

provide escape channels for the wash. The interdental collets should also be removed, and the modified putty impression replaced to check that it can be easily relocated (Figure 4). It may be thought that, if the first-stage putty impression is taken before any tooth preparation is performed, sufficient space will be created locally around that tooth. However, for this to be an effective method of overcoming recoil, the operator would have to place the exact volume of light body required to fill this space into the putty. Any excess would be unable to escape from the surrounding close-fitting putty, leading again to outward displacement of the putty and tray and/or difficulty seating the impression. Any flow of the light-bodied material which occurred across nearby teeth would create a step in the impression at the limit of its flow. A quicker method of creating room for the wash material to escape is to place a thin sheet of polythene over the putty as the first-stage is put into the mouth (Figure 5). On removal from the mouth, the polythene is discarded. This provides a thin space allowing movement of the wash in the second stage, and prevents the putty material passing interdentally or to the full sulcus depth (Figure 6). Spacer sheets can be purchased which have a raised pattern designed to increase the surface area for adhesion of the putty and wash. Bonding of the two phases does not appear, however, to be a problem as long as the putty surface has been carefully cleaned of saliva etc., and dried.

One-stage

Decreasing the number of steps should increase efficiency, and placing both materials in the tray for a one-stage impression is therefore an attractive option. Although seating difficulties are overcome, recoil of flexible trays still occurs. With such a contrast in the viscosities of the two materials, the wash may be pushed away by the putty, resulting in drags below undercut areas such as the axial surfaces of teeth and inclined preparations; critical areas (slots, grooves, finish margins) may be recorded by the putty alone which is less able to record fine detail. Where margins are extended into the gingival crevice, the unset putty will act to close up the gingival crevice, pushing out the wash and giving poor definition of essential margin detail. In the two-stage technique described previously, while the first putty phase is recorded, the crevice can be held open by retraction cord. At the second wash step, the pressure build-up occurring as the impression is re-seated tends to drive the wash into the opened crevice and clearer recording of the margins occurs.

A defect which, in the author's experience, occurs more with type 2 rather than type 1 putty/wash impressions and is not often recognized by the clinician, is failure of the two viscosities to blend fully. This manifests as a crease in the completed impression on the axial surfaces of teeth, frequently on the prepared teeth (Figure 7). This may be as a result of the relative differences in the surface tensions of the two viscosities, or it may be because the setting reaction of addition silicones starts earlier than for condensation silicones or polyethers, which means it develops elasticity quickly, and this effect is accelerated at increased temperature.[13] On placing the wash around the teeth, the material against the warm tooth will start to polymerize while the bulk of the wash still appears fluid. When the putty is applied, this partially set skin may be displaced or distorted, forming a crease. Since the wash is applied first to the prepared tooth, this effect is more likely to occur there. It is advisable, therefore, always to chill the wash material. Conversely, once apparently set, addition silicones need to be given longer to complete the reaction fully or distortion may occur on removing the impression. Although more steps are involved in a two-stage technique, it can be completed with a minimal increase in time. As the purpose of the first stage is only to create a custom tray, the putty impression can be removed before it has fully set, and this stage can be carried out at the start of the appointment while awaiting anaesthesia. Some practitioners make use of the putty taken before tooth preparation as a matrix with which to make a provisional restoration. This avoids the need for a separate impression with which to create a temporary restoration, and can also save time in temporization compared with the time taken to trim crown forms. However, any methacrylate type compounds, eg bis-acryl or methacrylate temporary crown materials, and also bonding resins which come into contact with addition silicones,

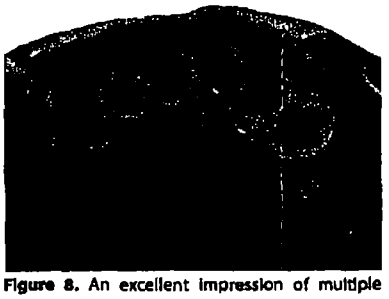

Figure 8. An excellent impression of multiple units achieved by careful preparation, moisture control, and gingival displacement. An individual tray with stops was indicated and a heavy and light combination of silicones used. Produced by a final year dental student (by kind permission of Ms E Hopkins).

will contaminate the platinum-containing catalyst and impede the setting of, and the bonding to, the light body silicone, so the putty must be carefully cleaned with alcohol to remove any temporary crown material residue.

Some laboratory studies suggest that the dies produced with single stage impressions are more dimensionally accurate than those from two-stage techniques.[14,15] Unfortunately, one can also find evidence that one-stage is superior[16,17] and that there is no significant difference in accuracy between the techniques.[18] Accuracy, however, is only one determinant of quality. Where margins extend into or close to the gingival crevice, the clear recording of the margins is also critical to producing acceptable restorations, and a careful two-stage technique can give superior marginal definition and avoid drag formation.

Heavy/light

The technique most often used with addition silicones is that originally devised for the condensation silicones, namely, one-stage putty and wash. Using any putty will give rise to recoil problems in non-rigid trays, and the potential offered by the superior material properties of the addition silicones will not be realized. Since the setting shrinkage of type 2 silicones is less than half that of the type 1 silicones, a less heavily filled material can be safely used in bulk in a stock tray placed simultaneously with a lighter viscosity material to capture detail. This gives the dentist the convenience of a single-stage method without its disadvantages; distortion of plastic trays is reduced, and the viscosities of the two materials are closer, which reduces drags and improves blending of the two phases. The lower viscosity material is not as readily displaced from the gingival crevice, permitting good margin definition, and the higher viscosity material can record detail better than a putty can (Figure 8). The heavy material is generally sufficiently thixotropic not to run out of the tray, but it requires some effort to express enough material from an automix syringe to fill a tray quickly. Automatic mixing machines introduced in the past few years overcome this problem; their extra cost must be weighed against the risks of repetitive strain injury! The polyether materials are not formulated as putties as they would be too rigid to use, and are used in a heavy/light combination, or in a single medium body viscosity – otherwise known as a monophase technique.

Monophase

The advantages of making impressions with a medium-bodied presentation are that the possible co-ordination problems of using two mixing guns and the need to stock more than one material are avoided, and there is no conflict between different viscosities. However, as this one material is not as heavily filled as the high viscosity described above, polymerization shrinkage will increase slightly, and it will have increased flow compared with the heavy tray material. For these reasons, it is probably safer to use monophase materials in a custom tray, which reduces volume and contains them better than would a stock tray. However, the thicker consistency compared with a light- or very light-bodied material may limit the ability of medium-bodied materials to flow into intra-coronal features or the gingival crevice.

Tray selection

The influence of the tray on the creation of a successful impression has been touched on in the preceding sections. However, the importance of correct tray selection is often overlooked. Clinicians will consider many other possible sources of failure when restorations do not fit, and may change their impression material, but rarely think of their tray. Trays should be as rigid as possible and not all disposable trays will resist deformation while loading heavy-bodied materials.[19,20] Metal trays offer the greatest rigidity but should be used with caution with polyether and type 2 silicones – if there are significant tissue undercuts the tray may need to be cut off, which is a lengthy, laborious and very traumatic procedure for the patient!

Custom trays can improve the chances of producing an accurate impression because they can offer greater rigidity, and allow control of the thickness of impression material. An optimum thickness (approximately 2–4 mm) of material[21] will provide the best compromise between having enough bulk of material to minimize the permanent deformation caused by removing the material from undercuts, and the need to reduce the volume so as to minimize the effect of shrinkage (and reduce cost)(Figure 2). Trays made from self-curing acrylics require a delay of 24 hours to allow complete polymerization before use, while light-curing materials can be safely used almost immediately. Both should have a thickness of 2–3 mm to ensure sufficient rigidity.[22,23] Impression materials adhere better to the light-curing composite tray materials and adhesion is also helped if, during manufacture, the spacer wax is covered with metal foil before the tray material is applied.[24] Requesting a custom tray is not the end of the matter. An even distribution of material can only be obtained if the tray is precisely positioned, and this control of position requires either luck, or the incorporation of stops in the tray which can guide the clinician in seating it. If the rationale for having a custom tray spaced is accepted, it is illogical not to have stops. They should give at least three widely spaced supports to the tray, offer very positive seating, and be on non-critical areas, ie non-functional cusps of unprepared teeth, edentulous areas or the palate. If a ramp is created leading to the stops, it will help direct the tray into position as the impression is seated.[25] When a custom tray is indicated, a putty/wash combination must not be used for several reasons:

Figure 9. Electrosurgical tip for gingival troughing.

- First, it is illogical since the purpose of the putty is to fill the large space of a stock tray and minimize the volume of the wash material – a custom tray is shaped to minimize impression material volume.
- Secondly, a close-fitting tray containing putty will be very difficult to seat without setting up enormous stresses in the putty, and
- Thirdly, most of the previously mentioned problems associated with the putty-wash technique will persist.

A custom tray will not always give a significantly better outcome clinically than a stock tray. A stock tray will suffice when:

- The stock tray is of a rigid type;
- The shape of the patient's arch conforms to that of the tray, ie an even thickness of impression material can be accommodated in the completed impression;
- Only one or two single units are being restored;
- Stops are placed as described;
- Overextensions are removed – these may prevent outflow of impression material at the peripheries and contribute to recoil (as can happen when a lower tray is used in the upper arch);
- The chosen materials (preferably avoiding putties) are used correctly.

On the other hand, where several units or a bridge are being constructed, the impression is required to deliver not only accurate individual dies, but also to reproduce the spatial relationships between the units. An individual tray is more likely to achieve this extra level of accuracy, and the extra cost will be recouped in less adjustment time and less material used.

Retention of the impression in the tray as it is removed is essential. Trays for elastomers should be perforated with holes of at least 2–3 mm diameter, to allow material to escape and lock on to the outer surface of the tray, and have an appropriate adhesive coating extending on to the outer surface. These are contact adhesives and, in the case of the silicones, need to be painted on at least 7–15 minutes before use.[28] If insufficient time is allowed for the solvents to evaporate, the adhesive will act more as a lubricant. Removing any impression made with an elastic material (this includes alginate) should be as rapid as possible. They are all visco-elastic, which means that, if pulled gradually or rocked out of the mouth, they will deform. With quick removal they will behave more elastically and not distort. Where the prepared teeth are tilted relative to the rest of the teeth, the impression should be brought out along the line of the prepared tooth to minimize any excessive strain and distortion of the impression of the preparation. With marked tilting, a correctly shaped custom tray should be used.

Tissue management

The most frequent visible fault identified in impressions received in laboratories is poor margin definition.[27] This may be owing to poor preparation, but is mostly attributable to inadequate displacement of the gingivae when the restoration is extended close to or below the gingival crest. Without an open gingival cuff, the precise extent of the margin will not be recorded, and the technician has to guess where to finish the restoration. Where sufficient depth exists, recording the shape of the tooth surface below the margin will help the technician to create a natural emergence profile, avoiding sudden changes in direction from the root to the restoration, which results in over-contoured margins which will encourage plaque retention.[28,29] For the elastomeric impression materials, the crevice needs to be opened to 0.2–0.3 mm to allow accurate detailed reproduction.[30,31] This can be achieved by surgical widening or mechanical displacement with or without chemical adjuncts.

Surgical widening

This entails removing the lining of the gingival crevice and can be accomplished using an electrosurgery unit, a rotary instrument, or with a laser.

Electrosurgery, or more accurately radiosurgery since the instrument emits high frequency radiowaves (3–4 MHz), produces rapid heating and cell destruction in the immediate vicinity of the electrosurgery probe as the radio waves pass through the tissue owing to the high resistance of the gingival tissue. A specific probe, which has an insulated tip from which extends a short metal projection, is available for some machines (Figure 9). This design helps to prevent contact with the adjacent teeth as a result of the insulation, and the short tip limits the depth of its use in the crevice. The heat generation helps to cauterize the cut tissue and reduces bleeding, but care must be taken to keep the tip moving whilst activated (0.7 m/sec is suggested) in order to prevent an excessive temperature rise; at least 5 seconds should be allowed before working in the same area again.[32] Touching the teeth, or metal restorations, with the electrosurgical probe can cause rapid heating and damage to the pulp. Rotary gingival curettage, also known as gingitage or gengitage, achieves removal of the crevicular lining with a high-speed diamond or ceramic bur directed around the tooth within the gingival crevice, usually at the same time as the preparation margin is prepared.[33] So-called soft lasers can vaporize superficial tissues and have also been used to widen the gingival crevice surgically for impression taking.[34]

Common concerns with all of these destructive techniques are whether recession of the gingivae will occur, and what potential there is for permanent damage to the tissues. A number of studies have compared these modalities, and each one has been shown to be at least equal, if not superior, to the others.[33-39] This conflicting evidence suggests that any differences between these techniques are likely to be clinically insignificant, *when they are used correctly*. There is, however, great potential for significant damage with all three. Overheating of the tissues with electrosurgery or laser can cause pulp death and alveolar bone necrosis. Rotary gingival curettage involves the least cost in new

equipment and allows the dentist to use an instrument with which he/she is very familiar. Nevertheless, in the interproximal areas, there is a high probability of contacting the adjacent tooth surfaces and permanently marking them. This is likely to encourage caries, and cause sensitivity. All of these methods should be avoided where the gingivae are thin and friable, as significant recession may then be likely.

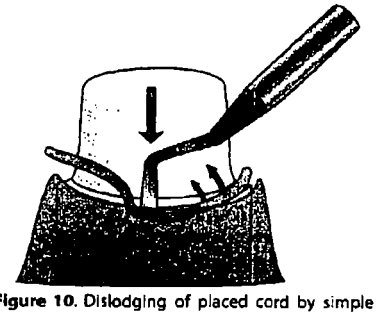

Figure 10. Dislodging of placed cord by simple vertical packing technique.

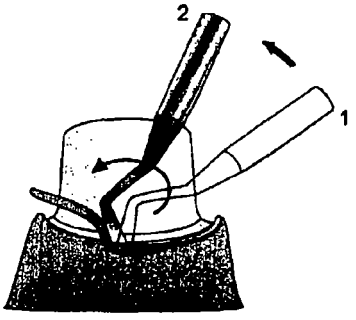

Figure 11. Rotating the packing instrument as the cord is seated helps to keep the earlier packed cord in place.

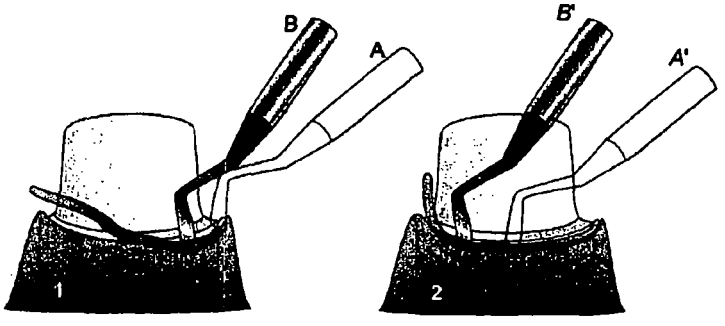

Figure 12. Using two instruments, walk around the tooth, to hold seated cord in place.

Mechanical displacement

Rather than destroy tissue to create space in the crevice, the natural elasticity of the gingivae can be exploited and the crevice temporarily widened by inserting a material into it. Cords are convenient for this purpose as they can be produced in varying diameters and are readily cut to length. Made from absorbent cotton strands, they can soak up crevicular fluids or can hold haemostatic agents *in order to provide a dry field. Twisted* cords have a tendency to unravel during placement, so knitted or braided cords are preferable. Either a single- or a double-cord technique can be used. If a marginal gap of 0.2–0.3 mm is required then, realistically, the clinician should aim to open the crevice by at least 0.3–0.4 mm to allow for some closure to occur while the impression is being placed. Therefore, with one cord, the largest diameter should be chosen which can be inserted *with gentle pressure* into the crevice. This provides displacement of *the gingival cuff. The pressure of the cord,* possibly supplemented by haemostatic solutions, creates a dry field locally. Additional lengths can be placed if there is a large bulk of gingivae to be pushed back. Before mixing the impression material, the teeth are washed and dried and the cord, which should be moistened to prevent tearing of the crevice lining, gently removed. It is essential to wait for 10–15 seconds to see if any bleeding now occurs. Placing the impression material immediately after removing the cord will not prevent such *bleeding, so it makes sense to see if further* applications of haemostatic agents are required before wasting time and money on an impression which will be flawed. In the two-cord technique, the functions of haemostasis/drying and displacement are divided between the two cords. A *narrow* cord is placed first to ensure a dry field but, as it is to stay in place during the impression taking, needs to be cut fairly precisely to the size of the periphery of the tooth. A second, thicker cord is placed on top to open up the crevice, and only this is removed before the impression material is placed. To use two cords requires more depth in the crevice, and so some operators use suture material as their first cord. It also takes more time, but gives greater control of the critical marginal area, and so is particularly useful where an impression of multiple units is being obtained or where persistent gingival bleeding occurs. Retraction cords should not be reserved solely for the impression stage. With the gingivae deflected, the margins can be seen and prepared more accurately, and the tissues are protected from bur damage which can add to the problems of achieving haemostasis. It may also be easier to place cord prior to margin cutting. Cords can themselves be harmful. A recent study suggests a direct effect on fibroblasts;[40] of more importance is direct trauma resulting from excessive force leading to recession. Common sense should guide the practitioner – thin, tight gingivae indicate narrower cords and lighter inserting force; wider diameters and greater pressure where the tissue is tougher. Baharav *et al.*[41] suggest that 4 minutes is needed to achieve an adequate displacement width, while longer times give no further benefit. It would seem sensible not to leave cord in longer than 10 minutes if working on multiple teeth, as this may lead to recession. Once cord is removed, the gingivae can rapidly close up, possibly within 30 seconds[42] therefore, if control of bleeding delays the taking of the impression, replacing the cord may be necessary.

Cord placement method

- Explore the gingival crevice around the anaesthetized tooth with a narrow flat plastic instrument – this will help indicate the appropriate diameter of cord to be used. It will also identify where the cord can be easily and securely anchored and so act as

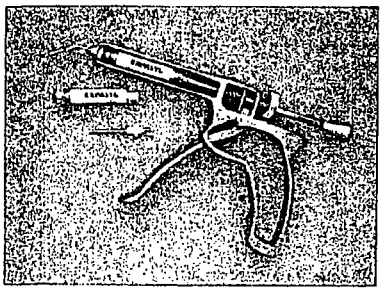

Figure 13. *Expasyl* gingival displacement equipment.

a reliable starting point from which to start cord packing.

- ☐ Cut a suitable length of cord and moisten with water or an astringent solution.
- ☐ Secure one end in the chosen anchor site using a narrow flat plastic instrument or preferably with a specifically designed cord packing instrument. Magnification will help to ensure that the cord is being pushed into the crevice and not against the gingivae or preparation margin.
- ☐ Simply packing vertically will tend to pull in the cord on either side, causing it to rise out of the crevice behind the packer (Figure 10). Rolling the instrument in the direction one is packing helps to avoid this (Figure 11); as does the use of two packers, where one instrument holds down the cord while the other packs the next section, stepping around the tooth (Figure 12). However, this is a more difficult technique to master.
- ☐ Inspect the preparation to ensure the margins can all be seen – place additional cord if required.
- ☐ Leave the cord for at least 4 minutes, but do not allow the tooth to dehydrate.
- ☐ After sufficient time, wash and dry the tooth before gently removing the cord (top cord in the two-cord technique). Washing, and especially forceful air-drying after cord removal, can encourage bleeding.
- ☐ Check the crevice for adequate displacement and watch for bleeding which can occur after a few seconds. Clear any coagulum and debris carefully with a CPITN probe. If necessary, dry the crevice with a gentle stream of air.
- ☐ If the conditions are right, proceed to the impression – if not, correct the situation; don't waste your expensive impression material.

Haemostatic agents

Pressure alone may not stem gingival bleeding, and it is not uncommon to apply an astringent liquid into the crevice and on to the cord before it is placed. These compounds are usually solutions of metal salts – chlorides and sulphates of aluminium and iron. The most effective astringent, ferric sulphate, is also the most aggressive in its effect on the tissues and can temporarily stain the gingivae black for 24–48 hours. They are all quite acidic,[43] and have the potential to etch dentine, opening its tubules, which may lead to sensitivity and allow bacteria to enter.[44] They also have a terrible taste, and must be placed with care. Some are presented as gels which can give greater control. Concerns over possible inhibition of the setting reaction of addition-cured silicones by the sulphate-containing astringents appear unfounded. Where this inhibition has occurred, it is thought that sulphur-containing additives from latex gloves rubbed on to the teeth have been responsible.[45]

Adrenaline solutions and impregnated cords are not recommended as they have the potential to cause serious systemic effects.[46] Using local anaesthesia has been shown to improve the quality of subsequent impressions.[47] This may be due to the haemostatic effect of the adrenaline contained in the solution when injected locally, but may also be because, once the gingivae are anaesthetized, retraction cords can be more effectively placed and vital teeth adequately dried without causing discomfort.

Expasyl (Kerr UK Ltd, Peterborough, UK) is an alternative mechanical displacement method. Consisting of a blend of kaolin(china clay) with the astringent aluminium chloride, it is presented in cartridges with a dedicated syringe and disposable wide bore delivery tubes (Figure 13). After tooth preparation, the thick, putty-like material is injected into the gingival crevice, which is thereby dilated. After 5 minutes it is removed by water spray, the preparation is dried and impression material can then flow into the opened and dried crevice. This has the distinct advantage of being probably the

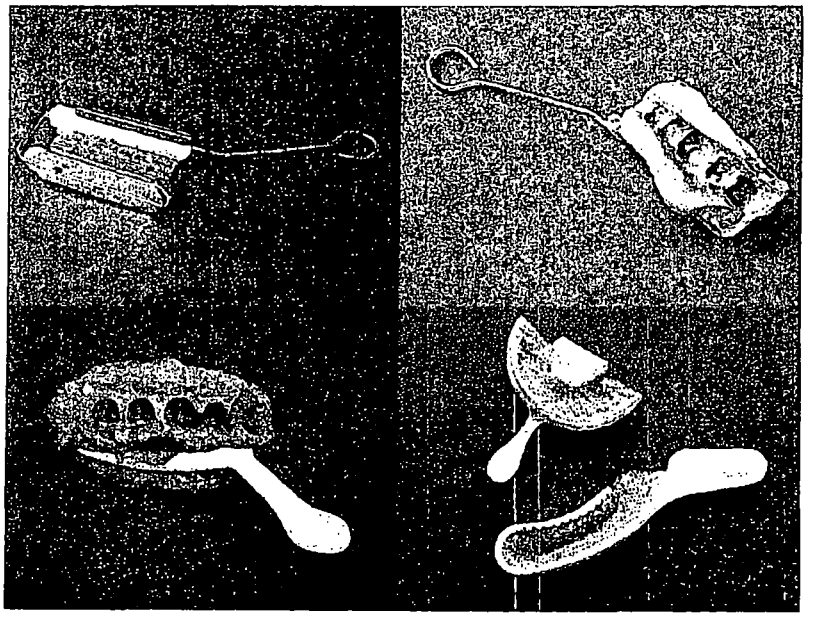

Figure 14. Metal (top) and plastic dual arch trays.

least traumatic, and therefore painless, displacement technique, and does not require additional anaesthesia for its use. However, it may not be sturdy enough to cope with thick gingivae, and cannot easily be used to protect the tissues while margins are being prepared.[48]

Gingival health

Problems of gingival bleeding and concerns about recession will be minimized if the gingivae are free from inflammation. This will be the case when the patient has good oral hygiene and any existing restorations have well-fitting and contoured margins. Dentists should not have to battle against bleeding gums to try and achieve decent impressions. Patients have increasing expectations regarding their dental care but, in turn, must be made aware of the impact poor gingival health will have on the quality of restorations and their responsibility to maintain that health. They also need to appreciate that provisional restorations may be required to allow effective cleaning and a return to stable tissue conditions before they can be provided with first class dentistry.[49]

Dual-arch impression

Also known as closed bite, triple tray or double arch impression, this method has been in use in the US for about five decades, but is still not widely used elsewhere. Various designs of trays are available which aim to achieve the simultaneous recording of the prepared tooth/teeth, the opposing teeth, and their intercuspal relationship (Figure 14). It offers several practical advantages over the traditional method. Less material is needed, it is quicker because both arches are recorded at the same time, and patients have been shown to prefer this technique over traditional full-arch impressions.[50] Laboratory investigations show that dies have comparable accuracy compared to those obtained from full-arch impressions,[51-52] and that the quality of restorations produced is at least equal to that which can be obtained with conventional full-arch impressions.[50,53] Both plastic and more rigid metal trays are available for posterior quadrants and the anterior sextant. No clear superiority has been demonstrated between either, nor between different viscosities of silicone.[52,54] However, if the patient's alveolae or palate contacts the tray on closing it will be distorted, giving an inaccurate result. As the plastic trays are more flexible, the patient may not notice the distortion and not alert the dentist. With any new technique there is a learning curve; this applies to the dentist and possibly even more so to the technician, so initial results may be inferior.[55] The impressions are shallow, and this makes them difficult to pour, and mounting can be problematic without specific cast relators. This method is not recommended for all situations, but where appropriate yields very good results, and has some real advantages.

Indications and requirements for dual-arch impressions are as follows:

- One or two units bounded by intact and opposed teeth;
- Stable, reproducible and obvious intercuspal position;
- Co-operative patient able to close directly into intercuspal position on request;
- Tray does not contact axial tooth surfaces, or the adjacent tissues on closure;
- In quadrant trays, there is space for the connector bar behind the last molars;
- Technician familiar with the specific pouring and mounting procedures.

A checklist for the dual-arch technique includes the following:

- Check that the tray can be placed into the appropriate position with the tray sidewalls out of contact with the tissues, ie is the tray wide enough?;
- Check that the patient can close with the tray in place, ie no contact. (This is best done before anaesthesia so the patient can identify any obstruction);
- Check that the patient can close repeatedly into intercuspal with tray in place, ie not contacting teeth on opposite side;
- Complete tooth preparation and cord placement if required;
- Apply adhesive to tray but not the gauze;
- Dry prepared tooth and remove cord – check haemostasis;
- Assistant fills top and bottom of tray (heavy or monophase) while the dentist syringes impression material around prepared tooth (light or monophase);
- Orient and seat tray over arch with prepared tooth;
- Ask patient to close (into intercuspal position) and maintain closure until instructed to open. Check correct closure using reference teeth noted previously;
- Once completely set, ask patient to open quickly and forcefully. Dentist completes removal from other arch.

Alternative techniques

Reversible/irreversible technique

While the dual-arch method is popular in the US, the use of irreversible with reversible hydrocolloid has been used in Sweden to fabricate indirect restorations with similar survival rates as those made with other impression materials.[56] Suggested in 1951 by Schwartz,[57] the combined use of reversible and irreversible hydrocolloid can produce casts of sufficient accuracy and detail on which to make indirect restorations.[58] A low viscosity reversible hydrocolloid is syringed over all the teeth to record fine detail, and an alginate in a stock tray is placed over it to contain the wash and fill the tray. The wash material is simple to keep fluid in a small heated water bath, ready for use. This method allows the operator to use inexpensive materials and gain the benefits of reversible hydrocolloids' hydrophilic properties and accuracy; using alginate as the tray material avoids the need for expensive bulky water-cooled trays. Poor dimensional stability and low tear strength are still a concern, and specific alginates formulated for this technique should be used to avoid the two materials separating on removal as can happen if a conventional alginate is used.

Injection techniques

The principal claimed advantage of the two-stage putty/wash method is that the low viscosity material can be driven in to the gingival crevice by the set putty, enhancing the definition of the margins. There is still the risk that the build-up of pressure which causes this may give rise to the problems of recoil. To avoid this, Lococo[59] described his hydrodynamic impression technique whereby a high viscosity silicone material is first used to obtain an impression of the teeth. Channels are cut into this, leading to the teeth to be prepared. After preparation and gingival displacement, the tray is reseated and a light-bodied material is

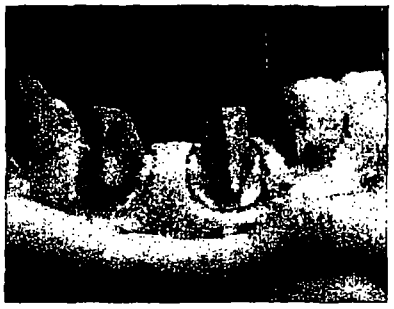

Figure 15. Extreme example of dies produced from impression with vertical drags as a result of poor flow of putty phase.

then injected through one hole until the excess is seen escaping from the other. The force of injection acts to push the wash material into the crevice, opening it further. Similar approaches have been described by Schoenrock[60] in his laminar impression technique using a dual-arch tray, and by Millar[61] with a full arch tray where the injection hole is sited over the occlusal surface of the prepared tooth with a buccal relief hole.

Matrix impressions

Despite improvements in material properties, capturing marginal detail can still be a problem which has inspired some alternative solutions. We need a material which has sufficient viscosity to be directed into the crevice and displace it (while being able to record detail), but then we need to prevent it from being displaced and the crevice collapsing, as more impression material is placed to record the rest of the arch. The now largely abandoned copper ring technique achieved some of these goals – the gingivae were displaced by a trimmed metal tube and the viscous thermoplastic compound, which was the impression material. An overall impression of the arch was made over the copper ring, usually in alginate, to relate the prepared tooth to the rest of the teeth. Improvements on this technique included substituting elastomers for the inflexible compound and alginate, and using plastic crown forms which are easier to adjust as the matrix.[62,63] Livaditis[64] has further extended this concept by using an initial impression of the prepared teeth taken in rigid occlusal registration type polyether. This is trimmed to the gingival margins and is then used as a matrix to carry a higher viscosity material which, as it is seated, drives the unset material into the gingival crevice. Once set, a third impression is taken in a conventional tray with a lower viscosity material over the matrix, which joins all three elements together. Martignoni,[65] in his 1990 text, describes using a putty silicone matrix and provisional restorations trimmed as before to carry a silicone foam which again is driven into the crevice, and held under pressure. In this case, however, the purpose is to achieve gingival displacement only; a conventional impression technique is then followed to produce the working cast. Recently, Coltene (Coltene/Whaledent Ltd, Burgess Hill, West Sussex, UK) have produced *Magic FoamCord*, which uses the same principle of a silicone which expands on setting to open the crevicular space prior to the working impression. It is syringed around the gingival margins, and then an appropriately sized cotton wool 'thimble' is positioned over the tooth and pressed down by the operator, and then by the patient's opposing teeth for five minutes. For multiple preparations, it is suggested that a putty in a sectional tray be used to provide the additional force. The action of the expanding foam and the pressure applied to the carrier opens the crevice atraumatically.

Troubleshooting

Impression pulling out of the tray

Increase the retention with more perforations of appropriate size and paint on the adhesive at least 5 minutes ahead. If there are deep tooth or tissue undercuts gripping the impression, block them out with soft wax or cotton wool.

Persistent bleeding

If persistent bleeding is the result of general inflammation of the tooth's gingivae:

- Provide a provisional restoration with good margins;
- Ensure that the patient can and will keep the area plaque free; and
- Delay impression taking for at least 10 days.

If, on the other hand, it is the result of bur damage, insert cord before preparing subgingival margins to deflect the gingivae. Local measures will usually cope with isolated bleeding points. Try burnishing a very small cotton wool pledget or microbrush soaked in ferric or aluminium sulphate directly against the site. Papillary injections of local anaesthesia can temporarily halt bleeding and are particularly useful if some oozing starts at the moment of placing the impression. The two cord technique gives better moisture control than a single cord.

Margin defects

These are more commonly seen with the one-stage putty wash method.

Horizontal ridges

These are not obvious unless deliberately looked for, and are often seen on the buccal/lingual side of prepared teeth when a one-stage putty wash technique has

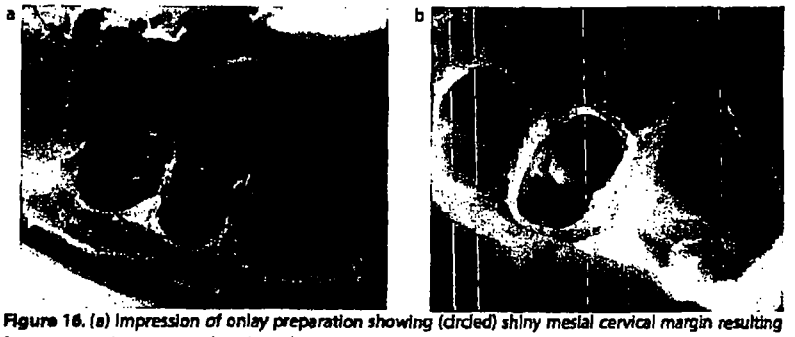

Figure 16. *(a) Impression of onlay preparation showing (circled) shiny mesial cervical margin resulting from poor moisture control, and no clear edge to the margin.* **(b)** *A further attempt made using a two-cord technique has achieved a dry field, and the margins are easily identified.*

been used. They represent poor blending of the two viscosities and do not occur on the interproximal areas as the materials are enclosed and there is a greater build-up of pressure here. Heat from the prepared tooth causes the wash in this area to start to react first and become more elastic, reducing its ability to homogenize with the putty. All addition-cured silicones should be placed as quickly as possible before the polymerization starts; chilling them, especially the wash material, gives the operator some extra time. Teardrop defects may be seen at the back of the last tooth, particularly on tall teeth and at edentulous areas as the putty escapes posteriorly. The tray needs to be closed off with self-cure acrylic or greenstick additions. In a two-stage technique, the wash material will fill up any such putty defects.

Vertical drags

Commonly seen extending from below undercuts when one-stage putty impressions are taken (Figure 15). This is again owing to the poor flow characteristic of putties preventing them adapting well to irregular contours. Where marked undercuts present on prepared teeth, use a two-stage, or a heavy-light combination. The sensitivity of the polymerization reaction to temperature of the vinyl polysiloxanes can also contribute to drags. If partial setting occurs, the material's ability to flow will be reduced. Refrigerating these materials and ensuring their rapid placement once mixed should prevent this problem. Allowing additional time before removing the impression, beyond the manufacturer's recommendations, will ensure that complete cure has occurred.

Margin defects

Voids are the result of air or moisture inclusions. Hand-mixing is more likely to trap air within the mix than using the more current auto-mix guns. When injecting wash materials, ensure that the tip remains within the expressed material and pushes it ahead while moving around the preparation margin. If grooves or boxes have been included in the resistance form, fill the base of these first and move the syringe tip up to the occlusal surface. The appearance of rounded polished margins in the impression indicates a wet surface (Figure 16). Small teardrop defects can occur as small amounts of fluid within the gingival crevice are driven around the crevice by impression material, and then across the margin as the tooth is completely encircled. Thorough but gentle use of the air syringe should avoid this, but also consider using a two cord technique. Unclear margins may be due to poor preparation, or inadequate gingival displacement. Where margins are at or below the gingival crest, some form of gingival displacement is essential and needs to provide sufficient separation of the gingivae from the tooth for the technician to identify the preparation's limits.

Conclusions

Obtaining impressions of sufficient detail and accuracy for the construction of indirect restorations is dependent on the interplay of several factors. Modern materials are more user-friendly than their predecessors but can still produce poor results if not manipulated correctly. The increased choice of viscosities now available brings with it the need to understand how best to use them. Inappropriate use of trays, poor moisture control, and inadequate retraction methods will negate the potential of the best impression material. Dentists should have an appreciation of all these factors, and understand how each influences their results. More critical examination (with magnification) of impressions, and especially the resulting casts before they are trimmed, may reveal defects which can be corrected in the future, if the clinician can recognize how each has been caused. The apparently small details of technique are important and can mean the difference between impressions which visually appear adequate and ones which are truly accurate. Going to these lengths will result in restorations which fit more accurately and require less adjustment. Not only will chairside time be saved, but patients will feel more confident, your technician will be happier to make your restorations and, most importantly, your job satisfaction will increase.

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Cochrane Synopses

M Esposito, P Coulthard, P Thomsen, HV Worthington. Interventions for *replacing missing teeth: different types of* dental implants. *The Cochrane Database of Systematic Reviews* 2005, Issue 1. Art. No.: CD003815. DOI: 10.1002/14651858. CD003815.pub2.

'There is limited evidence showing that implants with relatively smooth surfaces are less prone to loose bone due to chronic infection (perimplantitis) than implants with rougher surfaces. However, there is no evidence showing that any particular type of dental implant has superior long-term success.

Missing teeth can sometimes be replaced with dental implants into the jaw, as bone can grow around the implant. A crown, bridge or denture can then be attached to the implant. Many modifications have been developed to try to improve the long-term success rates of implants, and different types have been heavily marketed. More than 1300 types of dental implants are now available, in different materials, shapes, sizes, lengths and with different surface characteristics or coatings. However, the review found there is not enough evidence from trials to demonstrate superiority of any particular type of implant or implant system.'

JM Zakrzewska, H Forssell, AM Glenny. Interventions for the treatment of burning mouth syndrome. *The Cochrane Database of Systematic Reviews* 2005, Issue 1. Art. No.: CD002779. DOI: 10.1002/14651858. CD002779.pub2.

'There is insufficient evidence to show the effect of painkillers, hormones or antidepressants for 'burning mouth syndrome' but there is some evidence that learning to cope with the disorder, anticonvulsants and alpha-lipoic acid may help.

A burning sensation on the lips, tongue or within the mouth is called 'burning mouth syndrome' when the cause is unknown and it is not a symptom of another disease. Other symptoms include dryness and altered taste and it is common in people with anxiety, depression and personality disorders. Women after menopause are at highest risk of this syndrome. Painkillers, hormone therapies, antidepressants have all been tried as possible cures. This review did not find enough evidence to show their effects. Treatments designed to help people cope with the discomfort and the use of alpha-lipoic acid may be beneficial. More research is needed.'

JV Keenan, AG Farman, Z Fedorowicz, JT Newton. Antibiotic use for irreversible pulpitis. *The Cochrane Database of Systematic Reviews* 2005, Issue 2. Art. No.: CD004969. DOI: 10.1002/14651858. CD004969.pub2.

'Antibiotics do not appear to significantly reduce toothache caused by irreversible pulpitis.

Irreversible pulpitis, where the dental pulp (nerve) has been damaged beyond repair is characterised by intense pain and considered to be one of the most frequent reasons that patients attend for emergency dental care. This review, which included 1 trial (40 participants), found that there is a small amount of evidence to suggest that the administration of penicillin does not significantly reduce the pain perception, the percussion perception or the quantity of pain medication required by patients with irreversible pulpitis.'

An Innovative Tissue-Retraction Material

CE 3

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Private Practice
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Abstract: *One of the most challenging problems of fixed prosthodontics is tissue control. Gingival retraction before a final impression can be very frustrating and time consuming. Many different techniques have been developed over the years to accommodate the clinician's struggle to obtain tissue control and achieve an ideal impression. This article discusses several of those techniques and how the new, innovative product Expa-syl™ can be incorporated into these techniques. Expa-syl™ is an injectable retraction and hemostatic agent that can cause little trauma to the tissue as well as save the dentist time and money. The author elaborates on the multiple uses of Expa-syl™ and the correct techniques for making this material a successful tool in any dental office.*

Four gingival retraction techniques are described in this article: rotary curettage, electrosurgery, retraction cord, and a new injectable retraction material.[1]

Rotary Curettage Method

The first technique, rotary curettage, has two main advantages: it is easy to perform and it requires no special equipment. It is also the least expensive of the four techniques presented here. Although rotary curettage is one of the easiest techniques, it has numerous disadvantages. The bleeding it can cause can be difficult to control, which can make the final impression difficult to obtain. The amount of tissue that can be removed is limited, and there is also a great deal of patient discomfort.

Electrosurgery Method

The second technique for tissue control is electrosurgery.[2] The main advantage to electrosurgery is that posthemorrhage is well controlled provided the tissue is not inflamed. However, there are multiple disadvantages with electrosurgery. The first is the unpredictable way in which the tissue will heal. In an anterior tooth there would be considerable concern about the possibility of recession. Second, if the clinician is not careful, and too much heat is generated, there could be a considerable amount of collateral damage to the surrounding tissue. Third, caution must be used in patients with pacemakers as well as patients undergoing radiation therapy.

Retraction Cord Method

Retraction cords are the most common method for retracting tissue.[3] There are two main techniques: the single cord and the double cord. The choice of cord depends on the amount of tissue that needs to be retracted. There are three advantages to the cord technique. First, it is the most universal technique used today. Second, there is a variety of cords that can be used to achieve different results and different degrees of retraction. Third, retraction cord is very inexpensive. However, in some instances, cord can provide a challenge for the clini-

Learning Objectives

After reading this article, the reader should be able to:

- discuss different types of gingival retraction methods.
- compare different types of hemostatic agents.
- discuss predictable techniques for the use of Expa-syl™.

CE 3

Figure 1A—Gingival irritation after post-and-core buildup.

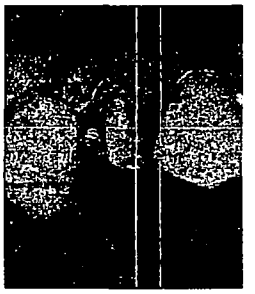

Figure 1B—Expa-syl™ needle placed to the long axis of the tooth.

Figure 1C—Injecting the Expa-syl™.

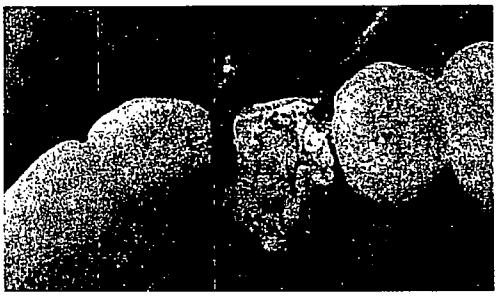

Figure 1D—Expa-syl™ placed around the entire tooth.

Figure 1E—Rinsing Expa-syl™ with air and water.

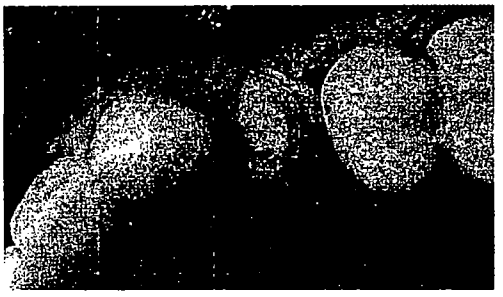

Figure 1F—Dry field is ready for impression.

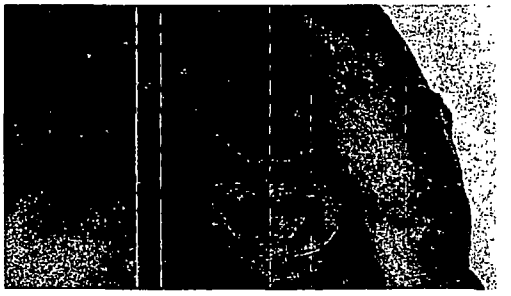

Figure 1G—Final polyvinyl impression exhibiting accurate marginal replication.

cian. Positioning the cord in a shallow sulcus can be quite difficult and runs the risk of creating a lesion in the epithelial attachment. There is also a risk of bleeding upon removal of the cord. The double-cord technique presents some of the same challenges as the single-cord technique. Additionally, anesthesia will most likely have to be used and chairtime is increased dramatically.[3]

There is also a variety of hemostatic agents that can be used in conjunction with retraction cord. Aluminum chloride provides hemostasis by constricting the blood vessels in the gingival tissues. It is the least reactive agent with polyvinyl impressions.[4] Ferric sulfate provides hemostasis by cauterizing the tissue. The downside is that ferric sulfate turns the tissue black and may inhibit the setting of the impression material.[5] Aluminum sulfate controls bleeding by constricting the blood vessels, but patients complain about the bitter taste. While epinephrine is also a popular agent used with retraction cord to control bleeding, its vasoconstrictive properties can lead to problems with some patients because it can increase the heart rate. The patient's health history is critical when deciding whether to use epinephrine for hemostasis.

Injectable Retraction Method

A fourth technique for gingival retraction and hemostasis recently became available—

CE 3

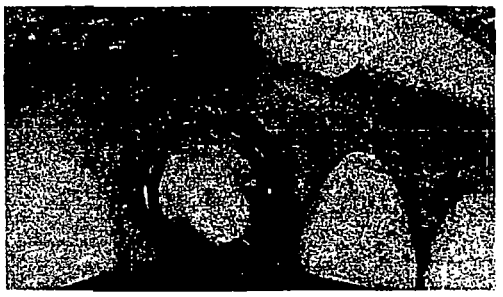

Figure 2A—Gingival irritation after the crown is removed.

Figure 2B—Injecting Expa-syl™ around the tooth.

Figure 2C—Injecting Expa-syl™ around the tooth.

Figure 2D—Dry sulcus is ready for impression.

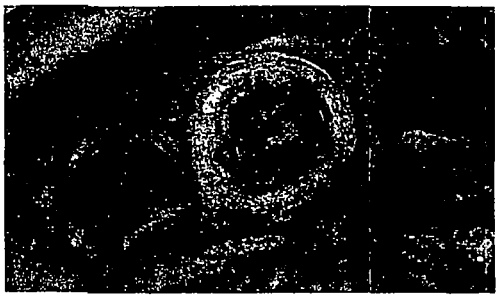

Figure 2E—Polyvinyl impression with clear margins.

Expa-syl™[3]—a new, innovative material from the Kerr® Corporation. The aim of the Expa-syl™ system is to detach the marginal gingiva without injuring the epithelial attachment. With Expa-syl™, exposure of the sulcus no longer causes bleeding or oozing. The system consists of an injectable material that contains a hemostatic agent, a specially designed gun, and tips. This injectable material is prepackaged in a carpule. Expa-syl™ consists of a highly viscous organic binder, kaolin, which is essentially clay. A small amount of aluminum chloride is mixed with the kaolin to act as a hemostatic agent. Because of its consistency, Expa-syl™ can displace tissue and, because of the aluminum chloride, will act as a hemostatic agent. Unlike cord, Expa-syl™ does not have to be placed around the entire tooth in every situation; it is used only where needed.

There are many advantages to this system, such as convenience and reduced chair-time. Because the delivery of Expa-syl™ is gentle to the tissue, the risk of damage to the epithelial attachment, gingival recession, and bone resorption is greatly reduced. Expa-syl™ is a viscous paste that can be injected directly into the sulcus. It not only opens the sulcus, but also leaves the field dry, ready for an impression or cementation. Expa-syl™ creates and maintains space in the sulcus, although there is no change in the material once it is applied—there is no chemical reaction, material expansion, or trauma to the tissue. The aluminum chloride controls the bleeding and, along with the kaolin, keeps the working field dry.

The physical properties of Expa-syl™ are remarkable. Expa-syl™ exhibits a yield stress higher than the force exerted on the tooth by the gingiva. Therefore, it is able to keep the gingival sulcus open. The forces exhibited by Expa-syl™ are still nearly 20 times less than that of a single cord and almost 50 times less than the double-cord technique.[6] When

[3] Kerr® Corporation, Orange, CA 92867; 800-537-7123

CE 3

Figure 3A—Gingival seepage before cementation.

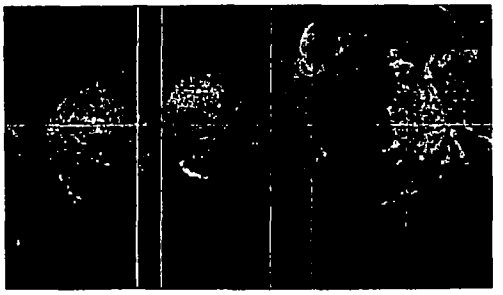

Figure 3B—Expa-syl™ placed to control gingival seepage.

Figure 3C—After rinsing Expa-syl™ away, the tooth is ready for cementation.

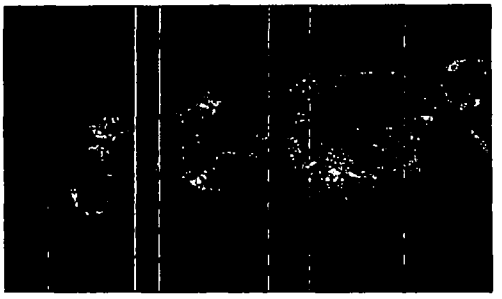

Figure 3D—The ceramic crown is successfully cemented in place.

Expa-syl™ absorbs moisture, the yield stress drops dramatically. It is very important to keep the Expa-syl™ as dry as possible, especially from saliva.[6]

Case 1

A 52-year-old man presented with tooth No. 4 broken off at the gingival. A post-and-core was placed (Figure 1A). The gingival tissue was irritated and inflamed. It is best for the field to be dry before placing Expa-syl™; however, in this situation it was very difficult to do so. The tip on the Expa-syl™ was placed at a 90-degree angle to the long axis of the tooth (Figures 1B and 1C). If possible, it is best to use the tip to mechanically displace the tissue as the material is injected. Because there was bleeding around the entire tooth, Expa-syl™ was placed accordingly (Figure 1D). The aluminum chloride in Expa-syl™ was sufficient to stop the bleeding and dry the field for the final impression. After only 2 minutes, a heavy blast of air and water was used to flush out the Expa-syl™ (Figure 1E). Even with the heavy pressure of the air and water, there was no seepage of blood or any other gingival fluids (Figure 1F). The tissue remained sufficiently retracted to make a polyvinyl impression (Figure 1G).

Case 2

A 29-year-old woman wanted to enhance the esthetics of tooth No. 9. She had an existing porcelain-fused-to-metal crown in which the margins were subgingival. After the crown was removed, there was a considerable amount of gingival hemorrhaging (Figure 2A). Expa-syl™ was placed for 2 minutes (Figures 2B and 2C). After rinsing thoroughly, the field was dry enough to make a polyvinyl impression using materials such as Take One®[a] or Aquasil™[b] (Figures 2D and 2E). In this instance it would have been very difficult to pack cord and not cause excess trauma to the tissue.

Case 3

Expa-syl™ is also an excellent material to use during cementation. Often, provisionals can lead to gingival irritation. The clinician can control the placement of Expa-syl™ to exactly where it is needed, and once it is rinsed off, the tooth is ready for cementation whether it is conventionally cemented or the restoration is bonded in place. In this situation, after the provisional was removed, Expa-syl™ was used to dry any gingival seepage (Figures 3A and 3B). The restoration could now be bonded

[6] DENTSPLY®/Caulk®, Milford, DE 19963; 800-LD-CAULK

in place (Figures 3C and 3D).

Expa-syl™ also can be used for Class V restorations that require gingival retraction. The techniques used in such cases are the same as described earlier.

Conclusion

Expa-syl™ offers many advantages to the patient as well as to the clinician. Expa-syl™ represents certainty of obtaining access to the true anatomical cervical margin. When Expa-syl™ is removed, the clinician can obtain a clean clinical site that is ideal for a perfect impression. It is quick and easy for the dentist, saving valuable chairtime. The procedure is painless for the patient, and anesthesia is no longer required because there is no damage to the sulcus. Expa-syl™ can change the way clinicians manage tissue in a variety of restorative procedures, providing a win-win situation for both the clinician and the patient.

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Chapter 5.

Hemostatics, Astringents and Gingival Retraction Cords

Kenneth H. Burrell, D.D.S., S.M.; Michael Glick, D.M.D.

Hemostatics

An understanding of hemostasis, identification of patients with excessive bleeding tendencies, and interventions to stop abnormal bleeding is essential to the provision of safe and appropriate dental care.

Hemostasis can be divided arbitrarily into four phases: a vascular phase and a platelet phase, also referred to as "primary hemostasis"; and a coagulation phase and a fibrinolytic phase, also referred to as "secondary hemostasis."

Defects in any phase of normal hemostasis have characteristic signs and symptoms. Most commonly, dental health care providers will be faced with patients who have defects of the platelet and coagulation phases.

People with quantitative or qualitative platelet disorders usually have superficial signs such as petechiae and ecchymosis on the mucosa and skin. Furthermore, patients may report spontaneous gingival bleeding, epistaxis, prolonged postextraction bleeding or prolonged bleeding after minor trauma. Spontaneous clinical hemorrhage is usually present when the platelet count drops below 15,000-20,000/mm^3. (For normal laboratory values, see Appendix H.)

The clinical value of a bleeding time for dental procedures has been challenged. However, significant prolonged bleeding times beyond 15-20 min may suggest significant hemorrhage after dental surgery.

Causes of defects of primary hemostasis include congenital as well as acquired disorders. The most common inherited bleeding disorder in the United States is von Willebrand's disease. This disorder is characterized by various degrees of deficiency of the von Willebrand factor, which is needed primarily for platelet adhesion. In severe cases of von Willebrand's disease, spontaneous bleeding may occur. However, mild cases may be associated with prolonged bleeding only after major trauma. Common acquired dysfunctions of primary hemostasis include idiopathic thrombocytopenia purpura, liver disease and drug-induced platelet disorders. Also, both acute and chronic leukemia are associated with thrombocytopenia. Some medications are used intentionally to decrease platelet functions, such as aspirin-containing medications and ticlopidine, in patients with disorders such as coronary artery disease.

Disorders of secondary hemostasis include hemophilia, vitamin K deficiency and liver disease. Hemophilia is usually classified according to the specific factor deficiency, such as hemophilia A for factor VIII deficiency and hemophilia B for factor IX deficiency. Patients with hemophilia lack the ability to form fibrin and have bleeding episodes particularly within stress-bearing joints (deep-seated

bleeding). This eventually can cause destruction of these joints.

General dentistry can be performed in patients with > 50% factor activity, but 100% activity is recommended for surgical procedures. In a 60-kg patient with hemophilia A, a 100% plasma level equals 6,000 units of factor VIII.

Vitamin K deficiency causes decreased activation and production of factors II, VII, IX and X, resulting in a defective coagulation cascade and consequent decreased fibrin production. Virtually all coagulation factors are produced in the liver, and vitamin K is stored in the liver. Thus, liver disease may result in increased bleeding tendencies. Medications such as warfarin, an anticoagulant that impairs the action of vitamin K, is used to prevent thrombosis in patients with such disorders as atrial fibrillation, deep venous thrombosis, ischemic cardiovascular disease and stroke.

A thorough medical history, examination and laboratory evaluation will identify most patients who have increased bleeding tendencies. Included in the patient assessment should be questions addressing whether the patient has relatives with bleeding problems, has experienced prolonged bleeding after trauma, or takes medications or has diseases associated with increased bleeding tendencies. Examination should focus on signs of bruising, jaundice, hyperplastic gingival tissue, spontaneous gingival bleeding and hemarthrosis. Screening tests for impaired hemostasis include platelet count and bleeding time for primary hemostasis, as well as prothrombin time, international normalization ratio, activated partial thromboplastin time and thrombin time for secondary hemostasis. (See Appendix H for normal values.)

Dental treatment of patients with impaired hemostasis includes the use of both local and systemic measures. The use of the appropriate technique or agent depends on the patient's underlying condition and specific hemostatic impairment.

Accepted Indications

If blood flow is profuse, mechanical aids such as a compress, hemostatic forceps, a modeling compound splint or hemostatic ligatures can be used. Mechanical obliteration with cryosurgery, electrocauterization and laser also can be used. Although these thermal methods are effective, they may be associated with impaired healing. A third kind of mechanically aided hemostasis is the use of chemical glues, such as n-butyl cyanoacrylate and bone wax. These compounds have a mechanical effect without directly affecting the coagulation process.

For slow blood flow and oozing, a combination of hemostatics can be used. The three kinds of hemostatics to be noted here are absorbable hemostatic agents, agents that modify blood coagulation and vasoconstrictors. Vasoconstrictors act by constricting or closing blood vessels. They are used to a limited extent to control capillary bleeding. Vasoconstrictors are described in detail in Chapter 1 (Tables 1.3, 1.6). See Table 5.1 for a comparison of various hemostatics useful in dentistry.

Absorbable Gelatin Sponge

The absorbable gelatin sponge consists of a tough, porous matrix prepared from purified pork skin gelatin, granules and water that is indicated as a hemostatic device for control of capillary, venous or arteriolar bleeding when pressure, ligature or other conventional procedures are either ineffective or impractical. It can be used in extraction sites and is absorbed in 4-6 w.

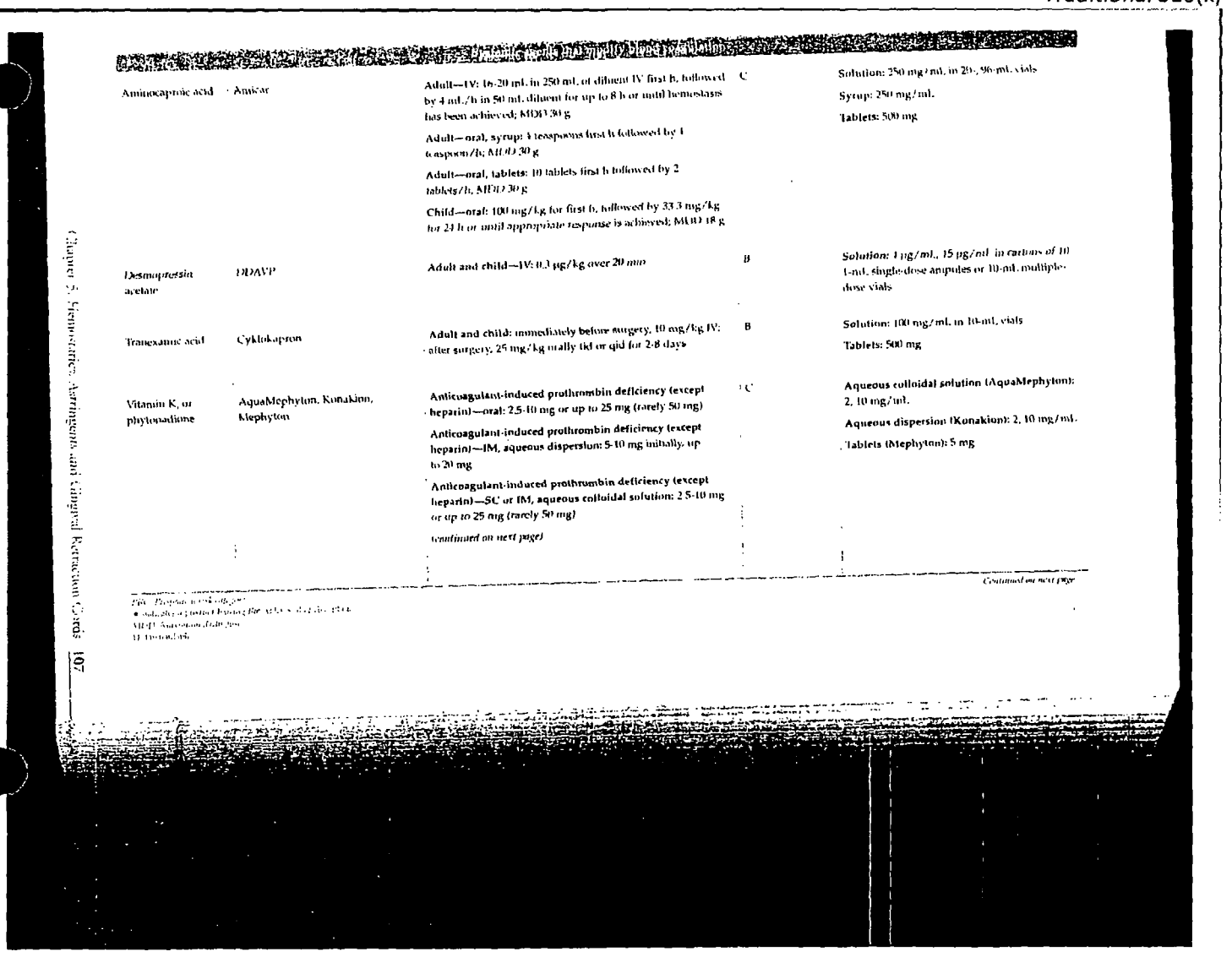
Oxidized Cellulose

Oxidized cellulose is a chemically modified form of surgical gauze or cotton that is used to control moderate bleeding by forming an artificial clot when suturing or ligation is impractical and ineffective. Because it is friable, oxidized cellulose is difficult to place and retain in extraction sockets, but can be used as a sutured implant or temporary pack-

Table 5.1

Hemostatics: Dosage and Prescribing Information

Generic name	Brand name(s)	Dosage	PRC	Form
		Topical that locally coagulates		
Absorbable gelatin sponge	*Gelfoam*	*Absorbable gelatin sponge may be cut; may be applied to* bleeding surfaces to cover area	U	**Dental packing blocks:** 20 × 20 × 7 mm **Powder:** 1 g
Oxidized cellulose	Oxycel	Hemostatic effect is greater when material is applied dry as opposed to moistened with water or saline	U	**Pad:** 3 × 3 in **Pledget:** 2 × 1 × 1 in **Strip:** 18 × 2, 3 × ½, 36 × ½ in
Oxidized regenerated cellulose	Surgicel Absorbable Hemostat ®, Surgicel Nu-Knit Absorbable Hemostat	Can be laid over extraction socket for control of bleeding; minimal amounts of the material should be placed on bleeding site; may be held firmly against tissue	U	**Surgicel sheets:** 2 × 14, 4 × 8, 2 × 3, ½ × 2 in **Surgicel Nu-Knit sheets:** 1 × 1, 3 × 4, 6 × 9 in
Microfibrillar collagen hemostat	Avitene, Collacote ®, Collaplug, Collatape ®, Instat MCH	Is applied topically and adheres firmly to bleeding surfaces	U	**Avitene Flour:** ½-, 1-, 5-g syringes **Avitene Sheets:** 35 × 35, 70 × 35, 70 × 70 mm **Collacote, Collaplug, Collatape:** 1 × 3, ¾ × 1½, ⅛ × ¾ in **Instat MCH:** Coherent fibers packaged in 0.5- and 1.0-g containers
Collagen hemostat	Instat	Should be applied directly to bleeding surface with pressure; is more effective when applied dry, or may be moistened with sterile saline or thrombin solution; may be left in place as necessary; is absorbed 8-10 w after placement	U	**Pads:** 1 × 2, 3 × 4 in



Aminocaproic acid	Amicar	Adult—IV: 16-20 mL in 250 mL of diluent IV first h, followed by 4 mL/h in 50 mL diluent for up to 8 h or until hemostasis has been achieved; MDD 30 g Adult—oral, syrup: 4 teaspoons first h followed by 4 teaspoon/h; MDD 30 g Adult—oral, tablets: 10 tablets first h followed by 2 tablets/h; MDD 30 g Child—oral: 100 mg/kg for first h, followed by 33.3 mg/kg for 24 h or until appropriate response is achieved; MDD 18 g	C	Solution: 250 mg/mL in 20-, 96-mL vials Syrup: 250 mg/mL Tablets: 500 mg
Desmopressin acetate	*DDAVP*	Adult and child—IV: 0.3 μg/kg over 20 min	B	*Solution: 1 μg/mL, 15 μg/mL in cartons of 10 1-mL single-dose ampules or 10-mL multiple-dose vials*
Tranexamic acid	Cyklokapron	Adult and child: immediately before surgery, 10 mg/kg IV; after surgery, 25 mg/kg orally tid or qid for 2-8 days	B	Solution: 100 mg/mL in 10-mL vials Tablets: 500 mg
Vitamin K, or phytonadione	AquaMephyton, Konakion, Mephyton	Anticoagulant-induced prothrombin deficiency (except heparin)—oral: 2.5-10 mg or up to 25 mg (rarely 50 mg) Anticoagulant-induced prothrombin deficiency (except heparin)—IM, aqueous dispersion: 5-10 mg initially, up to 20 mg Anticoagulant-induced prothrombin deficiency (except heparin)—SC or IM, aqueous colloidal solution: 2.5-10 mg or up to 25 mg (rarely 50 mg) *(continued on next page)*	C	Aqueous colloidal solution (AquaMephyton): 2, 10 mg/mL Aqueous dispersion (Konakion): 2, 10 mg/mL Tablets (Mephyton): 5 mg

Continued on next page

Table 5.1 (cont.)

Hemostatics: Dosage and Prescribing Information

Generic name	Brand name(s)	Dosage	PRG	Form
Vitamin K_1 or phytonadione (cont.)		**Hypoprothrombinemia owing to other causes and factors limiting absorption or synthesis—SC or IM, aqueous colloidal solution:** 2.5-25 mg or more (rarely up to 50 mg) **Hypoprothrombinemia owing to other causes and factors limiting absorption or synthesis—IM, aqueous dispersion:** 2-20 mg **Hypoprothrombinemia owing to other causes and factors limiting absorption or synthesis—oral:** 0.5-25 mg or more (rarely up to 50 mg)		
Vitamin K_3 or menadione	generic	2-10 mg/day, 4-7 days before surgery	U	**Powder**
Vitamin K_3 or menadiol sodium diphosphate	Synkayvite	**Injection:** 5-10 mg q day, 4-7 days **Oral:** 5 mg q day, 4-7 days	U	**Injection:** 5, 10, 37.5 mg/ml. **Tablets:** 5 mg
Thrombin	Thrombin-JMI, Thrombinar, Thrombogen, Thrombostat	**For profuse bleeding—solution:** 1,000-2,000 units/ml **For bleeding from skin or mucosa—solution:** 100 units/ml.	C	**Powder:** 1,000, 5,000, 10,000, 20,000 units; 50,000 units (Thrombinar only) **Powder with isotonic saline diluent:** 5,000-, 10,000- and 20,000-unit containers with 5-, 10-, and 20-ml, of isotonic saline **Thrombostat:** Also contains 0.02 mg/ml. phenerol as a preservative

ing. The cotton or gauze can be removed before dissolution is complete by irrigation with saline or a mildly alkaline solution.

Absorption of oxidized cellulose ordinarily occurs between the second and seventh day after implantation of material, but complete absorption of large amounts of blood-soaked material may take six weeks or longer.

Oxidized Regenerated Cellulose

Oxidized regenerated cellulose is prepared from alpha-cellulose by reaction with alkali to form viscose, which is then spun into filaments and oxidized. This process results in greater chemical purity and uniformity of physical structure than oxidized cellulose. It is a sterile, absorbable, knitted fabric that is strong enough to be sutured or cut. It has less tendency to stick to instruments and gloves and is less friable than oxidized cellulose.

Oxidized regenerated cellulose is used to control capillary, venous and small arterial hemorrhage when ligature, pressure, or other conventional methods of control are impractical or ineffective. The product can be used as a surface dressing because it does not retard epithelialization. It is bactericidal against numerous gram-negative and gram-positive microorganisms, both aerobic and anaerobic.

It can be placed over extraction sites.

Microfibrillar Collagen Hemostat

Microfibrillar collagen hemostat is a hemostatically active agent prepared from bovine deep flexor tendon (Achilles tendon) as a water-soluble, partial-acid salt of natural collagen. It reduces bleeding from surgical sites such as those involving cancellous bone and gingival graft donor sites. It should not be left in infected or contaminated spaces because it may prolong or promote infection and delay healing.

Collagen Hemostat

Collagen hemostat is absorbable and composed of purified and lyophilized bovine dermal collagen. Used as an adjunct to hemostasis, collagen absorbable hemostat can be sutured into place. It reduces bleeding when ligation and other conventional methods are ineffective or impractical. Excess material should be removed before the wound is closed.

Aminocaproic Acid

Aminocaproic acid, or ε-aminocaproic acid, is used in patients with excessive bleeding due to underlying conditions such as systemic hyperfibrinolysis and coagulopathies stemming from promyelocytic leukemia. This medication is seldom used for elective oral surgery procedures, but rather during emergency situations in combination with transfusion of fresh frozen blood and fibrinogen.

Desmopressin Acetate

Desmopressin acetate is used primarily to reduce spontaneous bleeding in patients with von Willebrand's disease and in patients with moderate-to-mild hemophilia A (factor VIII levels above 5%). It also is used prophylactically during procedures to reduce the incidence of bleeding, as well as after procedures to achieve better hemostasis in these patient populations.

Tranexamic Acid

Tranexamic acid is used primarily to reduce the amount of factor replacement necessary after dental extractions in hemophiliac patients. It is indicated for only 2-8 days during and after the dental procedure. It also is used for other patient populations with impaired secondary hemostasis, including patients who are receiving anticoagulation therapy.

Vitamin K

Vitamin K therapy is required when hypoprothrombinemia results from inadequately available vitamins K_1 and K_2. This occurs when there is decreased synthesis by intestinal bacteria, inadequate absorption from the intestinal tract or increased requirement by the liver for normal synthesis of prothrombin.

Vitamin K, in its various forms, is an essential component of blood coagulation. Vitamins K_1, K_2 or menadione (vitamin K_3) are required for the production of the functional

forms of six coagulation proteins: prothrombin, factors VII, IX and X and proteins C and S.

Phytonadione (vitamin K_1)

Phytonadione—known as vitamin K_1—is used for

- anticoagulant–induced prothrombin deficiency;
- prophylaxis and therapy of hemorrhagic disease of the newborn;
- hypoprothrombinemia resulting from oral antibacterial therapy;
- hypoprothrombinemia secondary to factors limiting absorption or synthesis of vitamin K such as obstructive jaundice, biliary fistula, sprue, ulcerative colitis, celiac disease, intestinal resection, cystic fibrosis of the pancreas and regional enteritis;
- other drug-induced hypoprothrombinemia such as that which results from salicylate use.

Menadione (vitamin K_3)

Menadione is a synthetic form of vitamin K, which is sometimes referred to as vitamin K_3.

Menadiol sodium diphosphate (vitamin K_4)

Menadiol sodium diphosphate is effective as a hemostatic agent only when bleeding results from prothrombin deficiency.

Thrombin

Thrombin is useful as a topical local hemostatic agent when blood is oozing from accessible capillaries or venules. In certain kinds of hemorrhage, it can be used to wet pledgets of absorbable gelatin sponge and placed on bleeding tissue or in extraction sockets with or without sutures. It is particularly useful whenever blood is flowing from accessible capillaries and small venules.

General Dosing Information

Table 5.1 lists the general dosing information for specific hemostatics.

Dosage Adjustments

The actual dose for each patient must be individualized according to factors such as his or her size, age and physical status. Reduced doses of vitamin K may be indicated for patients who are taking anticoagulants as opposed to those who have malabsorption problems. The other hemostatic agents should be used as needed.

Special Dental Considerations

Cross-Sensitivity

Patients may experience delayed healing using the gelatin, cellulose and collagen hemostatics. This is more often observed when the surgical site is infected.

Patient Monitoring: Aspects to Watch

Patients receiving vitamin K, especially parenterally, may experience allergic reactions such as rash, urticaria and anaphylaxis.

Adverse Effects and Precautions

The incidence of adverse reactions to hemostatic agents is relatively low. Many reactions are temporary. Idiosyncratic and allergic reactions account for a small minority of adverse responses. See Table 5.2.

Pharmacology

Absorbable Gelatin Sponge

The absorbable gelatin sponge promotes the disruption of platelets and acts as a framework for fibrin, probably because of its physical effect rather than the result of its alteration of the blood clotting mechanism. It can be placed in dry form or may be moistened with sterile saline or thrombin solution and used in extraction sites.

Oxidized Cellulose

Oxidized cellulose is a chemically modified form of surgical gauze or cotton. Its hemostatic action depends on the formation of an artificial clot by cellulosic acid, which has a marked affinity for hemoglobin.

Oxidized Regenerated Cellulose

Oxidized regenerated cellulose probably serves as a hemostatic by providing a physi-

Table 5.2

Hemostatics: Adverse Effects, Precautions and Contraindications

Agent	Adverse effects	Precautions/contraindications
	Absorbable hemostatic agents	
Oxidized cellulose	May lead to a foreign-body reaction	Extremely friable and difficult to place Should not be used at fracture sites because it interferes with bone regeneration Should not be used as a surface dressing except for the immediate control of hemorrhage, as cellulosic acid inhibits epithelialization Should not be used in combination with thrombin because the hemostatic action of either alone is greater than that of the combination
Oxidized *regenerated* cellulose	NS	Placement in extraction sites may delay healing; it should not be placed in fracture sites because it may interfere with callus formation and may cause cyst formation Encapsulation of fluid and foreign bodies possible
Collagen hemostat	Incidence of pain has been reported to increase when this material is placed in extraction sockets Allergic reactions can occur in patients with known sensitivity to bovine material	Should not be used in mucous membrane closure because it may interfere with healing due to mechanical interposition Should not be left in infected or contaminated space because of possible delay in healing and increased likelihood of abscess formation Should not be used in patients with a known sensitivity to bovine material Should not be overpacked because collagen absorbable hemostat absorbs water and can expand to impinge on neighboring structures Should not be used in cases where point of hemorrhage is submerged, because collagen must be in direct contact with bleeding site to achieve desired effect
Microfibrillar collagen hemostat	May potentiate abscess formation, hematoma and wound dehiscence	Is not intended to treat systemic coagulation disorders Placement in extraction sites has been reported to increase pain Should not be left in infected or contaminated spaces because of possible adhesion formation, allergic reaction, foreign body reaction Interferes with wound margins
Absorbable gelatin sponge	May form a nidus for infection or abscess formation	Should not be overpacked in extraction sites or surgical defects because it may expand to impinge on neighboring structures

Continued on next page

Table 5.2 (cont.)

Hemostatics: Adverse Effects, Precautions and Contraindications

Agent	Adverse effects	Precautions/contraindications
Aminocaproic acid	Headache, dizziness, convulsions, weakness, psychosis, dysrhythmias, orthostatic hypotension, thrombosis, renal failure, ejaculatory failure, tinnitis, nasal congestion, rash	Use with caution in patients with mild-to-moderate renal failure, hepatic disease, thrombosis, cardiac disease or hypertension, as well as in lactating women *Contraindicated in patients with abnormal bleeding, postpartum bleeding, new burns, nephrogenic diabetes insipidus*
Desmopressin acetate	Headache, drowsiness, lethargy, flushing, increased blood pressure, nausea, heartburn, vulval pain	See note above
Tranexamic acid	Giddiness, nausea, vomiting, diarrhea, blurred vision; hypotension with IV dose	Dose should be reduced for patients with renal impairment *Contraindicated in patients with acquired defective color vision and subarachnoid hemorrhage*
Vitamin K, or phytonadione	Parenteral administration can cause transient "flushing sensations" and "peculiar sensations" of taste; also (rarely) dizziness, rapid and weak pulse, profuse sweating, brief hypotension, dyspnea and cyanosis; allergic sensitivity, including an anaphylactoid reaction, has been reported	Patient undergoing prothrombin reduction therapy should not receive vitamin K preparations except under a physician's supervision Determine if patient is taking anticoagulants, as the drug can decrease effect of anticoagulant Contraindicated in patients with known sensitivity to the drug
Vitamin K_3 or menadione	Adverse reactions are similar to those produced by phytonadione, but incidence is low	Requires normal flow of bile or administration of bile salts Patient undergoing prothrombin reduction therapy should not receive vitamin K preparations except under physician supervision
Vitamin K_4 or menadiol sodium diphosphate	See note above	Before administering drug, determine if patient is receiving anticoagulant therapy; a patient undergoing prothrombin reduction therapy should not receive vitamin K preparations except under physician supervision If patient is taking anticoagulants, this agent may decrease their effectiveness
Thrombin	Allergic reactions can occur in patients with known sensitivity to bovine material	Thrombin must not be injected into blood vessels because it might cause serious or even fatal embolism from extensive intravascular thrombosis; instead, should be applied to surface of bleeding tissue as solution or powder

cal effect rather than altering the normal physiological clotting mechanism.

Microfibrillar Collagen Hemostat

This hemostatic agent is used topically to trigger the adhesiveness of platelets and stimulate the release phenomenon to produce aggregation of platelets leading to their disintegration and to release coagulation factors that, together with plasma factors, enable fibrin to form. The physical structure of microfibrillar collagen hemostat adds strength to the clot.

Collagen Hemostat

When collagen comes into contact with blood, platelets aggregate and release coagulation factors, which together with plasma factors, cause the formation of fibrin and a clot.

Aminocaproic Acid

Aminocaproic acid is an antifibrinolytic agent that slows or stops fibrinolysis by inhibiting the action of plasminogen. Consequently, it delays the breakdown of the hemostatic plug. This medication is administered both intravenously and orally in the form of tablets and syrup. Concurrent use of other hemostatic agents in patients with significant bleeding tendencies is recommended.

Desmopressin Acetate

Desamino-*D*-arginine vasopressin is a synthetic analogue of the natural pituitary hormone 1-8-D-arginine vasopressin. This medication increases plasma levels of von Willebrand factor-VIII complex and factor VIII levels. It is administered 30 min before the dental appointment. It facilitates outpatient care for patients with hemophilia, but should always be used in conjunction with other hemostatic agents.

Tranexamic Acid

Tranexamic acid is an antithrombolytic hemostatic agent that acts by decreasing conversion of plasminogen to plasmin. At much higher doses, it acts as a noncompetitive inhibitor of plasmin. It is indicated for prophylaxis and treatment of patients with hemophilia, to prevent or reduce hemorrhage during and after tooth extraction. Unlabeled uses include topical use as a mouthwash, along with systemic therapy to reduce bleeding after oral surgery. It is contraindicated for use in patients receiving anticoagulant therapy. This medication is administered both intravenously and orally.

Vitamin K

Two forms of naturally occurring vitamin K have been isolated and prepared synthetically. The naturally occurring forms are designated vitamins K_1 and K_2. Vitamin K_1 is present in most vegetables, particularly in their green leaves. Vitamin K_2 is produced by intestinal bacteria. Menadione has vitamin K activity and is derived from a breakdown of the vitamin K molecule by intestinal bacteria and is sometimes referred to as vitamin K_3. Menadiol sodium diphosphate, or vitamin K_4, is a water-soluble derivative that is converted to menadione in the liver.

Hypoprothrombinemia may result from inadequately available vitamins K_1 and K_2 because of decreased synthesis by intestinal bacteria, inadequate absorption from the intestinal tract or increased requirement by the liver for normal synthesis of prothrombin. Liver dysfunction may also decrease the production of prothrombin, but the hypoprothrombinemia from hepatic cell injury may not respond to the administration of vitamin K as many coagulation proteins are produced in hepatocytes.

Insufficient vitamin K in ingested foods becomes significant only when the synthesis of the vitamin by intestinal bacteria is markedly reduced by the oral administration of antibacterial agents. Biliary obstructions or intestinal disorders may result in an inadequate rate of absorption of vitamin K.

Phytonadione (vitamin K_1)

Vitamin K_1 is required for the production of the functional forms of six coagulation proteins: prothrombin, factors VII, IX and X and proteins C and S.

Menadione (vitamin K_3)
Although it is readily absorbed from the intestine, menadione must be converted to vitamin K_2 by the liver. Therefore, it requires a normal flow of bile into the intestine or the concomitant administration of bile salts.

Menadiol sodium diphosphate (vitamin K_4)
Vitamin K_4, because of its water solubility, is absorbed from the intestinal tract even in the absence of bile salts.

Thrombin

Thrombin is a sterile protein substance that is an essential component of blood coagulation. It combines with fibrinogen to form fibrin.

Patient Advice

- Let the patient know that a hemostatic has been used, what kind of hemostatic it is and why it was used.
- Advise the patient to let you know if bleeding continues from the surgical site.

Astringents

Astringents cause contraction of tissues. They accomplish this by constricting small blood vessels, extracting water from tissue or precipitating protein.

Accepted Indications

Dentists can apply astringents to gingival tissues before taking impressions or placing Class V or root-surface restorations. They can be used alone or in combination with retraction cords. Aluminum and iron salts are the compounds used as astringents in dentistry.

Aluminum Chloride

Aluminum chloride causes contraction or shrinking of tissue, making it useful in retracting gingival tissue. It also reduces secretions and minor hemorrhage.

Aluminum Potassium Sulfate

Aluminum potassium sulfate, or alum, is not widely used even though it is relatively innocuous, because its tissue retraction and hemostatic properties are limited.

Aluminum Sulfate

Aluminum sulfate, as with other aluminum salts, serves as an effective astringent for gingival retraction and hemostatic action.

Ferric Sulfate

Ferric sulfate is an effective and safe astringent and hemostatic for use in gingival retraction. It also can be used in vital pulpotomies.

General Dosing Information

Table 5.3 lists the general dosing and administration information for specific astringents.

Adverse Effects

The incidence of adverse reactions to astringents is relatively low. Most reactions (presented in Table 5.4) are temporary. The adverse effects listed in Table 5.4 apply to all major types of astringents.

Pharmacology

The ability of any astringent to contract or shrink mucous membrane or skin tissue is related to its mode of action involving protein precipitation and water absorption.

Gingival Retraction Cords

Gingival retraction cords can be used alone or in combination with astringents or vasoconstrictors. They are usually made of cotton and are woven in various ways to suit the practitioner's preference. They are also available in a variety of diameters to accommodate the variation in gingival sulcus width and depth.

These cords can be impregnated with astringents or vasoconstrictors either by the manufacturer or at chairside. Aluminum chloride, aluminum sulfate and ferric sulfate

Table 5.3

Astringents: Dosage and Prescribing Information

Generic name	Brand name(s)	Adult dosage	Content/form
Aluminum chloride	Gingi-Aid, Hemodent ★, Hemodettes, Hemogin-L, Rastringent, Styptin, Ultradent	Apply product directly to tissues using a cotton pledget or apply to gingival retraction cords	**Gel:** 20% (Hemodettes) **Solution:** 20% (Hemodent, Styptin), 25% (Gingi-Aid, Rastringent, Ultradent) **Ointment:** 25% (Hemogin-L) **Retraction cords:** Average concentration of 0.915, 3.5 mg/in
Aluminum potassium sulfate	generic	Any concentration, including 100% powder, can be used	**Powder:** 100% Various concentrations, all available and prepared by chemical supply houses
Aluminum sulfate	Gel-Cord	Apply product directly to tissues using a cotton pledget or apply to gingival retraction cords	**Gel:** In unit-dose cartridge **Impregnated retraction cord:** Average concentration of 0.48, 0.85, 1.45 mg/in **Topical solution:** 25%
Ferric sulfate	Astringedent ★, Hemodent-FS, Stasis, ViscoStat	Apply product directly to tissues using a cotton pledget or apply to gingival retraction cords	**Solution:** 13.3% (Astringedent), 13.5 (Hemodent-FS), 20% (ViscoStat—for use in infuser kit), 21% (Stasis)

★ indicates a product bearing the ADA Seal of Acceptance.

are used as the astringents, while racemic epinephrine is used as the vasoconstrictor.

Although epinephrine cord is used by a majority of practitioners rather than an astringent cord for gingival retraction and hemostasis, epinephrine cord is contraindicated in patients with a history of cardiovascular diseases, diabetes and hyperthyroidism and in those taking monoamine oxidase inhibitors, rauwolfias and ganglionic blocking agents.

Some practitioners and educators believe that epinephrine-containing retraction cord and solutions should not be used in dentistry. However, plasma epinephrine concentration increased significantly only after 60 min in a study of healthy subjects without a history of high blood pressure. In spite of the elevated plasma epinephrine levels, the subjects' heart rates, mean arterial pressures and pulse pressure products were not significantly different when the same subjects were exposed to a potassium aluminum sulfate (alum) impregnated cord. The gingival tissues of the subjects were intact, however. Therefore, the patient's medical history, oral health, type of procedure to be done, amount and length of retraction, and exposure of the vascular bed should be considered before deciding to use epinephrine-containing retraction cords. Table 5.5 provides gingival retraction cord information; Table 5.6 shows the adverse effects, precautions and contraindications of a variety of commercially available retraction cords.

Accepted Indications

Gingival retraction cord is used for all kinds of gingival retraction before taking impressions or placing restorations.

Table 5.4

Astringents: Adverse Effects

Agent	Adverse effects
Aluminum chloride	Concentrated solutions of aluminum chloride are acidic and may have an irritating and even caustic effect on tissues
Aluminum potassium sulfate	May have an irritating effect
Aluminum sulfate	May have an irritating and even caustic effect
Ferric sulfate	Compound may cause tissue irritation to a greater degree than aluminum compounds

Table 5.5

Gingival Retraction Cords: Usage Information*

Generic name	Brand name(s)	Content/form
Retraction cord, plain	Gingi-Plain, Gingi-Plain Z-Twist, Hemodent, Retrax, Sil-Trax Plain, Ultrapak	**Gingi-Plain Firm Cord:** #1 (thin); #2 (medium); #3 (thick) **Gingi-Plain Z-Twist Braided Cord:** #00 (very thin); #1 (thin); #2 (medium); #3 (thick) **Hemodent:** #9 (medium thin), #3 (medium heavy) **Retrax Twisted Cord:** #7 (thin); #8 (small); #9 (medium); #10 (large) **Sil-Trax Plain Braided Cord:** #7 (thin); #8 (small); #9 (medium); #10 (large) **Ultrapak:** Ultrapak #000 (ultra thin); #00 (very thin); #0 (thin); #1 (medium); #2 (thick); #3 (ultra thick)
Retraction cord with aluminum chloride	Hemodent +, Retreat	**Hemodent:** #9 (medium thin); #3 (medium heavy), 0.915 mg/in **Retreat:** #1 (thin); #2 (medium); #3 (thick)

* [illegible]

Continued on next page

Table 5.5 (cont.)
Gingival Retraction Cords: Usage Information*

Generic name	Brand name(s)	Content/form
Retraction cord with aluminum sulfate	Gingi-Aid Z-Twist, Pascord, R-Cord, Sil-Trax AS	**Gingi-Aid Z-Twist Braided Cord:** #00 (very thin); #1 (thin); #2 (medium); #3 (thick); 0.5 mg/in **Pascord Twisted Cord:** #7 (thin), 0.48 mg/in; #8 (small), 0.48 mg/in; #9 (medium), 0.85 mg/in; #10 (large), 1.45 mg/in **R-Cord:** Braided cord with or without epinephrine **Sil-Trax AS Braided Cord:** #7 (thin), 0.48 mg/in; #8 (small), 0.48 mg/in; #9 (medium), 0.85 mg/in; #10 (large), 1.45 mg/in
Retraction cord with potassium aluminum sulfate	GingiBraid, GingiKnit, Gingi-Tract, Sulpak, Sultan Ultra, UniBraid	**GingiBraid:** 0 (fine); 1 (small); 2 (medium); 3 (large); also available plain **GingiKnit:** 000 (very fine); 00 (fine); 0 (small); 1 (medium); 2 (large); 3 (extra large) **Gingi-Tract:** Thin, medium, thick **Sulpak:** Braided cord in thin, medium, large **Sultan:** Braided cord in thin, medium, large; available with either aluminum potassium sulfate or racemic epinephrine **UniBraid:** 0 (fine); 1 (small); 2 (medium); 3 (large); also available plain
Retraction cord with epinephrine	Gingi-Pak	#1 (thin); #2 (medium); #3 (thick); 0.5 mg/in
Retraction cord with racemic epinephrine	R-Cord, Racord, Sil-Trax EPI, Sultan	**Racord Twisted Cord:** #7 (thin), 0.50 mg/in.; #8 (small), 0.50 mg/in.; #9 (medium), 0.85 mg/in.; #10 (large), 1.15 mg/in **Sil-Trax EPI Braided Cord:** #7 (thin), 0.50 mg/in; #8 (small), 0.50 mg/in; #9 (medium), 0.85 mg/in; #10 (large), 1.15 mg/in **Sultan:** 0.108-0.48 mg/in
Retraction cord with zinc chloride	Sultan	0.06-0.218 mg/in

Table 5.6

Gingival Retraction Cords: Adverse Effects, Precautions and Contraindications

Type of cord	Adverse effects	Precautions/contraindications
Retraction cord, plain	NS	NS
Retraction cord with aluminum chloride	May cause irritation or tissue destruction	Contraindicated in those with a history of allergy
Retraction cord with aluminum sulfate	See note above	NS
Retraction cord with potassium aluminum sulfate	See note above	NS
Retraction cord with epinephrine	See note above	Patient's medical history and oral health, type of procedure to be done, amount and length of retraction, and exposure of the vascular bed should be considered before epinephrine-containing retraction cords are used Contraindicated in patients with a history of cardiovascular diseases, diabetes, hyperthyroidism, hypertension or arteriosclerosis and in patients taking tricyclic antidepressants, monoamine oxidase inhibitors, rauwolfias, or ganglionic blocking agents
Retraction cord with racemic epinephrine	See note above	See note above

NS, None of significance to dentistry

General Dosing Information

Dosage Adjustments

The actual maximum dose for each patient must be individualized depending on factors such as oral health and sensitivity.

Adverse Effects and Precautions

The incidence of adverse reactions to gingival retraction cords is relatively low. Most reactions are temporary, but gingival tissue destruction may permanently alter gingival architecture, especially after vigorous cord placement.

Pharmacology

Gingival retraction cords work mechanically to widen the gingival sulcus. With the addition of astringents or vasoconstrictors, the gingival tissue is retracted further. The astringents act by constricting blood vessels, extracting water from tissue or precipitating proteins.

Suggested Readings

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TISSUE MANAGEMENT NEEDS FOR ADHESIVE DENTISTRY NOW AND IN THE FUTURE

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HISTORY AND METHODOLOGIES

Dental Impressions

Reproducing a tooth preparation for the purpose of generating a stone replica became a standardized procedure as early as 1937, when Sears[18] introduced reversible hydrocolloid for fixed prosthodontics. The single greatest challenge to accurate reproduction of subgingival surfaces, including the finished margins of the tooth preparation, has been and continues to be in obtaining (1) predictable hemostasis, (2) sulcular fluid control, and (3) adequate displacement of overlying gingival tissue. Clinical unpredictability has been demonstrated for years when attempting to overcome the above-mentioned challenges. In addition, many of the hemostatics in use have significant limitations or possess the potential of causing mild to serious systemic or local adverse reactions.[2, 10, 11, 17, 20, 25]

Electrosurgery has been used in dentistry for more than 60 years,[13, 24] even though the principles of the technique as well as improved equipment were not available until the late 1960s.[17] Electrosurgery has been touted as an effective method of preimpression tissue management. One of the most obvious limitations in using this method of tissue management is the incalculable prognosis of the gingival contours on healing. Careful consideration for esthetics, whereby it is imperative to hide the margin of the restoration, exposes the shortcomings

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Figure 1. Placement of hemostatic solution using infusion device and scrubbing action.

of electrosurgery as well as its unpredictable nature as a method of hemostasis on placement of impression material.

In 1981, the author introduced a new concept for hemostasis known as the *infusion technique.*[7] This process used the Dento-Infusor device (Ultradent Products, Inc., South Jordan, UT), a unique tip attached to a syringe. The device was designed to facilitate placement of the coagulating hemostatic into the cut capillary openings (Figs. 1 and 2). The purpose was to produce coagulum plugs

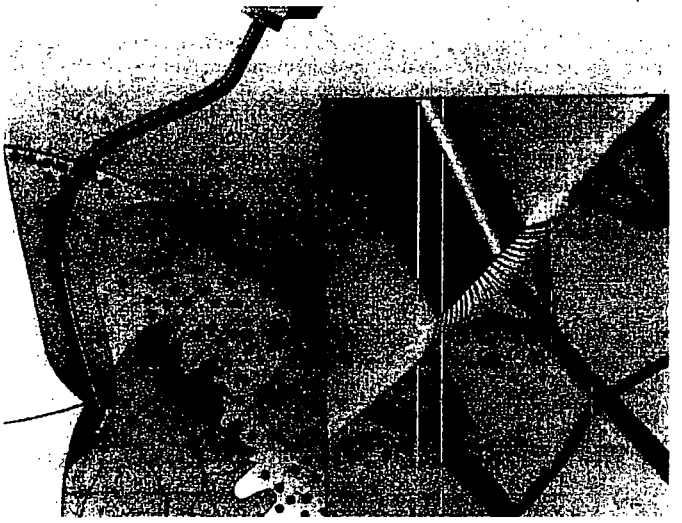

Figure 2. Scrubbing action produces coagulum plugs in the open capillaries.

within each capillary orifice below the cut tissue only, thereby preventing their dislodgment during cleaning and impression material placement. These coagulum plugs are best achieved by using a scrubbing action during application, which also prevents coagulum residue from competing with impression material for reproduction of the sulcus, preparation (especially the margin), and tooth surface just apical to the margin. Several articles have addressed this technique of hemostatic placement.[4, 7–9, 12, 21] Later, a unique knitted cord was introduced to simplify further the total technique and to offer greater flexibility.[5, 8, 9, 15]

Direct Restorative Dentistry

Although directly placed restorations constitute approximately 85% of all restorations placed, clinicians have failed to view tissue management as an integral segment of these procedures. Since its introduction in the early 1800s,[19] amalgam has maintained its status as the most widely used material for directly placed restorations. One of the greatest advantages to using amalgam is that it is more forgiving than other restorative materials. Despite the need for good hemostatic control before placement, many amalgam fillings are placed in the presence of blood or saliva (or both) and almost miraculously manage to survive. Because of the silver corrosion of amalgam, which tends to seal the spaces caused by inadequate tissue management among other things, an *E* to *D* grade restoration manages to upgrade itself to a *D* or *C* grade. This phenomenon is certainly difficult to brag about. Logic should dictate that the tissue management requirements and techniques for impression making should be extrapolated for use with any directly placed restoration including amalgam.

CURRENT AND FUTURE NEEDS

As important as hemostasis and other tissue control have been for proper impression making, never before have their needs been felt more than they are today for adhesive dentistry. Bondable restorations, whether directly or indirectly placed, demand as contaminant-free a field as possible. In 1955, Buonocore[1] established that acid etching of teeth made the teeth more receptive to bondable materials. In 1983, the author was developing a phosphoric acid etchant formula (Ultra-Etch, Ultradent Products, Inc., South Jordan, UT) to improve the delivery and control of this process. Initially, it was thought that only the enamel should be etched, whereas etching of the dentin should be avoided (Fig. 3). The literature now reports that etching of enamel and dentin (where dentin has been exposed) provides better bond strengths, provided that state-of-the-art dentin bonding technologies are used after etching. Acid etchants should have colorants in them to allow visualization of the etchant placement and, more importantly, to ensure isolation to the desired application site. Contact of phosphoric or other strong acids with cut tissues that have been treated for hemostasis can reinitiate bleeding. Contact with the tongue or other tissues can produce additional adverse reactions. Contrary to its green appearance in Figure 3, the colorant used in this R & D etchant is a sky blue dye commonly used in many personal care products and referenced by the Food, Drug and Cosmetic (FD&C) Act as *Blue Number 1*. When the pH is low, however, *Blue Number 1* becomes green. This is consistent with many organic dyes—as pH changes, color also changes. Hence, Blue Number 1 is blue unless the pH is low (acidic), then it becomes green. This is one of the methods using various dyes to determine

Figure 3. In 1983, only enamel was being etched. Note the green color of the etchant except at the gingival margin where it is blue because the sulcular fluid has neutralized the pH.

Figure 5. Etchant has not changed colors from its original blue.

Figure 6. Note profound discoloration of right central incisor (#8).

Figure 7. This type of discoloration migrates inward starting at the gingival margin.

Figure 10. Two months post-operative.

Figure 3.

Figure 5.

Figure 6.

Figure 7.

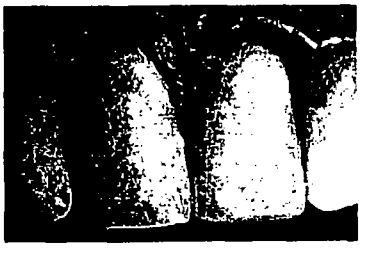

Figure 10.

pH changes of chemical solutions. Even though the preparation's margin was supragingival and no bleeding occurred, sulcular fluid migrated into the etchant, thereby neutralizing it (note blue-colored etchant at gingival margin), thus potentially contaminating the tooth surface with sulcular fluid protein. Although a rubber dam can be effective in such cases, a viable alternative is a displacement/barrier cord soaked in an astringent, then packed into the sulcus. If the tissues are healthy, the astringent can be diluted with water. Astringent hemostatics, such as alum, aluminum chloride, and ferric sulfate (Fig. 4), effectively seal epithelium (in this case, sulcular epithelium) against fluid flow. This sealing capability is inherent with all astringents. After cord placement, the preparation, cord, and surrounding tissues must be thoroughly washed. Any residual astringent can potentially contaminate the tooth surface to be bonded, thereby causing adverse effects on the bond strengths, and threaten the integrity of the bond and the restoration. The etchant in Figure 5 does not change colors. Now, adhesive chemistries, including primers and bonding resins, can also be placed with a high level of confidence.

Figure 6 shows five class V restorations in the anterior teeth. The bonded restorations were placed 6 weeks before the photograph. Note the right central incisor (#8) with its profound discoloration (Figs. 6 and 7). This type of discoloration migrates inward starting at the gingival margin; this is also visualized with the resin-bonded porcelain veneer. All five composites shown were placed

Figure 4. Barrier-cord soaked in ferric sulfate, placed in sulcus.

Figure 8. The composite roof is easily separated from the non-bonded surface.

subgingivally, and all five had barriers placed with cords soaked in ferric sulfate.[23] All hemostatics can be potential contaminants to the bonding procedure. Because all hemostatics are hydrophilic, their presence on the primer layer, bonding resin layer, or between layers of composite immediately contaminates and prevents intimate adaptation of succeeding hydrophobic or semihydrophilic resins. Just as important, the chemistries themselves of the hemostatics can also be potential contaminants. The composite roof is easily separated from the nonbonded surface (Fig. 8). It is clear that the dark color was from microleakage rather than discoloration of the composite itself. Soon after placement of the *nonbonded* restoration, blood pigments containing iron or possibly ferric sulfate migrated between the composite and the tooth surface. These pigments turn dark, similar to what occurs when blood accumulates under the skin when a person gets a bruise. In cases such as these, further darkening may occur if hydrogen sulfide from anaerobic bacteria reacts with the iron in the blood to produce ferric sulfide. Whether these additional problems occur or not, a discolored leaking restoration is unacceptable. The good news regarding this case and cases similar to it is that because of the translucency of the composite resin, the microleakage was easily identified. This is not possible with metallic or other opacious restorative materials. The preparation is redefined and cleaned. Once the hemostatic-laden barrier-cord (UltraPak, Ultradent Products, Inc., South Jordan, UT) is placed,[23] it is imperative that all of the residual hemostatic/astringent from the exposed cord, preparation, and adjacent soft tissue be washed thoroughly with firm water and air spray (Fig. 9). The preparation is then etched and washed (including exposed adjacent cord), and excess water is blown from the cord to prevent *wicking* water onto succeeding resin layers. Although the tooth surface should be slightly wet for optimal dentin adhesion, excess water can and should be removed from the cord; if necessary, the tooth surface can be rehydrated carefully with a damp cotton pellet. After the primer is applied, further assurance of complete water removal from the cord is accomplished with a firm air blast to the exposed cord followed by reapplication of primer to the preparation. In the case of a one-component bonding system, the primer/bonding resin should be reapplied. Note the final result 2 months postoperatively (Fig. 10).

Figure 9. All residual hemostatic/astringent from the exposed cord, preparation, and adjacent soft tissue must be washed thoroughly with firm water and air spray.

Tissue management is also essential for proper bonding of anterior indirect restorations. Figure 11 demonstrates both barrier to sulcular fluid flow and displacement for controlled bonding of a porcelain veneer. Without an adequate barrier and thorough cleaning of potential contaminants from the tooth surface before bonding veneers, microleakage can occur in one to multiple units.[6] This problem can be particularly frustrating not only because of the multiple appointments, but also because of the additional laboratory work and expense. Some clinicians and manufacturers have claimed that the ferric sulfate hemostatic

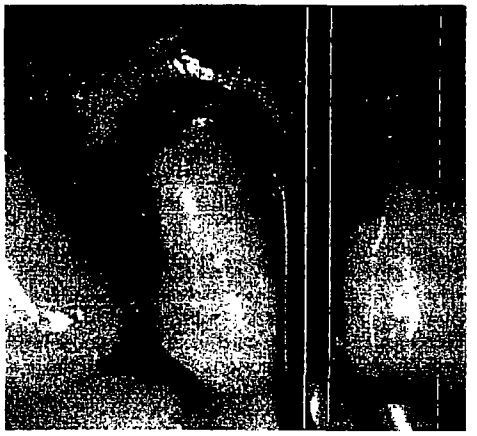

Figure 11. Cord serving as both barrier to sulcular flow as well as displacement for controlled bonding of a porcelain veneer.

discolors composite or luting resin, causing the unacceptable discolorations. Several tests by the author have shown that this is not the case. The cause is contamination with resultant microleakage. Potential contaminants include all hemostatics, blood, sulcular fluid, and saliva. These contaminants result in a nonbonded, nonsealed restoration with secondary blood infiltration (microleakage).

The wants and needs of society have changed. Improving the quality of life seems to be the primary motivating factor. Exciting new technologies in adhesives as well as improved physical properties of esthetic restorative materials have made the direct and indirect posterior esthetic restoration a reality. One of the greatest tools in dentistry, especially for the posterior bonded restoration, is the rubber dam. When the preparation must extend subgingivally or the interproximal tissues have been chronically irritated by an old and possibly poorly fitting amalgam restoration, the soft tissues may bleed past the rubber dam and significantly challenge the bonding procedure. At other times, conditions may occur that preclude use of the rubber dam.

A key thing to remember whenever performing a bonded procedure: never start the procedure in the presence of blood whether a rubber dam is being used or not. Figure 12 shows a class II preparation in which the proximal recurrent decay extends beyond the old amalgam and subgingivally down the root. Before placing the rubber dam and before addressing decay toward the pulp, the clinician should establish position of and refine the gingival margin in the proximal box. To prevent tearing of the rubber dam during instrumentation, the clinician should establish and refine sufficient solid gingival floor width before placing the rubber dam to preclude the need to instrument the margin after the rubber dam is placed (approximately 1 mm in from the margin is usually adequate). With the Dento Infusor and syringe loaded with Viscostat[23] (use Astringedent X[1] if inflamed tissues or if systemic conditions such as anticoagulant therapy mandate a stronger hemostatic), the clinician rubs the bleeding tissues firmly until profound hemostasis is achieved. The site is washed with a

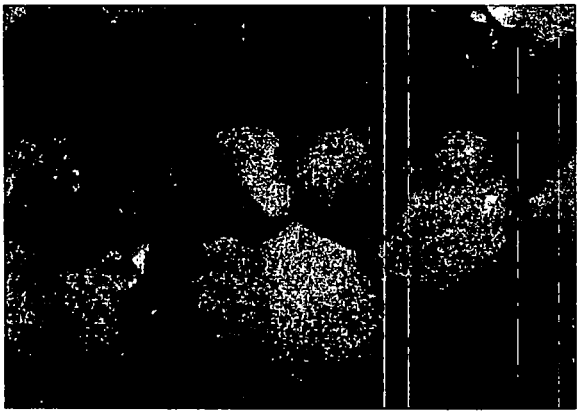

Figure 12. Class II preparation in which proximal recurrent decay extends beyond the old amalgam and subgingivally down the root. Gingival margins and adequate hemorrhage control must first be established.

firm air/water spray both to clean and to check for complete hemostasis. If any bleeding is observed, the process is repeated. After washing, the clinician inspects to make sure that hemostasis is afforded with no apparent coagulum being present on the surface of the tissues, sealing of blood vessels has occurred within the cut capillaries, and extraneous coagulum has been wiped or scrubbed from the surfaces of the cut tissue. The rubber dam is now placed, and any remaining caries is removed. The preparation is refined complete with toileting of the preparation. In this case, an added benefit to rubber dam placement before deep caries removal was that the deeper decay acted as a protective barrier to the fragile pulpal tissues on exposure until after a sound barrier of sealed tissues plus rubber dam was in place (Fig. 13). This situation leads to superior and more predictable pulp capping techniques[18] in addition to more predictable subgingival adhesive dentistry.

With current techniques for tissue management, including hemostasis, there is seldom if ever the need to be bonding in a compromised environment. Humans are living biologic entities with all the unexpected variables one would expect. These variables become quite evident when performing dental procedures. For predictable near-gingival or subgingival bonding, clinicians should understand the *whys* of adhesive dentistry and should feel comfortable as to the course of action to follow for some of the unexpected *what ifs*. For example: (1) What if after hemostasis and on etching of the preparation or shortly thereafter, a little blood oozes up onto the preparation? What should be done? For all systems using a phosphoric etchant, the clinician should first stop the bleeding using the ferric sulfate with infusor or cord,[25] then thoroughly and firmly wash all residual hemostatic away. The clinician should re-etch to ensure all ferric sulfate or other astringent is removed from the preparation, including the dentin decalcification zone. The clinician then washes and continues. (2) What if after etching during or shortly after primer application, a little blood oozes onto the surface? Again, the bleeding is controlled as mentioned previously, then the clinician thoroughly and firmly washes the preparation. The clinician dries and

Figure 13. Deeper decay acts as a protective barrier to the fragile pulpal tissues upon exposure until after a sound barrier of sealed tissues plus rubber dam is in place.

reapplies the primer. There is no need to re-etch before reapplying primer. The same would be true for bonding resin.

The basic logic is to control the bleeding, wash, dry, and reapply the previous material used in the previous step. For saliva contamination, the clinician should wash with a firm air/water spray, dry, and reapply the component used in the previous step. The above-mentioned procedure has been proven to be successful with laboratory testing when using the Perma Quick bonding system.[22] For all bonding systems using phosphoric acid etchants, the results are predictable should ferric sulfate make its way to the etched surface before primer or resin placement. Phosphoric acid readily breaks down and removes ferric sulfate. The clinician should follow with thorough washing. Testing has not been done with other bonding systems to substantiate that primers or bonding resins need only to be reapplied after hemostatic contact and washing. Manufacturers are encouraged to test their systems under similar protocols to determine the correct steps to take when contamination occurs during bonding procedure, and to verify that resulting bond strengths are not compromised.

CONCLUSION

The demands of new technologies and modern societies can be challenging to dentists. Posterior bonded restorations that extend near or under the gingiva can be some of the most challenging. There are solutions. Even though they may take more time to address appropriately, the successful and esthetic result is exciting for both the patient and the clinician. In short, many dentists state, "it makes dentistry fun again." Most importantly, quality bonded restorations possessing both a quality bonding system and a material condusive for strong bonding, such as state-of-the-art composites, have the ability to strengthen teeth significantly and even facilitate treatments to more socioeconomic groups in more esthetic ways than ever before possible. Predictable quality tissue management is the primary fulcrum to successful placement for all bonded restorations with near-gingival or subgingival extensions.

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Tissue Management, Gingival Retraction and Hemostasis

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2011-07-01

The oral cavity is a difficult area to treat in restorative dentistry because of the constraints of the lips, tongue, cheeks, challenges for access to visualize and manipulate instruments, as well as, the position of the teeth that are being treated relative to the gingival tissues, which if improperly managed, bleed. While for operative dentistry and single tooth restorations, the use of the dental dam provides control of the field and access to tooth preparation and restoration, there are many times in restorative dentistry that use of the dental dam is precluded. When caries or non-carious cervical lesions are at or below the free margin of the gingiva other tissue management techniques with gingival retraction must be used. (Fig. 1). For fixed prosthodontics, crown or inlay/onlay margins are at or below the free margin of the gingiva and access to them for both preparation, impressioning, and cementation is impossible without additional techniques to displace the gingival tissues and control gingival hemorrhage and sulcular fluids. (Fig. 2).

One of the most challenging aspects of crown and bridge is management of the gingival tissues when making an impression. Tissue management includes placing the gingival tissues away from the preparation margins so they can be impressed combined with providing for hemostasis when the gingival tissues are susceptible to bleeding.1,2 The rationale for tissue management is a critical aspect of impression making whether the impression is made with a conventional impression material or by a digital impression technique so that all tooth preparation margins are captured in the impression to assure an excellent marginal fit of a laboratory fabricated restoration.1,3

Methods And Materials
For Soft Tissue Management,

Displacement-Retraction
Aand Hemorrhage Control

Mechanical methods

Among the first techniques developed and available to clinicians for displacement of gingival tissues, especially for crown and bridge impressions, were mechanical displacement. Mechanical displacement refers to physically moving the gingival tissues aside from the tooth/tooth preparation margins to allow for visualization and access for treatment.1,2,4,5 In many cases, the materials used for gingival retraction can be used by themselves or in combination with other materials and techniques.

Among the most popular methods of gingival displacement is the use of gingival retraction cord.1,2,4,5,6-8 Gingival retraction cords can be woven, braided or twisted in a variety of configurations to provide for different diameters and thicknesses.

The choice of gingival retraction cord has proven itself to be one of personal preference by the clinician. Keep in mind that different cord types offer a variety of properties that to some make them more desirable. Also many manufacturers have a range of options of non-impregnated and chemically impregnated cords. Of importance, when handling gingival retraction cord one should use latex-free gloves. Indirect latex contamination can have an inhibitory effect on the setting of vinyl polysiloxane impressions materials. This is especially critical in the gingival sulcus, where a minimal amount of light body is placed as an incomplete cure may result in gingival tears of the impression materials.(9)

Clinician preference to braided cords relates to their tight and consistent weave, e.g, First String Retraction Cord, (Clinical Research Dental) and GingiBraid (Dux Dental). Braided cords for many clinicians are easier to place in the gingival sulcus with packing-placement instruments, both serrated and smooth, non-serrated, because they are solid and can be pushed to place. Knitted cords have increased in popularity. Knitted cords when saturated with astringents and when placed in the gingival sulcus expand creating a physical effect of enlarging the sulcus for access for impressions or to displace the gingival tissues when placing direct restorative materials. Also the unique knitted weave (UltraPak, Ultradent) (Fig. 3). minimizes unraveling and fraying after cutting and during cord placement. Knitted cords offer an ease in their placement and they expand when wet opening up the sulcus greater than the original diameter of the cord.1,2 The knitting and yarn selection allows for a greater range of knitted cotton cord diameters/sizes. In the authors' experience, when using knitted cord, a smooth, non-serrated placement instrument allows for precise placement without pulling the cord out of a gingival sulcus. Also, the range of sizes/diameters allow for placement in both the easy to access gingival sulcus and the tighter, healthier gingival sulcus. (Fig. 4)

When describing mechanical displacement of gingival tissues with gingival retraction cords, one would be remiss if there was no mention of retraction cord placement, packing instruments. Key to placement of cord with instruments is that the end of the cord packer be thin enough to be placed in the gingival sulcus without damaging the gingival tissue and potentially causing bleeding, the angle of the instrument allow for orientation so that cord placement can be accomplished around all surfaces of the tooth. Most commonly, the clinician will use double-ended instruments. Recently a novel double-ended instrument with multiple orientations of a dual-packing blade (TN010 Double Cord Packer, Garrison Dental Solutions) has been introduced so that the instrument does not need to be twirled to get the end orientation needed. (Fig. 5). A good friend, Dr. Bob Margeas designed this instrument because when using magnification, he found that this design maintains the instrument in the field of view while packing cord around the tooth.

Mechanicochemical methods

A variety of chemical solutions and gels have been recommended for use with gingival retraction cords because of the properties as drugs to act as an astringent or hemostatic agent.1,2,4 In most cases these drugs are both astringent, causing contraction-retraction of the gingival tissues, and hemostasis, constricting blood flow through coagulation. When these reagents are placed on a retraction cord they cause a transient ischemia shrinking the gingival tissue and blood vessel coagulation. Common astringent-hemostatic agents include ferric sulfate, aluminum chloride, and racemic epinephrine, aluminum potassium sulfate, aluminum sulfate, and zinc phenolsulfonate/racemic epinephrine. Gingival retraction cords are available unimpregnated or impregnated with astringent-hemostatic agents. Chemically impregnated cords offer greater sulcus displacement with the combined physical and chemical effect.1 Also, cord diameter, astringent-hemostatic agent, and cord type have a direct effect on the physical properties of the cord.10 In some cases both solutions and gel formulations are recommended for direct placement into the gingival sulcus with specialized tips (Tissue Goo, Clinical Research Dental, Astringedent, Ultradent; ViscoStat, Ultradent; Racecord, Septodont) to achieve an excellent hemostatic effect with some ischemic effect before cord placement.

A 20-25% aluminum chloride and 15.5-20% ferric sulfate are among the most popularly used chemical reagents. When used for durations within the gingival sulcus of less than 10 minutes, they cause minimal tissue damage.1,2,11 Ferric sulfate has been shown to interfere with surface detail of impression materials, as well as, it can discolour dentin by precipitating ferric sulfide in an anaerobic environment.12 It has been suggested that both ferric sulfate and aluminum chloride can have a negative effect on adhesion.12,13 When using these materials, before cementing the final restoration with a composite resin cement, both etch and rinse and self-etch, one should thoroughly clean the dentin surface with a pumice-water paste to create a dentin smear layer. There has been concern with the use of an 8% racemic epinephrine impregnated cord.4,14-18 It has been reported that epinephrine impregnated cords should be used with care. It has been reported that an 8% racemic epinephrine cord can cause elevation in blood pressure and tachycardia, especially if the gingival tissue is bleeding due to laceration.15 In fact it has been demonstrated that no clinical benefit in gingival retraction could be recognized between an epinephrine containing cord and other cords.16.

Of special note, the solutions that are used as astringents and for hemostasis, are acidic (pH range of 0.7-2.0). There has been evidence demonstrating that the use of these products remove the smear layer.18,19 There has been some concern that if the root surfaces beyond the crown preparation margins, as well as, the dentin of tooth preparations are exposed to these solutions that there may be an increase in postoperative sensitivity. If as a clinician you have this problem, it is recommended that after making the impression and before cementation of the provisional restoration, the preparations be treated with a desensitizing agent, e.g., G5 Desensitizer, (Clinical Research Dental) or Gluma (Heraeus-Kulzer).

Cordless retraction

In most cases, gingival retraction cord is the most effective method for retracting tissue to the depth of the sulcus. Unfortunately, many times on the day of the tooth preparation, gingival bleeding is difficult to control or when packing a cord into the sulcus, the tissues start to bleed making impression difficult or impossible. For this reason a new class of gingival retraction materials have been introduced. These cordless retraction materials, e.g, Expasyl (Kerr); Racegel (Septodont) Traxodent (Premier); GingiTrac (Centrix) provide for excellent hemostasis and some gingival retraction.20-23 Some of the materials incorporate the use of a compression cap GingiTrac (Centrix) to enhance the retraction effects of the material. (Fig. 6) Using these cordless retraction techniques provide for a non-traumatic, non-invasive tissue management and hemostasis in the gingival sulcus for fixed prosthodontic impressions. These materials and techniques can be used by

themselves or in combination with the use of gingival retraction cord, electrosurgery or laser tissue sculpting when bleeding is difficult to control.

Clinical Technique For Predictable Gingival Retraction and Hemostasis With Gingival Retraction Cord

When deciding which technique to use with gingival retraction cord, it is important to evaluate the health of the gingiva and the depth of the gingival sulcus. When there is minimal sulcus depth, the clinician is limited in many cases to placing only a single cord. When possible, recommendations for improved gingival retraction with cord include use of a double cord technique where a thin cord is placed flush in the sulcus, followed by a wider diameter cord. Both braided and knitted cords can be used with this technique. It is advisable to use a chemical astringent-hemostatic agent in combination with the gingival retraction cord. These two authors prefer high viscosity hemostatic gel that can be placed in the sulcus to both help with hemostasis and act as a lubricant for atraumatic placement of the gingival retraction cord and can be placed on the cord itself.

For this case a 25% aluminum sulfate hemostatic gel (Tissue Goo, Clinical Research Dental) was used to impregnate and lubricate a knitted cord (Fig. 7). Using an atraumatic cord placement technique, a thin diameter knitted cord (UltraPak, Ultradent) is placed to the base of the gingival sulcus without overlap (Fig. 8) and cut with a small tipped suture scissors (Micropoint Scissors, Clinical Research Dental) to be flush within the sulcus. (Fig. 9) This cord will be maintained during the impression to control any bleeding from the base of the sulcus. A second wider diameter UltraPak cord was then placed on top of the first cord to achieve tissue displacement. (Fig. 10) Immediately before making the impression and before the wider diameter cord's removal, the cord should be wetted with water so as not to grab and tear the gingival tissues when the cord is removed which can create bleeding. The wider diameter cord was then removed leaving excellent tissue displacement and hemorrhage control for the impression. Once the cord is removed the retraction is maintained for only 30 seconds.1 Before making the impression, it is important there are no contaminants on the tooth preparation surface. By using a 10% EDTA cavity cleanser (Detail, Clinical Research Dental) one can be assured that the tooth surface is free of hemostatic agent contaminants and any associated debris. The EDTA leaves the dentin tubules plugged and decreases the surface tension of the dentin facilitating flow of light body impression material resulting better adapatation of the impression material to the preparation and in better surface detail of the impression. **Clinical tip: If bleeding is persistent when the first cord is removed continue with the impression making certain to syringe the impression material within the sulcus. Even with the expectation that the impression will be unsuccessful this impression will maintain the retraction while allowing for hemostasis. Remove the first impression and DO NOT look at it. Immediately make a second impression. The sulcus will still be open and will not be bleeding.**

Conclusion

There are a variety of techniques and materials that allow the clinician to manage the gingival tissues during restoration and when making an impression. These include gingival retraction cords, chemical reagents, electrosurgery, laser tissue sculpting, copper tube impressions, hydraulic impressions, and non-invasive, atraumatic displacement/hemostatic materials. In most cases gingival retraction cord is the most effective method for retracting tissue to the depth of the sulcus. The other methods have their advantages and indications. In any case, the control of the soft tissue for exposing the margins of the tooth preparation for

restoration and impressioning is critical. It would be worthwhile for the clinician to understand all the choices available.**OH**

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Oral Health welcomes this original article.

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24 efficacy issues

Nonsurgical Gingival Displacement in Restorative Dentistry

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Compendium of Continuing Education in Dentistry

Abstract

Gingival displacement is critical for obtaining accurate impressions for the fabrication of fixed restorations, especially when the finish line is at or just within the gingival sulcus. Displacement of the gingival tissue is also important when dealing with the restoration of cervical lesions due to their proximity to the periodontal tissue. The methods of gingival tissue displacement can be broadly classified as nonsurgical and surgical techniques, with nonsurgical being the more commonly practiced method. Dentists must alter their armamentarium and gingival displacement techniques to meet specific demands and obtain predictable results. Hence, the purpose of this article is to describe the different means by which nonsurgical gingival displacement can be achieved effectively under a variety of clinical situations.

Harmony between a restoration and the periodontium that surrounds the teeth is crucial to the success of a restorative procedure. Key to achieving such a relationship is an accurately made impression for indirect restorations or a properly placed direct restoration into the prepared cavity.[1] Displacement of the gingival tissue is essential for obtaining accurate impressions for the fabrication of fixed restorations, particularly when the finish line is at, or just within, the gingival sulcus. This is also true when dealing with the restoration of cervical lesions due to their proximity to the periodontal tissue.

Gingival displacement is defined as the deflection of marginal gingiva away from the tooth. This is performed to create sufficient lateral and vertical space between the preparation finish line and the gingival tissue to allow the injection of adequate bulk of the impression material into the expanded crevice. Impression along the subgingival margin is critical to the marginal fit and emergence profile of the prosthesis.[2] A bulk of the impression material is required to obtain maximum accuracy and to improve the tear strength of the impression material so it can be removed from the mouth intact with no tearing. The critical sulcular width in this regard seems to be approximately 0.2 mm at the level of the finish line. Control of moisture in the sulcus, particularly when a

hydrophobic impression material is used, is also necessary because moisture can cause an incomplete impression of the critical finish line.[3] The displacement of the gingiva is also required during the preparation of the tooth cervically and even while placing and finishing the restoration located cervically. This is done to avoid trauma to the periodontal tissue.

The techniques of gingival tissue displacement can be broadly classified as nonsurgical and surgical methods (Table 1). Since surgical methods are usually effective in skilled hands, these techniques are used only by a minority of clinicians in their profession, and even then they are used only as adjuncts to mechanical or mechano-chemical means of gingival displacement. Therefore, the purpose of this article is to describe the different means by which nonsurgical gingival displacement can be achieved effectively under a variety of clinical situations (Table 2).

Retraction Crown/Sleeve

Temporary crown filled with thermoplastic stopping material or bulky temporary cement: In order to displace the gingiva a temporary crown can be adapted to the finish line of the tooth and lined with an excess of temporary stopping material. The crown is then placed on the prepared tooth, and any excess stopping material protruding into the gingival crevice is rounded and smoothened with a hot instrument. In a different method, a custom temporary restoration is placed in which the gingival ends are blunted and covered with bulky temporary cements such as zinc oxide eugenol or non-eugenol-containing periodontal pack. The temporary crown thus fabricated is left in place until the next appointment, at which time the final impression is made.

These methods are no longer practiced since a temporary crown filled with thermoplastic stopping material or temporary cement can cause prolonged or lasting recession if left in place for more than 12 hours. The resulting uncovered neck of the tooth may be sensitive and susceptible to caries. Also, impressions cannot be made the same day as the tooth preparation.[4,5]

Anatomic compression caps: Anatomically formed compression caps with semicircle spaces on two opposite sides can be easily placed on adjacent teeth. After placement of the adjusted anatomic cap, the patient bites on it and maintains pressure. The cap stops bleeding naturally by compression, opens the sulcus wide, and ensures a dry, clean area with well-defined gingival margin.

Modified Impression Techniques for Gingival Retraction

Copper band impression technique: A copper band can serve as a means of carrying the impression material as well as a mechanism for displacing the gingiva to ensure that the gingival finish line is captured in the impression. One end of the tube is festooned, or trimmed, to follow the contours of the free gingival margin. The tube with the impression material is mechanically carried to the finish line of the preparation and displaces the gingiva to produce an adequate impression. This technique can be used with impression compound and elastomeric impression. If utilized with an elastomeric material, the copper band must be filled with acrylic, fitted to the preparation, and subsequently relieved and vented. An adhesive must also be applied prior to taking the impression. Without the acrylic reinforcement, the band might get distorted during removal. Copper bands are especially useful when multiple preparations are recorded in an elastomeric impression and a localized impression defect has occurred.

The use of a copper band could negate the need to remake an entire full-arch impression just to capture one or two preparations.[6] On the basis of wound healing and gingival recession, the metal band with impression material is shown to be better than either surgery or retraction cord. Disadvantages of this technique include the amount of time required to fit and adapt the band, the difficulty in removing the modeling compound-filled band from undercuts, and the trauma to tissue caused by the band itself.[4]

Temporary acrylic coping: In another technique, a temporary acrylic resin coping is constructed. The inside of this coping is relieved by approximately 1 mm, and a tray adhesive is applied. The temporary coping is then filled with elastomeric impression material and reseated. The tissue is displaced mechanically when the impression

material is mechanically forced into the sulcus. A complete arch impression is subsequently made over the coping, and the coping becomes an integral part of the complete arch impression.[4] This is a cumbersome technique that is not very popular.

Matrix impression system: A technique called the matrix impression system (MIS) has been described by Livaditis.[7] The MIS is done in three steps: 1) a suitable elastomeric semi-rigid material is used initially to form the matrix; 2) a high-viscosity elastomeric impression material that will preferably bond to the matrix-forming material and which is required to make an impression of the preparations in the matrix is used to facilitate displacement of the gingival tissue and effectively flush debris out of the sulcus; and 3) a stock tray with a medium-viscosity elastomeric impression material is used to pick up the matrix impression and the remaining arch not covered by the matrix.[7]

Modified custom tray technique: In another method, a custom tray is modified by intraoral relining with autopolymerizing resin that is polymerized at 100°C for 5 minutes. Relined areas are refined by trimming excess resin with burs of a known diameter to create a 2-mm clearance for the elastomeric impression material. For areas with subgingival finish lines, only 0.5 mm of resin is removed to direct the elastomer into the gingival sulcus. The procedure is said to be time-saving because it reduces the need for a retraction cord and minimizes inaccuracies that would necessitate another impression.[8]

Mechanical Retractor

Gingival protector: A gingival protector can be used to displace soft tissue to protect gingiva from rotary instruments during tooth preparation and finishing (Figure 1). A unit is available that features a crescent-shaped tip on an adjustable ball-joint attached to a metal handle. The tip can be rotated to an angle that precisely matches the tooth's facial surface, thereby achieving gingival fit. Such protectors can be used for veneer preparations, finishing porcelain or resin veneer margins, cervical (facial) subgingival caries, and removal and checking marginal fit of crowns. Autoclavable metal protector tips prevent cross-contamination.

Matrices and wedges: Wooden wedges can be placed interproximally to mechanically depress the gingiva, thus providing retraction. Matrices with gingival extension can also displace the gingival tissue when placing interproximal restorations.

Rubber dam: Heavy, extra heavy and special heavy gauges of rubber dam with proper interseptal dimensions can be used when a limited number of teeth in one quadrant are being restored and in situations where the preparations do not extend very far subgingivally. The use of rubber dam is valuable during the preparation of a tooth cervically and also when placing, finishing, and polishing cervical restorations on the buccal/lingual aspect. Inversion of the rubber dam will also aid in gingival displacement. For extra retraction a Ferrier 212 clamp (cervical clamp) can be used (Figure 2 , Figure 3 and Figure 4). Use of the rubber dam helps not only in preparing the tooth but also when making the impression. Impressions can be taken with modified trays with the rubber dam on if the bows and wings of the clamp are blocked out.

This procedure, however, is very tedious, and complete arch impressions are not compatible with the technique.[4] The sulfide compounds utilized in the manufacturing of latex can inhibit the polymerization of polyvinyl siloxane (PVS) impression material. Hence, rubber dam should be avoided when this material is used.[6]

Retraction Cords

Plain retraction cords can be gently forced into the gingival sulcus to displace the gingiva laterally from the tooth. Cords can be fabricated from cotton yarn or purchased commercially in a variety of forms. Retraction cords are supplied as twisted/braided/knitted cord. Desirable qualities of a cord are that it is:[9] dark in color, to maximize contrast with the tissues, tooth, and cord; absorbent, to allow the uptake of the liquid medicaments; and available in different diameters to accommodate the varying morphologies of the gingival sulcus. Unfortunately, their effectiveness is limited because the use of pressure alone often will not control sulcular hemorrhage. Pre-

impregnating and/or soaking a cord with a hemostatic can control the sulcular hemorrhage and improve its tissue retraction qualities. The chemicals used along with retraction cords (gingival displacement medicaments) can be broadly classified into vasoconstrictors and astringents.[10]

Vasoconstrictors

Epinephrine: The vasoconstrictor used is typically epinephrine in the racemic form. Endogenous epinephrine is the l-form, whereas the racemic form contains equal amounts of d- and l-form. The overall activity of the racemic epinephrine is about one-half of that of endogenous epinephrine. The epinephrine is used in the concentration of 0.1% and 8%. There is some debate regarding the use of epinephrine for gingival retraction. The local use of epinephrine as a gingival displacement medicament can be absorbed into the systemic circulation and, consequently, affect the cardiovascular system.[10] Epinephrine-impregnated retraction cords contain 0.2 mg to 1 mg of racemic epinephrine per inch of cord depending on the diameter and the brand. One inch of the retraction cord with 0.2 mg of racemic epinephrine is capable of exposing the patient to the maximum dose of 0.2 mg (200 µg) for a healthy adult and nearly five times the recommended amount of 0.04 mg (40 µg) for a cardiac patient.[11] The amount absorbed depends on its concentration in the cord, length of cord used, amount of vascular bed exposed, and duration of the cord application.[10] The possible cumulative effect of epinephrine from cord combined with epinephrine from other sources (epinephrine administered in the local anesthetic and endogenous epinephrine that may be secreted by the patient in reaction to stress associated with dental procedures) must also be considered.[11]

For patients with cardiovascular disease, hypertension, diabetes, hyperthyroidism, or known hypersensitivity to epinephrine, a cord impregnated with some other agent must be substituted. Epinephrine should also not be used on patients taking monoamine oxidase or tricyclic antidepressants, rauwolfia compounds, ganglionic blockers, or cocaine. Patients without the aforementioned contraindications can also exhibit "epinephrine syndrome" (tachycardia, rapid respiration, elevated blood pressure, anxiety, and postoperative depression). Clinicians should avoid using epinephrine for gingival displacement because of the significant number of contraindications for its use.

Sympathomimetic amine: Several sympathomimetic amines capable of producing local vasoconstriction with minimal systemic side effects are available as nonprescription nasal and ophthalmic decongestants. These include tetrahydrozoline HCl, 0.05%; oxymetazoline, 0.05%; and phenylephrine HCl, 0.25%. Retraction cord can be dipped in these prescriptions to assist in hemostasis.[12] Newer hemostatic agents such as the tetrahydrozolines and oxymetazolines have a more acceptable pH and are thought to be kinder to the tooth structure and soft tissues than the conventional solutions.[13]

Astringents

Astringents act primarily by precipitation of protein and inhibiting transcapillary movement of plasma proteins. They have relatively low cell permeability and act generally as irritants in moderate concentrations and as caustics in higher concentrations. The astringents used in gingival displacement are as follows:

Aluminum sulfate compounds (aluminum potassium sulfate [Alum] and aluminum sulfate): Alum in 100% concentration has been shown to be only slightly less effective in shrinking the gingival tissues than epinephrine, and it shows good tissue response.[14] Alum is safer and has fewer systemic effects than epinephrine and, therefore, has been recommended for use in place of epinephrine. Cords saturated with 100% alum can be safely left in the sulcus for as long as 20 minutes without any adverse effect.[4]

Aluminum sulfate, which differs from alum, has been suggested as a gingival retraction material. The available data indicate that the material is effective and biologically acceptable.[15] A practical concern is that, like most sulfates, aluminum sulfate compounds can inhibit/retard the setting reaction of additional reaction impression materials.[16]

Aluminum chloride: Aluminum chloride is one of the most commonly used astringents.[17] The actions of aluminum chloride result from its ability to precipitate protein, constrict blood vessels, and extract fluid from tissues.[18] It is used in the concentration of 5% to 25%. Studies have shown that solutions stronger than 10% can cause local tissue destruction. A 10-minute application is usually sufficient.[4] Aluminum chloride is the least irritating of the medicaments used for impregnating retraction cords, but it is shown to disturb the setting of PVS impression materials.[19] The inhibitory effect can be greatly reduced by thoroughly rinsing the preparation with water after the treated cord is removed.

Ferric sulfate: Ferric sulfate provides good hemostasis on exposed connective tissue. This astringent is provided in solution form only, generally in the concentration of 13% to 20%. Solutions of ferric sulfate above 15% are very acidic and can cause significant tissue irritation and postoperative root sensitivity. The recommended packing time for cord dipped in ferric sulfate solution is 1 to 3 minutes. When tissues are hemorrhaging, the solution should be rubbed into the bleeding areas with an applicator (dento-infusor) or a soaked cotton pellet. Ferric sulfate can modify the accuracy of surface detail reproduction during impressions because it disturbs the setting reaction of polyvinyl siloxanes. Therefore, all traces of medicament should be carefully removed from the tissues before the impressions are recorded.[19] Due to its iron content, ferric sulfate stains gingival tissues a yellow -brown to black color for several days after being used as a retraction agent.[20] The esthetics of the anterior all-ceramic crowns may also be compromised due to the use of ferric sulfate since it has shown to produce internalized discoloration of the tooth structure.[21]

The acidity of the commonly used gingival displacement medicaments are high, with pH ranging from 1 to 3.[13,22,23] This could result in the removal of the smear layer and can negatively affect the bonding mechanism of the self-etch dentin bonding systems.[24] The removal of smear layer could also cause the opening up of the dentinal tubules cervically and cause dentinal hypersensitivity.[23]

Many different instruments are available for placing cord in the gingival sulcus. Some are purpose-designed packing devices with smooth, nonserrated circular heads that can be used to place and compress twisted cord with a sliding motion. Other devices have serrated circular heads for use with braided cords. The thin edges of these serrated circular heads sink into the braided cord, and the fine serrations keep it from slipping off and cutting the gingival attachment.[20] The instrument design used is a matter of the dentist's individual preference.

Techniques for Retraction Cord Placement

Two procedures for placing the retraction cord are the single-cord and double-cord techniques. The technique used is based on the clinical situation.[3]

The single-cord technique is indicated when making impressions of one to three prepared teeth with healthy gingival tissues, especially when the prepared margins are at or above the tissue. In this technique, a single cord is placed in the sulcus and removed before the impression is taken. This provides displacement about the width of the cord. In a deep sulcus, however, the tissue can collapse over the top of the cord, restricting access of the impression material to the retracted sulcus. This often causes the impression material to tear on removal. Even when tearing does not occur, impression material near the most critical margins will be extremely thin and easy to deform. Though commonly practiced, this technique is often unsatisfactory.

The double-cord technique can be used with single or multiple preparations. It is especially useful for making impressions when tissue health is compromised and the procedure absolutely cannot be delayed. The double-cord technique, which some clinicians use routinely for all impressions, employs two cords, one placed above the other. A thin cord such as silk suture or #000 retraction cord is first packed under the preparation margin to control gingival seepage and hemorrhage. This cord is typically left in place for the impression. The second, larger cord is impregnated with hemostatic agent and placed above the first cord for a minimum of 4 minutes and removed before the impression is taken, Figure 5, Figure 6, Figure 7, Figure 8 and Figure 9). The principal advantage of this technique is that the first cord remains in place within the sulcus, thus reducing the tendency of

the gingival cuff to recoil and displace partially set impression material. This approach not only helps to control gingival hemorrhage and exudates but also overcomes the problem of the sulcus impression tearing because of inadequate bulk.[25] Another advantage of the double-cord technique is that the first cord acts as a sulcus liner, preventing tearing of the epithelium and subsequent bleeding. The main disadvantage of this technique, however, is that failure to remove the first cord can cause gingival inflammation. Also, if the deeper cord is left in place the impression material may stick to it and cause the impression to tear upon removal.

Use of retraction cord, which can be laborious and time-consuming, must be done carefully as gingival bleeding may occur. It can also be uncomfortable for patients in the absence of anesthesia, and when inappropriately manipulated it can lead to direct injury and gingival recession.[26] Clinicians should be cautious when using retraction cords around implants since the junctional epithelium that surrounds an implant is not as adherent, is more permeable, and has a lower regenerative capacity than the junctional epithelium around teeth.[20] The artifacts caused by retraction cord fibers that may remain in the sulcus can also affect the accuracy of optical impressions used for CAD/CAM prostheses.[27] To overcome these problems, new products and techniques have been introduced into the market.

Retraction Strip

New retraction strips have been proposed for use in dentistry to displace gingival tissue prior to impression-making without damaging the tissue. The synthetic retraction material is chemically extracted from a biocompatible polymer (hydroxylate polyvinyl acetate) that creates net-like strips without debris or fragments. The material, which can be easily shaped and adapted into the sulcus without local anesthesia, is highly effective for absorption of intraoral fluids such as blood, saliva, and crevicular fluid.[28] Once inserted around the tooth, the sponge-like strips expand with absorption of fluids and exert pressure on gingival tissues to cause displacement.[3] Though time-consuming, this technique has shown to be suitable for the displacement of gingival tissue and to provide a readable impression that is gentle to the periodontium.[29]

Retraction Paste

Use of cordless retraction materials has gradually made impregnated retraction cords less competitive. Available in a paste-like form and supplied with a specialized dispenser, cordless retraction materials displace the gingiva when injected into the sulcus. Because of the passive technique used to place these pastes, they are significantly less traumatic to the tissue than conventional retraction cord.[30] Hence, they are preferred for gingival tissue displacement, especially around cement-retained implant prostheses.[20] These materials are also preferred when taking a digital impression for CAD/CAM prostheses since the artifacts caused by retraction cord fibers can be avoided.[27]

The amount of retraction offered by these pastes is limited, especially with extremely subgingival margins.[20] The high cost of retraction pastes, commercially available with or without hemostatic agents, has also prevented them from becoming a mainstream commodity.

Retraction paste with hemostatic agent: There are a number of retraction paste products available with hemostatic agents. One such product is an injectable viscous paste that depends on the hemostatic properties of aluminum chloride and the hygroscopic expansion of kaolin upon contact with the crevicular fluid to provide mild displacement of the gingiva in about 2 minutes. Retraction paste products contain as much as 15% aluminum chloride, which may be hazardous to the gingival tissue.[26] The viscosity of an injectable matrix may not be enough to provide sufficient displacement for deeper subgingival preparations, and aluminum chloride can inhibit the set of polyether and PVS materials if clinicians do not rinse it away properly before making impressions.[20]

Another product is a cordless gingival displacement system that utilizes the patient's bite pressure via a preformed matrix for single-tooth or a custom-made matrix for multiple teeth preparations. The bite pressure pushes the

hydrophilic silicone retraction paste to gently retract the gingiva with no tissue damage. The retraction paste also contains a mild, natural astringent to control the seepage of fluid.

Retraction paste without hemostatic agent: There are also various retraction paste products available without hemostatic agents. For example, one PVS material used for gingival displacement generates hydrogen to cause expansion of the material against the sulcus walls during setting. The product is syringed around the preparation margins of the abutment teeth and maintained under pressure using a compression cap for 5 minutes before impression taking. The manufacturer has reported such benefits as gentle placement without the need for local anesthetic, good product visibility in the sulcus due to its bright color, ease of removal, and minimal rinsing of residue. However, since there is no hemostatic agent, hemostasis should be achieved in all cases before using this technique. It is also less effective in cases of teeth with subgingival margins.[29]

Another type of product in this category is an injection-type retraction material that contains no aluminum chloride. It has shown to produce satisfactory gingival displacement without the drawbacks of pain and gingival recession.[31]

Conclusion

A healthy coexistence between restorations and their surrounding periodontal structures should be the goal of a diligent dentist. Several techniques have proven to be relatively predictable, safe, and efficacious in the management of the gingival tissue in restorative dentistry. No scientific evidence has established the superiority of one technique over the other. The selection of any one of the various methods of soft-tissue management to control the operative site depends on the clinical situation and the preference of the operator.

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About the Authors

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Abhishek Parolia, MDS
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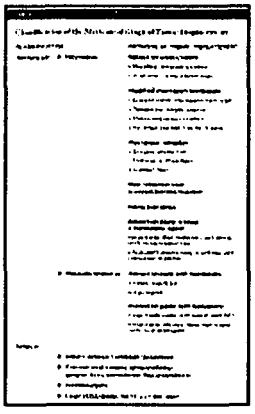

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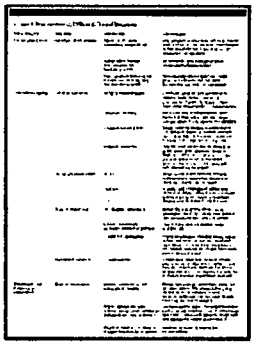

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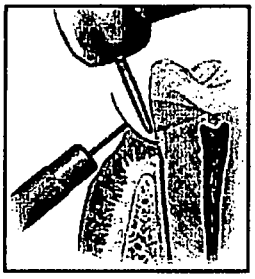
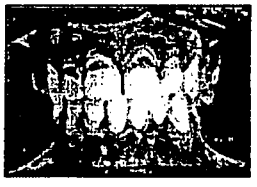


Figure 1



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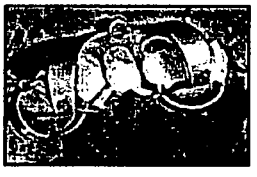

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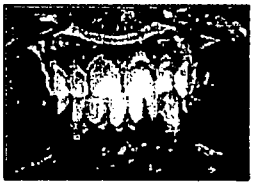

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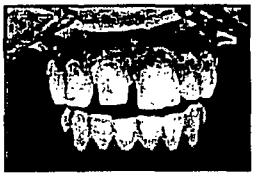

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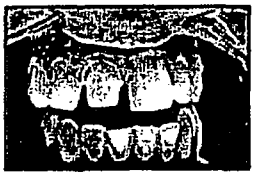

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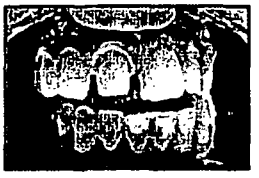

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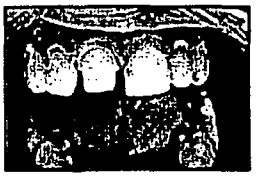

Figure 8

Figure 9

CREDITS: **2.0**
LOG IN or SIGN UP
COST:**$14.00**
PROVIDER:**AEGIS Publications, LLC**
SOURCE: *Compendium of Continuing Education in Dentistry*| June 2011
LEARNING OBJECTIVES:

After reading this article, the reader should be able to:

- enumerate the various methods of gingival tissue displacement
- list the advantages and disadvantages of various nonsurgical gingival displacement methods
- choose the appropriate method of gingival tissue displacement as the clinical situation demands

Appendix B : Stability Report

The stability report for ViscoStat Clear is attached, demonstrating the product can be released with a 42-month room temperature shelf life. Note that "Hemostatic Gel AC Clear" is a synonym for ViscoStat Clear. The former name is used interchangeably during Formulation and Testing phases, while "ViscoStat® Clear" is the final, branded name.

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K123215

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 5, 2013

Ms. Karen Kakunes, RN
Senior Regulatory Affairs Associate
Ultradent Products, Incorporated
505 West 10200 South
SOUTH JORDAN UT 84095

Re: K123215
Trade/Device Name: ViscoStat® Clear
Regulation Number: Unclassified
Regulation Name: Cord, Retraction
Regulatory Class: Unclassified
Product Code: MVL
Dated: September 26, 2012
Received: November 7, 2012

Dear Ms. Kakunes:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

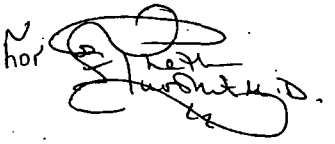
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Concurrence & Template History Page
[THIS PAGE IS INCLUDED IN IMAGE COPY ONLY]

Full Submission Number: K123215

For Office of Compliance Contact Information:

http://insideportlets.fda.gov:9010/portal/page?_pageid=197,415881&_dad=portal&_schema=PORTAL&org=318

For Office of Surveillance and Biometrics Contact Information:

http://insideportlets.fda.gov:9010/portal/page?_pageid=197,415881&_dad=portal&_schema=PORTAL&org=423

Digital Signature Concurrence Table	
Reviewer Sign-Off	Myra E. Browne Digitally signed by Myra E. Browne DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Myra E. Browne, 0.9.2342.19200300.100.1.1=1300013790 Date: 2013.02.05 12:23:05 -05'00'
Branch Chief Sign-Off AIS for MSR	Andrew I. Steen 2013.02.05 12:25:15 -05'00'
Division Sign-Off	Tejashri Purohit-Sheth, M.D. Clinical Deputy Director, DAGRID 2013.01.31 07:22:28 -05'00'

Template Name: K1(A) – SE after 1996

Template History:

Date of Update	By	Description of Update
7/27/09	Brandi Stuart	Added Updates to Boiler Table
8/7/09	Brandi Stuart	Updated HFZ Table
1/11/10	Diane Garcia	Liability/Warranty sentence added at bottom of 1st page
10/4/11	M. McCabe Janicki	Removed IFU sheet and placed in Forms
9/25/12	Edwena Jones	Added digital signature format
12/12/12	M. McCabe Janicki	Added an extra line between letter signature block and the word "Enclosure". Also, added a missing digit in 4-digit extension on letterhead zip code: "002" should be "0002".

Section 4: Statement of Indications for Use

510(k) Number (if known): K123215

Device Name: ViscoStat Clear

Indications for Use: ViscoStat Clear is intended for sulcus retraction prior to impression making and to control bleeding and gingival oozing in restorative and operative dentistry used with gingival retraction cord and/or the Dento Infusor. The gel facilitates the insertion of the cord into the sulcus.

Prescription Use _X_ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner DDS, MA 2013.01.30 11:55:56 -05'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K123215

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REASON FOR ERROR
E-1) HANG UP OR LINE FAIL
E-2) BUSY
E-3) NO ANSWER
E-4) NO FACSIMILE CONNECTION

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 5, 2013

Ms. Karen Kakunes, RN
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Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

From: Reviewer Name Myra Browne

Subject: 510(k) Number K123215

To: The Record

Please list CTS decision code SE

☐ Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)

☐ Hold (Additional Information or Telephone Hold).

☑ Final Decision (SE, SE with Limitations, NSE (select code below), Withdrawn, etc.).

Not Substantially Equivalent (NSE) Codes

☐	NO	NSE for lack of predicate
☐	NI	NSE for new intended use
☐	NQ	NSE for new technology that raises new questions of safety and effectiveness
☐	NU	NSE for new intended use AND new technology raising new questions of safety and effectiveness
☐	NP	NSE for lack of performance data
☐	NS	NSE no response
☐	NL	NSE for lack of performance data AND no response
☐	NM	NSE pre-amendment device call for PMAs (515i)
☐	NC	NSE post-amendment device requires PMAs
☐	NH	NSE for new molecular entity requires PMA
☐	TR	NSE for transitional device

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	*Attach IFU*	✓	
510(k) Summary /510(k) Statement	*Attach Summary*	✓	
Truthful and Accurate Statement.	*Must be present for a Final Decision*	✓	
Is the device Class III?			✓
If yes, does firm include Class III Summary?	*Must be present for a Final Decision*		
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)		✓	
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC			✓
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			✓
Is this device intended for pediatric use only?			
Is this a prescription device? (If both prescription & OTC, check both boxes.)		✓	
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?			✓
Is clinical data necessary to support the review of this 510(k)?			✓
For United States-based clinical studies **only**: Did the application include a completed FORM FDA 3674, *Certification with Requirements of ClinicalTrials.gov Data Bank*? (If study was			✓

conducted in the United States, and FORM FDA 3674 was not included or incomplete, then applicant must be contacted to obtain completed form.) ✓

Does this device include an Animal Tissue Source? ✓

All Pediatric Patients age<=21 ✓

Neonate/Newborn (Birth to 28 days) ✓

Infant (29 days -< 2 years old) ✓

Child (2 years -< 12 years old) ✓

Adolescent (12 years -< 18 years old) ✓

Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.) ✓

Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old) ✓

Nanotechnology ✓

Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html) *Contact OC.* ✓

Regulation Number	Class*	Product Code
	Unclassified	76 MVL

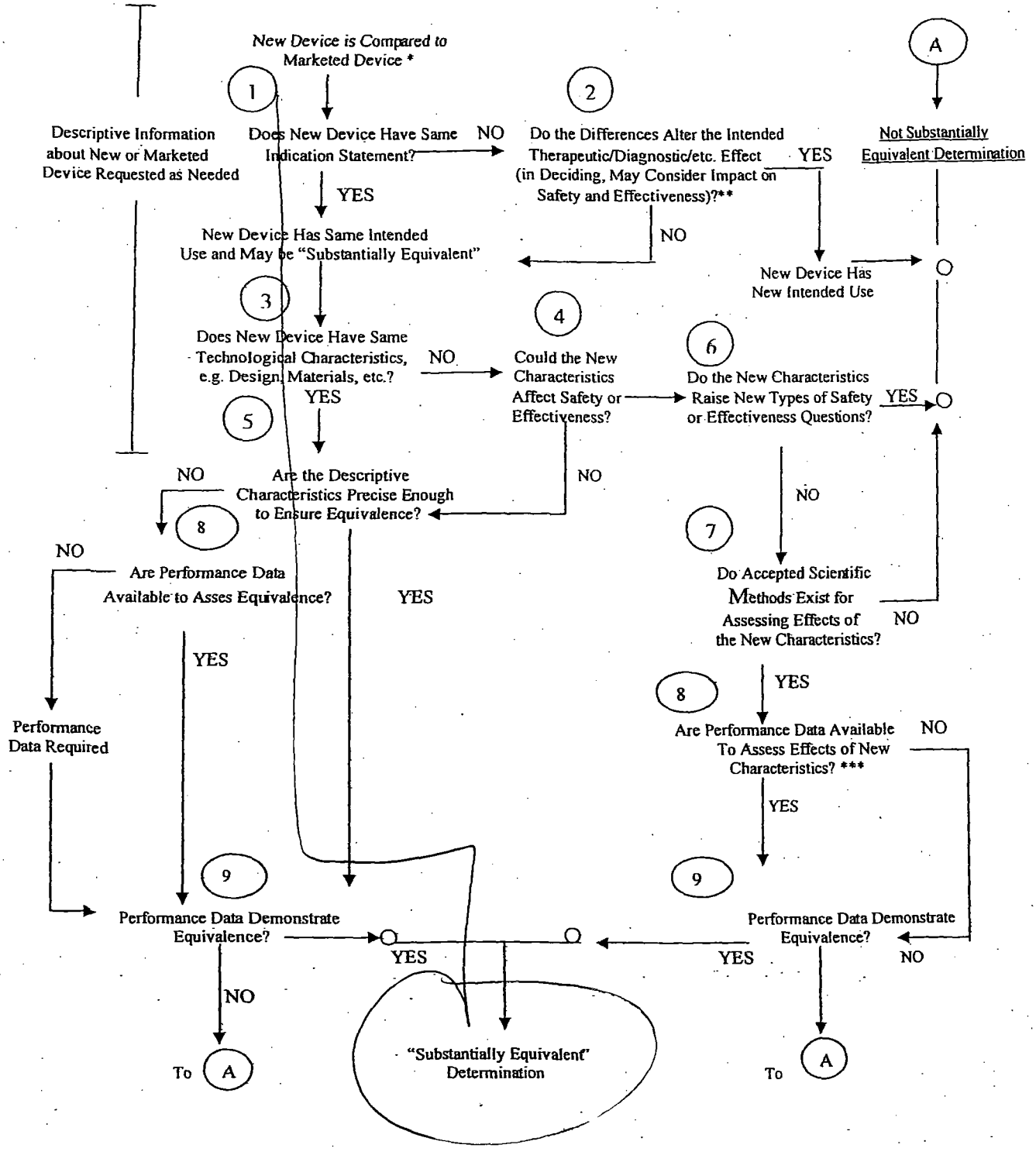
(*If unclassified, see 510(k) Staff)

Additional Product Codes:

Review: _____ DEDB 1/30/13
(Branch Chief) (Branch Code) (Date)

Final Review: _____ DAGRD 2/05/13
(Division Director) (Date)

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



* 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

*** Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.

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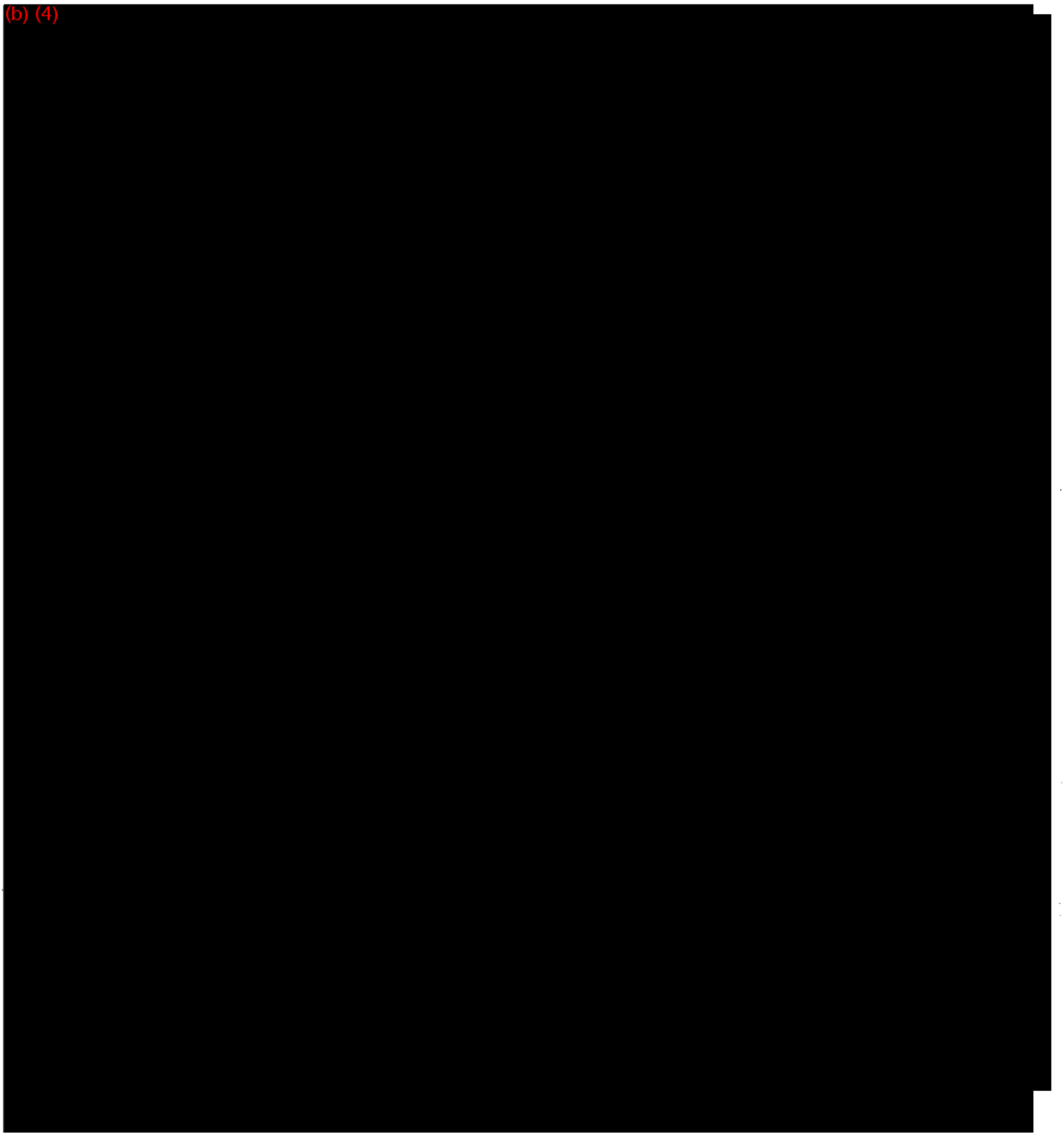

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DEPARTMENT OF HEALTH & HUMAN SERVICES **Public Health Service**

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

November 08, 2012

ULTRADENT PRODUCTS, INC.
505 WEST 10200 SOUTH
SOUTH JORDAN, UTAH 84095
ATTN: KAREN KAKUNES

510k Number: K123215

Received: 11/7/2012

Product: VISCOSTAT CLEAR

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), has received the Premarket Notification, (510(k)), you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act(Act) for the above referenced product and for the above referenced 510(k) submitter. Please note, if the 510(k) submitter is incorrect, please notify the 510(k) Staff immediately. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in all future correspondence that relates to this submission. We will notify you when the processing of your 510(k) has been completed or if any additional information is required. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (DMC) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official 510(k) submission.

On September 27, 2007, the President signed an act reauthorizing medical device user fees for fiscal years 2008 - 2012. The legislation - the Medical Device User Fee Amendments of 2007 is part of a larger bill, the Food and Drug Amendments Act of 2007. Please visit our website at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/default.htm
for more information regarding fees and FDA review goals. In addition, effective January 2, 2008, any firm that chooses to use a standard in the review of ANY new 510(k) needs to fill out the new standards form (Form 3654) and submit it with their 510(k). The form may be found at http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm.

We remind you that Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA) amended the PHS Act by adding new section 402(j) (42 U.S.C. § 282(j)), which expanded the current database known as ClinicalTrials.gov to include mandatory registration and reporting of results for applicable clinical trials of human drugs (including biological products) and devices. Section 402(j) requires that a certification form http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm accompany 510(k)/HDE/PMA submissions. The agency has issued a draft guidance titled: "Certifications To Accompany Drug, Biological

Product, and Device Applications/Submissions: Compliance with Section 402(j) of The Public Health Service Act, Added By Title VIII of The Food and Drug Administration Amendments Act of 2007" http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm134034.htm. According to the draft guidance, 510(k) submissions that do not contain clinical data do not need the certification form.

Please note the following documents as they relate to 510(k) review: 1) Guidance for Industry and FDA Staff entitled, "Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs and BLA Supplements". This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm. Please refer to this guidance for information on a formalized interactive review process. 2) Guidance for Industry and FDA Staff entitled, "Format for Traditional and Abbreviated 510(k)s". This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

In all future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA resources and may help reviewers navigate through longer documents more easily. Under CDRH's e-Copy Program, you may replace one paper copy of any premarket submission (e.g., 510(k), IDE, PMA, HDE) with an electronic copy. For more information about the program, including the formatting requirements, please visit our web site at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm134508.html. In addition, the 510(k) Program Video is now available for viewing on line at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm070201.htm .

Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.

Lastly, you should be familiar with the regulatory requirements for medical devices available at Device Advice http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm. If you have questions on the status of your submission, please contact DSMICA at (301)796-7100 or the toll-free number (800)638-2041 , or at their internet address http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm. If you have procedural questions, please contact the 510(k) Staff at (301)796-5640.

Sincerely,

510(k) Staff

(b) (4)

[redacted]

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

User Fee Hold Letter

October 16, 2012

Karen Kakunes, Sr. Regulatory Affairs Associate
Ultradent Products, Inc.
505 West 10200 South
South Jordan, UT 84095
United States

Dear Karen Kakunes:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) acknowledges receipt of your submission. This submission has been assigned the following unique document control number. Failure to reference this assigned number in future correspondence may result in processing delays.

510(k) Number: K123215
Device: Viscostat Clear
Dated: 26-SEP-2012
Received: 15-OCT-2012

The Federal Food, Drug, and Cosmetic Act (the Act), as amended by the Medical Device User Fee and Modernization Act of 2002 (MDUFMA), the FDA Amendments Act of 2007 (FDAAA) (Public Law 110-85), and the Medical Device User Fee Amendments of 2012 (MDUFA III), authorizes FDA to collect user fees for certain types of submissions. This submission cannot be accepted for review until the user fee is paid in full.

You have received this letter because we have not received your payment in full. Additional information on user fees, including how and where to submit your user fee payment and how to generate a User Fee Cover Sheet, may be found on our webpage entitled,"Premarket Notification [510(k)] Review Fees" at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketApprovalPMA/ucm048161.htm

In addition, please fax a completed copy of the User Fee Cover Sheet that includes the specific submission number above and the Payment Identification Number for this submission to our CDRH Document Control Center at (301) 847-8113.

You now have the option to pay online by credit card. We recommend this form of payment. Credit card payments are directly linked to your user fee cover sheet and are processed the next business day. You may also pay by check. If you choose to pay by check, make the check out to the Food and Drug Administration and reference the payment identification number, include a copy of the User Fee Cover sheet with the check, and mail them to one of the addresses listed below:

By Regular Mail

Food and Drug Administration
P.O. Box 956733
St. Louis, MO 63195-6733

By Private Courier (e.g., Fed Ex, UPS)

U.S. Bank
Attn: Government Lockbox 956733
1005 Convention Plaza
St. Louis, MO 63101
(314) 418-4821

When we have been notified that your user fee payment has been received, review of the submission will resume as of that date. Alternatively, you may request withdrawal of your submission.

If payment has not been received within 30 days, your 510(k) will be deleted from the system. If you have any questions concerning this letter, please contact Ms. Edwena Jones at (301) 796-6308 or by email at edwena.jones@fda.hhs.gov.

Sincerely yours,

Marjorie Shulman
Director, 510(k) Program
Program Operations Staff
Office of Device Evaluation
Center for Devices and Radiological Health

(b) (4)

TRADITIONAL 510(k) Premarket Notification

ViscoStat® Clear

Ultradent Products, Inc.
505 West 10200 South
South Jordan, UT 84095

Establishment Registration Number 1718912

Table of Contents

Section 1: Medical Device User Fee Cover Sheet (Form FDA 3601)

Form Approved. OMB No. 0910-51[illegible]

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
MEDICAL DEVICE USER FEE COVER SHEET

PAYMENT IDENTIFICATION NUMBER:
Write the Payment Identification number on (b) (4) [redacted]

A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/mdufma/coversheet.html

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)	2. CONTACT NAME
ULTRADENT PRODUCTS INC 505 West 10200 South South Jordan UT 84095 US	Diane Rogers 2.1 E-MAIL ADDRESS diane.rogers@ultradent.com 2.2 TELEPHONE NUMBER (include Area code) 801-553-4491
1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) *****6957	2.3 FACSIMILE (FAX) NUMBER (Include Area code) 801-553-4609

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/oc/mdufma

Select an application type:	3.1 Select a center
[X] Premarket notification(510(k)); except for third party	[X] CDRH
[ ] 513(g) Request for Information	[ ] CBER
[ ] Biologics License Application (BLA)	3.2 Select one of the types below
[ ] Premarket Approval Application (PMA)	[X] Original Application
[ ] Modular PMA	Supplement Types:
[ ] Product Development Protocol (PDP)	[ ] Efficacy (BLA)
[ ] Premarket Report (PMR)	[ ] Panel Track (PMA, PMR, PDP)
[ ] Annual Fee for Periodic Reporting (APR)	[ ] Real-Time (PMA, PMR, PDP)
[ ] 30-Day Notice	[ ] 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)

[ ] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA

[X] NO, I am not a small business

4.1 If Yes, please enter your Small Business Decision Number:

5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA?

[X] YES (*All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within* 30 days of FDA's approval/clearance of this device.)

[ ] NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see http://www.fda.gov/cdrh/mdufma for additional information)

6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.

[ ] This application is the first PMA submitted by a qualified small business, including any affiliates

[ ] The sole purpose of the application is to support conditions of use for a pediatric population

[ ] This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only

[ ] The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).

[ ] YES [X] NO

PAPERWORK REDUCTION ACT STATEMENT

Public reporting burden for this collection of information is estimated to average 18 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the address below.

Department of Health and Human Services, Food and Drug Administration, Office of Chief Information Officer, 1350 Piccard Drive, 4th Floor Rockville, MD 20850

[Please do NOT return this form to the above address, except as it pertains to comments on the burden estimate.]

(b) (4) [redacted]

[illegible]YMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION

22-Aug-2012

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 0910-0120
Expiration Date: December 31, 2013
See OMB Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number *(if known)*
09/26/2012	(b) (4)	

SECTION A TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Meeting
☐ Original Submission	☐ Regular (180 day)	☐ Original PDP	☒ Original Submission:	☐ Pre-510(K) Meeting
☐ Premarket Report	☐ Special	☐ Notice of Completion	☒ Traditional	☐ Pre-IDE Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☐ Special	☐ Pre-PMA Meeting
☐ Amendment	☐ 30-day Supplement		☐ Abbreviated (Complete section I, Page 5)	☐ Pre-PDP Meeting
☐ Report	☐ 30-day Notice		☐ Additional Information	☐ Day 100 Meeting
☐ Report Amendment	☐ 135-day Supplement		☐ Third Party	☐ Agreement Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Determination Meeting
	☐ Amendment to PMA & HDE Supplement			☐ Other *(specify)*:
	☐ Other			

IDE	Humanitarian Device Exemption (HDE)	Class II Exemption Petition	Evaluation of Automatic Class III Designation (De Novo)	Other Submission
☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ 513(g)
☐ Amendment	☐ Amendment	☐ Additional Information	☐ Additional Information	☐ Other *(describe submission)*:
☐ Supplement	☐ Supplement			
	☐ Report			
	☐ Report Amendment			

Have you used or cited Standards in your submission? ☐ Yes ☐ No *(If Yes, please complete Section I, Page 5)*

SECTION B SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name	Establishment Registration Number *(if known)*
Ultradent Products, Inc.	1718912
Division Name *(if applicable)*	**Phone Number *(including area code)***
	801-553-4366
Street Address	**FAX Number *(including area code)***
505 West 10200 South	801-553-4609

City	State / Province	ZIP/Postal Code	Country
South Jordan	UT	84095	USA

Contact Name	
Karen Kakunes	
Contact Title	**Contact E-mail Address**
Sr. Regulatory Affairs Associate	karen.kakunes@ultradent.com

SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

Company / Institution Name	
Division Name *(if applicable)*	**Phone Number *(including area code)***
Street Address	**FAX Number *(including area code)***

City	State / Province	ZIP Code	Country

Contact Name	
Contact Title	**Contact E-mail Address**

FORM FDA 3514 (12/10) Page 1 of 5 Pages

PSC Publishing Services (301) 443-6740 EF

SECTION D1 REASON FOR APPLICATION - PMA, PDP, OR HDE

- ☐ New Device
- ☐ Withdrawal
- ☐ Additional or Expanded Indications
- ☐ Request for Extension
- ☐ Post-approval Study Protocol
- ☐ Request for Applicant Hold
- ☐ Request for Removal of Applicant Hold
- ☐ Request to Remove or Add Manufacturing Site

- ☐ Change in design, component, or specification:
  - ☐ Software/Hardware
  - ☐ Color Additive
  - ☐ Material
  - ☐ Specifications
  - ☐ Other *(specify below)*

- ☐ Location change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager

- ☐ Process change:
  - ☐ Manufacturing ☐ Packaging
  - ☐ Sterilization
  - ☐ Other *(specify below)*

- ☐ Labeling change:
  - ☐ Indications
  - ☐ Instructions
  - ☐ Performance Characteristics
  - ☐ Shelf Life
  - ☐ Trade Name
  - ☐ Other *(specify below)*

- ☐ Report Submission:
  - ☐ Annual or Periodic
  - ☐ Post-approval Study
  - ☐ Adverse Reaction
  - ☐ Device Defect
  - ☐ Amendment

- ☐ Response to FDA correspondence:

- ☐ Change in Ownership
- ☐ Change in Correspondent
- ☐ Change of Applicant Address

- ☐ Other Reason *(specify)*:

SECTION D2 REASON FOR APPLICATION - IDE

- ☐ New Device
- ☐ New Indication
- ☐ Addition of Institution
- ☐ Expansion / Extension of Study
- ☐ IRB Certification
- ☐ Termination of Study
- ☐ Withdrawal of Application
- ☐ Unanticipated Adverse Effect
- ☐ Notification of Emergency Use
- ☐ Compassionate Use Request
- ☐ Treatment IDE
- ☐ Continued Access

- ☐ Change in:
  - ☐ Correspondent / Applicant
  - ☐ Design / Device
  - ☐ Informed Consent
  - ☐ Manufacturer
  - ☐ Manufacturing Process
  - ☐ Protocol - Feasibility
  - ☐ Protocol - Other
  - ☐ Sponsor

- ☐ Report submission:
  - ☐ Current Investigator
  - ☐ Annual Progress Report
  - ☐ Site Waiver Report
  - ☐ Final

- ☐ Response to FDA Letter Concerning:
  - ☐ Conditional Approval
  - ☐ Deemed Approved
  - ☐ Deficient Final Report
  - ☐ Deficient Progress Report
  - ☐ Deficient Investigator Report
  - ☐ Disapproval
  - ☐ Request Extension of Time to Respond to FDA
  - ☐ Request Meeting
  - ☐ Request Hearing

- ☐ Other Reason *(specify)*:

SECTION D3 REASON FOR SUBMISSION - 510(k)

- ☒ New Device
- ☐ Additional or Expanded Indications
- ☐ Change in Technology

- ☐ Other Reason *(specify)*:

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	MVL	2		3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

- [x] 510 (k) summary attached
- [ ] 510 (k) statement

Information on devices to which substantial equivalence is claimed *(if known)*

	510(k) Number	*Trade or Proprietary or Model Name*	*Manufacturer*
1	K093711	Racegel	Septodont
2			
3			
4			
5			
6			

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification name

Cord, Retraction

	Trade or Proprietary or Model Name for This Device	Model Number
1	ViscoStat Clear	6407, 6408, 6409, 6410,
2		
3		
4		
5		

FDA document numbers of all prior related submissions *(regardless of outcome)*

1	K052835	2		3		4		5		6	
7		8		9		10		11		12	

Data Included in Submission

- [x] Laboratory Testing
- [ ] Animal Trials
- [ ] Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code	C.F.R. Section *(if applicable)*	Device Class
MVL	N/A	☐ Class I ☐ Class II ☐ Class III ☒ Unclassified

Classification Panel

Dental

Indications *(from labeling)*

ViscoStat Clear is intended for sulcus retraction prior to impression making and to control bleeding and gingival oozing in restorative and operative dentistry used with gingival retraction cord and/or the Dento Infusor. The gel facilitates the insertion of the cord into the sulcus.

Note: Submission of the information entered in Section H does not affect the need to submit device establishment registration.

FDA Document Number *(if known)*:

SECTION H — MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

☒ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number: 1718912
☒ Manufacturer ☐ Contract Manufacturer ☐ Contract Sterilizer ☐ Repackager / Relabeler	
Company / Institution Name: Ultradent Products, Inc.	Establishment Registration Number: 171892
Division Name *(if applicable)*:	Phone Number *(including area code)*: 888-230-1420
Street Address: 505 West 10200 South	FAX Number *(including area code)*: 801-553-4609
City: South Jordan	State / Province: UT; ZIP Code: 84095; Country: USA
Contact Name: Karen Kakunes	Contact Title: Sr. Regulatory Affairs Associate; Contact E-mail Address: karen.kakunes@ultradent.com

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number:
☐ Manufacturer ☐ Contract Manufacturer ☐ Contract Sterilizer ☐ Repackager / Relabeler	
Company / Institution Name:	Establishment Registration Number:
Division Name *(if applicable)*:	Phone Number *(including area code)*:
Street Address:	FAX Number *(including area code)*:
City:	State / Province: ; ZIP Code: ; Country:
Contact Name:	Contact Title: ; Contact E-mail Address:

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number:
☐ Manufacturer ☐ Contract Manufacturer ☐ Contract Sterilizer ☐ Repackager / Relabeler	
Company / Institution Name:	Establishment Registration Number:
Division Name *(if applicable)*:	Phone Number *(including area code)*:
Street Address:	FAX Number *(including area code)*:
City:	State / Province: ; ZIP Code: ; Country:
Contact Name:	Contact Title: ; Contact E-mail Address:

SECTION I	UTILIZATION OF STANDARDS				
Note: Complete this section if your application or submission cites standards or includes a *"Declaration of Conformity to a Recognized Standard"* statement.					
	Standards No.	Standards Organization	Standards Title	Version	Date
1	ISO 10993-1	ISO	Biological Evaluation of Medical Devices	Fourth Ed.	10/05/2009
2					
3					
4					
5					
6					
7					

Please include any additional standards to be cited on a separate page.

Public reporting burden for this collection of information is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, Room 400
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Form Approved: OMB No. 0910-0120; Expiration Date: 12/31/13

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO 10993 Biological Evaluation of Medical Devices

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#2-156	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☒	☐
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

FORM FDA 3654 (6/11) Page 1 PSC Publishing Services (301) 443-6740 EF

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
ISO 10993 Biological Evaluation of Medical Devices

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
Entire standard used		☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

♦ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, Room 400
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

FORM FDA 3654 (6/11) Page 2

Form Approved: OMB No. 0910-0120; Expiration Date: 12/31/13

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO 7405: Dentistry - Evaluation of Biocompatibility of Medical Devices used in Dentistry

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☐	☒
FDA Recognition number [3]	# _____	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☒	☐
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

FORM FDA 3654 (6/11) Page 1 PSC Publishing Services (301) 443-6740 EF

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
ISO 7405: Dentistry - Evaluation of Biocompatibility of Medical Devices used in Dentistry

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
Entire standard used		☒ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ♦		
DESCRIPTION		
JUSTIFICATION		

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ♦		
DESCRIPTION		
JUSTIFICATION		

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ♦		
DESCRIPTION		
JUSTIFICATION		

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

♦ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, Room 400
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

FORM FDA 3654 (6/11) Page 2

Section 3: 510(k) Submission Cover Letter (Traditional 510(k))

26 Sep 2012

K69

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (W066-G609)
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Subject: Traditional 510(k) Notification for ViscoStat® Clear

Dear Sir or Madam,

In compliance with the Code of Federal Regulations, the enclosed 510(k) Notification (21 CFR 807.90 (e)) by Ultradent Products, Inc., hereby notifies the FDA of its intent to market ViscoStat Clear.

ViscoStat Clear is a device which has been submitted previously for 510k review in 2005 (K052835). It was determined at that time that the product was regulated as a drug as defined in 201(g) of the Federal Food, Drug, and Cosmetic Act rather than a device as defined in section 201(h) of the same Act. However, since the original submission, CDRH has cleared a similar product, which has been reviewed and granted 510(k) approval under product code MVL (cord, retraction). This 510k is being submitted for review and approval as a medical device. ViscoStat Clear will be manufactured and marketed by Ultradent Products, Inc., 505 West 10200 South, South Jordan, UT 84095, Establishment Registration Number 1718912. It is substantially equivalent to Racegel (K093711), manufactured by Septodont, in formulation, technology, and intended use.

This traditional 510(k) submission is considered proprietary and falls within the confidentiality of information as stipulated in 21 CFR 807.95. The contents in this 510(k) follow the FDA guidance document, "Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s", issued August 12, 2005.

ULTRADENT PRODUCTS, INC.
505 West 10200 South
South Jordan, Utah 84095, USA
www.ultradent.com
800.552.5512

The new product is classified as follows:

Device:	Cord, Retraction
Trade/Device Name:	ViscoStat® Clear
Review Panel:	Dental
Regulation Number:	None
Device Class:	Unclassified
Product Code:	MVL

Design and Use of the Device (from "Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s"):

Table 3-1: Design and Use

Question	Yes	No
Is the device intended for prescription use (21 CFR 801 Subpart D)?	X	
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?		X
Does the device contain components derived from a tissue or other biologic source?		X
Is the device provided sterile?		X
Is the device intended for single use?		X
Is the device a reprocessed single use device?		X
If yes, does this device type require reprocessed validation data?		
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?		X
Does the submission include clinical information?		X
Is the device implanted?		X

The enclosed information is true and correct to the best of my knowledge and no material facts have been omitted. [redacted] (b) (4)

[redacted] (b) (4)

Please do not hesitate to contact me if you require any clarification or information.

Sincerely,

Karen Kakunes, RN
Sr. Regulatory Affairs Associate
Ultradent Products, Inc.
505 West 10200 South
South Jordan, UT 84095 USA
TEL: 800-552-5512 x4366, 801-553-4366
Cell: 801-673-1072
FAX: 801-553-4609
Email: karen.kakunes@ultradent.com

Table 3-2: Screening Checklist for Traditional/Abbreviated Premarket Notification [510(k)] Submissions

based on
Guidance for Industry and FDA Staff
Format for Traditional and Abbreviated 510(k)s

Title	Related Information	Present	Inadequate	N/A
MDUFMA Cover Sheet	Medical Device User Fee Cover Sheet	X		
CDRH Premarket Review Submission Cover Sheet	CDRH Premarket Review Submission Cover Sheet	X		
510(k) Cover Letter	Appendix A of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005	X		
Indications for Use Statement	Device Advice "Content of a 510(k)" Section D	X		
510(k) Summary or 510(k) Statement	Device Advice "Content of a 510(k)" Section E	X		
Truthful and Accuracy Statement	Device Advice "Content of a 510(k)" Section G	X		
Class III Summary and Certification	Class III Summary and Certification Form			X
Financial Certification or Disclosure Statement	FORM FDA 3454, Certification: Financial Interests and Arrangements of Clinical Investigators FORM FDA 3455, Disclosure: Financial Interests and Arrangements of Clinical Investigators Financial Disclosure by Clinical Investigators	X		
Declarations of Conformity and Summary Reports (Abbreviated 510(k)s)	Use of Standards in Substantial Equivalence Determinations FDA Standards program Declaration of conformity Required Elements for Declaration of Conformity to Recognized Standard			X
Executive Summary	See section 10 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005	X		
Device Description	See section 11 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005	X		
Substantial Equivalence Discussion	Guidance on the CDRH Premarket Notification Review Program 6/30/86 (K86-3)	X		

Title	Related Information	Present	Inadequate	N/A
Proposed Labeling	Device Advice " Content of a 510(k)" Section H	X		
Sterilization/Shelf Life	Updated 510(k) Sterility Review Guidance (K90-1) For reuse of single use devices, see Guidance for Industry and FDA Staff – Medical Device User Fee and Modernization Act of 2002 Validation Data in Premarket Notification Submissions (510(k)s) for Reprocessed Single-Use Medical Devices	X		
Biocompatibility	FDA Blue Book Memo, G95-1, Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing"	X		
Software	Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices			X
Electromagnetic Compatibility/Electrical Safety	CDRH Medical Device Electromagnetic Compatibility Program See also IEC 60601-1- 2 Medical Electrical Equipment -- Part 1: General Requirements for Safety; Electromagnetic Compatibility -- Requirements and Tests (Second Edition, 2001)			X
Performance Testing – Bench	See section 18 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005	X		
Performance Testing – Animal	See section 19 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005			X
Performance Testing – Clinical	See section 20 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005 FORM FDA 3454, Certification: Financial Interests and Arrangements of Clinical Investigators FORM FDA 3455, Disclosure: Financial Interests and Arrangements of Clinical Investigators			X
Kit Certification	Device Advice: Special Considerations			X

Section 4: Statement of Indications for Use

510(k) Number (if known): K123215

Device Name: ViscoStat Clear

Indications for Use: ViscoStat Clear is intended for sulcus retraction prior to impression making and to control bleeding and gingival oozing in restorative and operative dentistry used with gingival retraction cord and/or the Dento Infusor. The gel facilitates the insertion of the cord into the sulcus.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of 1

(Posted November 13, 2003)

K123215

Section 5: 510(k) Summary

This summary of the Traditional 510(k) substantial equivalence information is being submitted in accordance with the requirements of 21 CFR 807.92.

I. Applicant's Name and Address

Ultradent Products, Inc.
505 West 10200 South
South Jordan, UT 84095

Contact Person:	Karen Kakunes, RN
Title:	Sr. Regulatory Affairs Associate
Telephone:	800-552-5512 x4420, 801-553-4366
FAX:	801-553-4609
Date Summary Prepared:	26 Sep 2012

II. Name of the Device

Trade Name:	ViscoStat® Clear
Common Name:	Cord, Retraction
Device Classification:	Unclassified
Classification Product Code:	MVL
Regulation No.	None

III. Legally Marketed Predicate Devices to Which Equivalence is Claimed

ViscoStat® Clear is substantially equivalent to Racegel™ (K093711), manufactured by Septodont, which is cleared under dental device product code MVL (cord, retraction). ViscoStat Clear is substantially similar to the predicate device in Indications for Use, chemical composition, mechanical and physical properties and method of application and removal.

IV. Device Description:

ViscoStat Clear is a 25% Aluminum Chloride gel in a viscous, aqueous vehicle which leaves no residue or stain and makes it ideal for use in the esthetic zone. The product is contained within a 30mL or 1.2mL plastic syringe. The 30mL syringe is a bulk container and, prior to application, will be dispensed into provided, empty 1.2mL plastic syringe

for delivery to the patient. Dento-Infusor application tips are included and are used to apply the product to the prepared area.

V. Statement of intended use:

ViscoStat Clear is intended for sulcus retraction prior to impression making and to control bleeding and gingival oozing in restorative and operative dentistry used with gingival retraction cord and/or the Dento Infusor. The gel facilitates the insertion of the cord into the sulcus.

VI. Comparison of technological characteristics

Table 5-1: Substantial equivalence comparison

Characteristic	Comparison Product (Racegel™ K093711)	ViscoStat Clear
Intended Use	Racegel is a gel containing aluminum chloride which is intended for sulcus retraction prior to impression taking; control of bleeding and gingival oozing, particularly in restorative dentistry; and, if using a gingival retraction cord, the gel facilitates the insertion of the cord into the sulcus	ViscoStat Clear is intended for sulcus retraction prior to impression making and to control bleeding and gingival oozing in restorative and operative dentistry used with gingival retraction cord and/or the Dento Infusor. The gel facilitates the insertion of the cord into the sulcus.
Intended user	Dental professional	Dental professional
Chemical Characteristics	Aluminum chloride gel	Aluminum chloride gel
Recommended contact time	2 minutes	1-3 minutes
Delivery system	Pre-filled syringe with applicator tip	1.2ml pre-filled syringe with applicator tip, 30ml Indispense syringe with 1.2ml empty syringe and applicator tip
Physical properties	Orange, odorless gel	Clear gel

ULTRADENT PRODUCTS, INC.
505 West 10200 South
South Jordan, Utah 84095. USA
www.ultradent.com
800.552.5512

	24 month shelf life	42 month shelf life
Biocompatibility	Acute oral toxicity Sensitization Oral Mucosa Irritation Cytotoxicity	Cytotoxicity
Functional Testing	Unknown	Aluminum Chloride content Effect on Shear Bond Strength Blood coagulation

ViscoStat Clear is a similar material used in the same way by the same types of users as the identified predicate device Racegel, introducing no new safety or efficacy questions. Biocompatibility testing shows that the product is safe when used as instructed by a dental professional. In-house comparison testing has been performed on ViscoStat Clear and the predicate device, Racegel. The data supports the functionality of ViscoStat Clear. In summary, this submission demonstrates that ViscoStat Clear is safe and effective and performs equivalently to the identified predicates for its intended use.

ULTRADENT PRODUCTS, INC.
505 West 10200 South
South Jordan, Utah 84095, USA
www.ultradent.com
800.552.5512

Section 6: Truthful and Accurate Statement

I certify in my capacity as a Senior Regulatory Affairs Associate of Ultradent Products, Inc., I believe, to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

Karen Kakunes, RN
Sr. Regulatory Affairs Associate

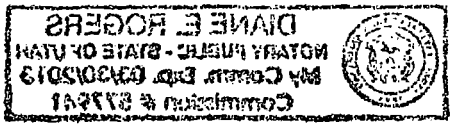
26 Sep 2012
Date

Premarket Notification 510(k) Number

State of Utah, County of Salt Lake
Subscribed and sworn to before me
this 26 day of Sept 2012

Diane E. Rogers
Diane Rogers, Notary Public

DIANE E. ROGERS
NOTARY PUBLIC - STATE OF UTAH
My Comm. Exp. 03/30/2013
Commission # 577941



Section 7: Class III Summary and Certification

ViscoStat Clear is not a Class III device; therefore, this section does not apply to this 510(k).

Section 8: Financial Certification or Disclosure Statement

This section does not apply to this 510(k) as no clinical studies were conducted for this product. A completed Form 3674 follows on the next page.

See OMB Statement on Reverse. Form Approved: OMB No. 0910-0616, Expiration Date: 2-28-2015

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Certification of Compliance, under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))

(For submission with an application/submission, including amendments, supplements, and resubmissions, under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.)

SPONSOR / APPLICANT / SUBMITTER INFORMATION

1. NAME OF SPONSOR/APPLICANT/SUBMITTER
Ultradent Products, Inc./Karen Kakunes

2. DATE OF THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES
Sep 26, 2012

3. ADDRESS *(Number, Street, State, and ZIP Code)*
505 West 10200 South
South Jordan, UT 84095 USA

4. TELEPHONE AND FAX NUMBERS *(Include Area Code)*
(Tel.) 801-553-4366
(Fax) 801-553-4609

PRODUCT INFORMATION

5. **FOR DRUGS/BIOLOGICS:** Include Any/All Available Established, Proprietary and/or Chemical/Biochemical/Blood/Cellular/Gene Therapy Product Name(s)
FOR DEVICES: Include Any/All Common or Usual Name(s), Classification, Trade or Proprietary or Model Name(s) and/or Model Number(s)
(Attach extra pages as necessary)

APPLICATION / SUBMISSION INFORMATION

6. TYPE OF APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES
☐ IND ☐ NDA ☐ ANDA ☐ BLA ☐ PMA ☐ HDE ☒ 510(k) ☐ PDP ☐ Other

7. INCLUDE IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/OTHER NUMBER *(If number previously assigned)*

8. SERIAL NUMBER ASSIGNED TO APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES

CERTIFICATION STATEMENT / INFORMATION

9. CHECK ONLY ONE OF THE FOLLOWING BOXES *(See instructions for additional information and explanation)*

☒ A. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply because the application/submission which this certification accompanies does not reference any clinical trial.

☐ B. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply to any clinical trial referenced in the application/submission which this certification accompanies.

☐ C. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, apply to one or more of the clinical trials referenced in the application/submission which this certification accompanies and that those requirements have been met.

10. IF YOU CHECKED BOX C, IN NUMBER 9, PROVIDE THE NATIONAL CLINICAL TRIAL (NCT) NUMBER(S) FOR ANY "APPLICABLE CLINICAL TRIAL(S)," UNDER 42 U.S.C. § 282(j)(1)(A)(i), SECTION 402(j)(1)(A)(i) OF THE PUBLIC HEALTH SERVICE ACT, REFERENCED IN THE APPLICATION/ SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES *(Attach extra pages as necessary)*

NCT Number(s):

The undersigned declares, to the best of her/his knowledge, that this is an accurate, true, and complete submission of information. I understand that the failure to submit the certification required by 42 U.S.C. § 282(j)(5)(B), section 402(j)(5)(B) of the Public Health Service Act, and the knowing submission of a false certification under such section are prohibited acts under 21 U.S.C. § 331, section 301 of the Federal Food, Drug, and Cosmetic Act.
Warning: A willfully and knowingly false statement is a criminal offense, U.S. Code, title 18, section 1001.

11. SIGNATURE OF SPONSOR/APPLICANT/SUBMITTER OR AN AUTHORIZED REPRESENTATIVE (Sign)
Karen Kakunes

12. NAME AND TITLE OF THE PERSON WHO SIGNED IN NO. 11
(Name) Karen Kakunes
(Title) Sr. Regulatory Affairs Associate

13. ADDRESS *(Number, Street, State, and ZIP Code) (of person identified in Nos. 11 and 12)*
Ultradent Products, Inc.
505 West 10200 South
South Jordan, UT 84095 USA

14. TELEPHONE AND FAX NUMBERS *(Include Area Code)*
(Tel.) 801-553-4420
(Fax) 801-553-4609

15. DATE OF CERTIFICATION
Sep 26, 2012

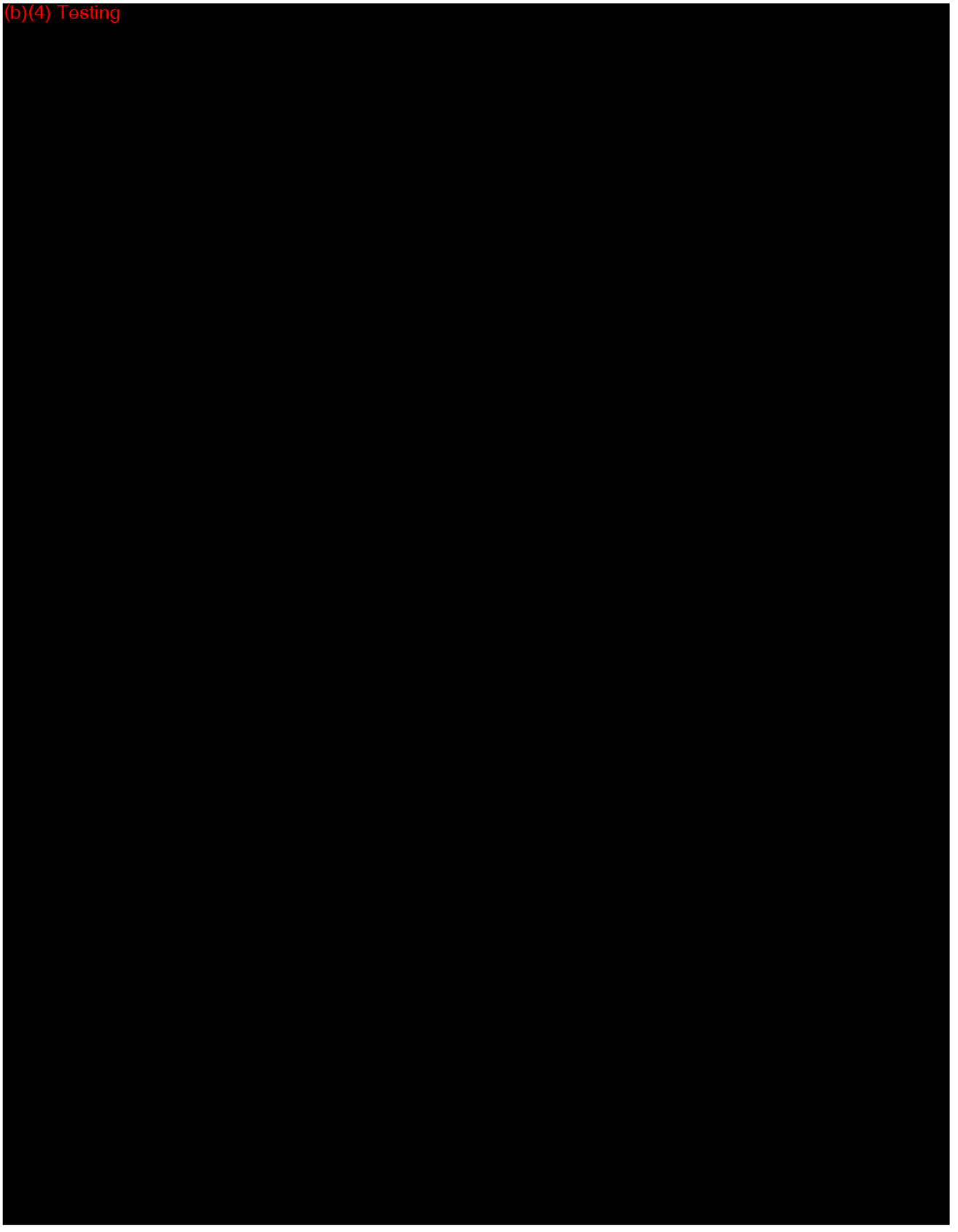
Form FDA 3674 (3/12) (FRONT)

PSC Publishing Services (301) 443-6740 EF

Section 9: Declarations of Conformity and Summary Reports

This is a traditional 510(k) submission, not an abbreviated 510(k); therefore, this section is not applicable.

(b)(4) Testing



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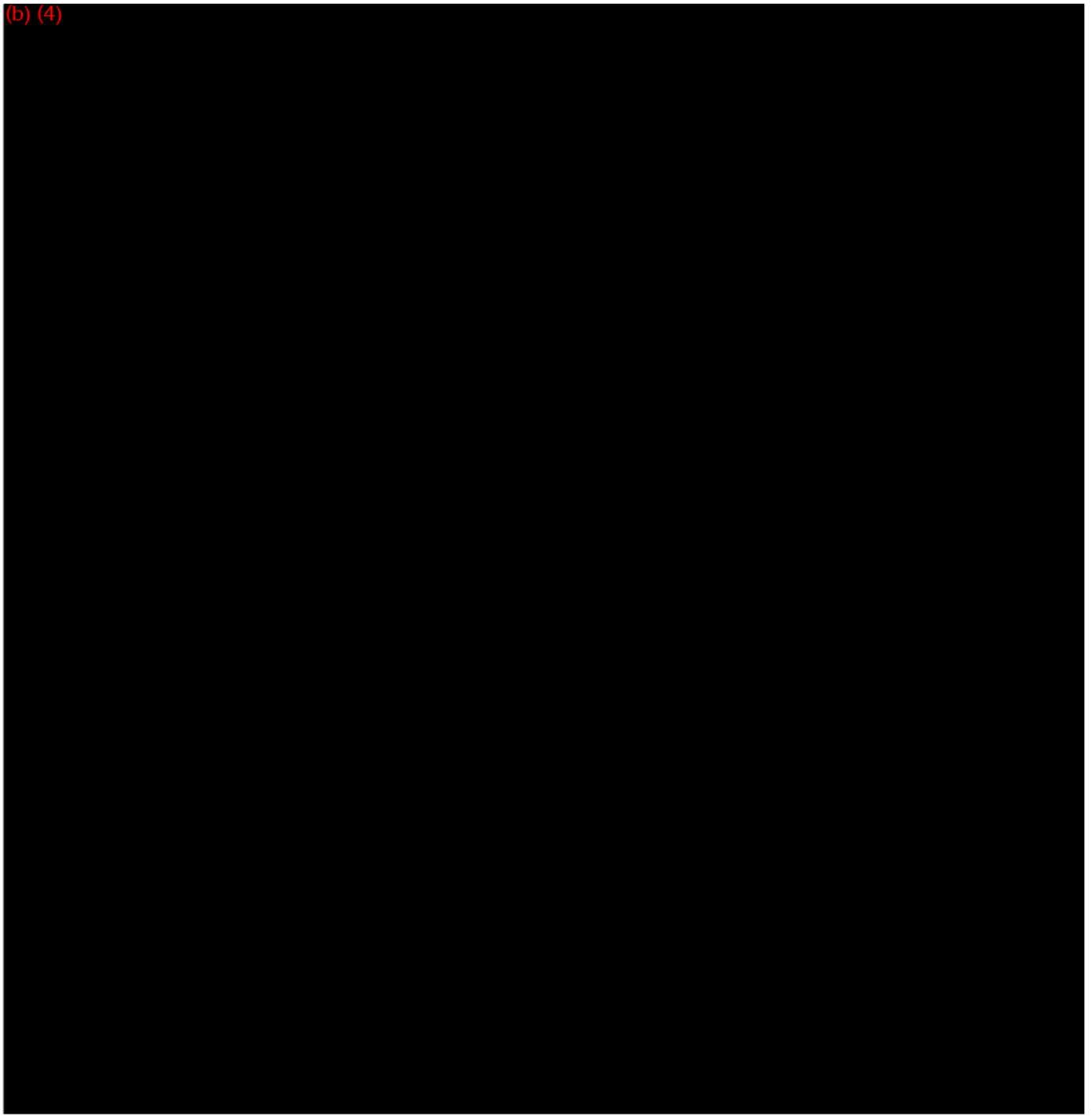

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(b) (4)

Section 12: Substantial Equivalence Discussion

Device Description ViscoStat Clear is a 25% Aluminum Chloride gel in a viscous, aqueous vehicle which leaves no residue or stain and makes it ideal for use in the esthetic zone.

Statement of intended use: ViscoStat Clear is intended for sulcus retraction prior to impression making and to control bleeding and gingival oozing in restorative and operative dentistry used with gingival retraction cord and/or the Dento Infusor. The gel facilitates the insertion of the cord into the sulcus.

Legally Marketed Predicate Devices to Which Equivalence is Claimed: The predicate device is Racegel (K093711), manufactured by Septodont 1050 Connecticut Ave., Nw, Washington, DC 20036.

Both ViscoStat Clear and the predicate, Racegel, are aluminum chloride based gels with similar characteristics and intended use, as indicated in Table 12-1. The shelf life of ViscoStat Clear is significantly longer; however, stability testing has been performed and data gathered to support the 42 month shelf life.

(b) (4)

(b) (4)

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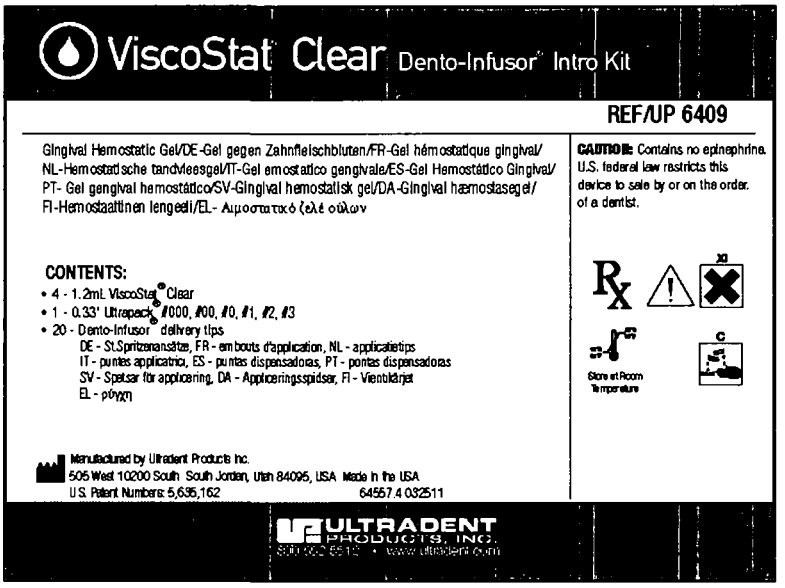
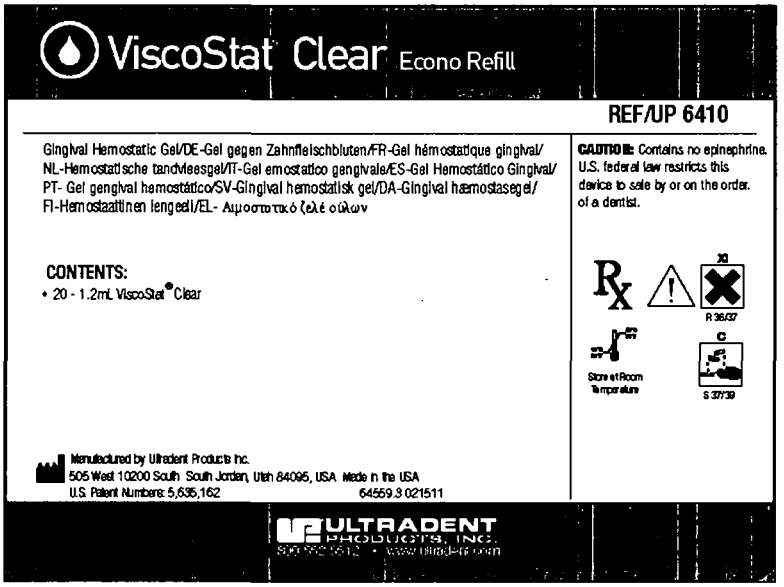
Section 13: Labeling

#6409 Dento-Infusor Kit Label:



#6410 Econo Refill Label:



(b) (4)

Instructions for Use:

ViscoStat Clear
25% Aluminum Chloride

Description

ViscoStat Clear is a 25% Aluminum Chloride gel in a viscous, aqueous vehicle which leaves no residue or stain and makes it ideal for use in the esthetic zone.

Indications

ViscoStat Clear is intended for sulcus retraction prior to impression making and to control bleeding and gingival oozing in restorative and operative dentistry used with gingival retraction cord and/or the Dento Infusor. The gel facilitates the insertion of the cord into the sulcus.

Directions for Use - General

1. For 1.2ml syringe
   a. Remove Luer cap.
   b. Securely attached working tip of choice (Metal Dento-Infusor or Blue Mini Dento-Infusor tip).
   c. Verify flow prior to applying intraorally.
2. For IndiSpense Syringe
   a. Remove Luer cap from Indispense syringe.
   b. Attach a 1.2ml syringe to the male threads of the IndiSpense syringe.
   c. Depress IndiSpense plunger while guiding 1.2ml syringe plunger to desired fill.
   d. Separate syringes and re-cap IndiSpense syringe.
   e. Securely attach working tip of choice (Metal Dento-Infusor or Blue Mini Dento-Infusor tip).
   f. Verify flow prior to applying intraorally.
3. Using a palm grasp, slowly express solution while rubbing against bleeding tissue. (Fig. X)

NOTE: To avoid cross contamination, use new syringes and tips for additional volumes.

NOTE: Recommended contact time for ViscoStat Clear is 1-3 minutes.

Directions for Use - Impressions

1. Follow "General" steps above.
2. Rub around the full circumference of the preparation expressing the solution into bleeding tissue surface to control bleeding.
3. When hemostasis is obtained, use a firm air/water spray to clean preparation. Check for hemostasis. If bleeding occurs, repeat step 2 above to bleeding area. Re-check with air/water spray until bleeding has stopped.
4. Displace tissue by packing size appropriate Ultrapak or displacement cord into sulcus. For optimum displacement and hemostasis, place a small amount of ViscoStat Clear in a dappen dish and soak cord prior to packing.
5. Wait 1-3 minutes before removing cord.
6. Remove cord, rinse with a firm air/water spray, check for hemostasis, and make impression.

Directions for Use – Direct and Indirect Bonded Restorations

1. Follow "General" steps above.
2. Lightly rub around the full circumference of the preparation expressing the solution into bleeding tissue surface to control bleeding.
3. When hemostasis is obtained, use a firm air/water spray to clean preparation. Check for hemostasis. If bleeding occurs, repeat step 2 above to bleeding area. Re-check with air/water spray until bleeding has stopped.
4. Soak Ultrapak or cord in ViscoStat Clear solution.
5. Gently pack size appropriate cord into sulcus.
6. Thoroughly rinse preparation and surrounding tissue using a firm air/water spray to clean and check for hemostasis and sulcular fluid control.
7. Scrub preparation surface with pumice or Ultradent's Consepsis Scrub.
8. Wait 1-3 minutes and remove cord. If using an unsoaked cord for tissue displacement, cord may be left in place during restorative procedure to protect soft tissue or may be removed.
9. Rinse again with a firm air/water spray and dry.
10. Apply bonding agent and restorative as per manufacturer's instructions.

CLEANSING NOTE: The tooth and surrounding tissue should be thoroughly cleaned and all residual hemostatic agent and coagulum removed to avoid contamination of the dentin and/or enamel substrate. Failure to do so may jeopardize the bond and seal causing microleakage. Temporary cements may also contaminate the surface causing microleakage and bonding failure.

Precautions and warnings:

1. For professional use only.
2. Carefully read and understand all instructions, precautions and warnings before use.
3. Do not use on patients with known allergies to aluminum chloride or chemical sensitivities.
4. ViscoStat Clear, temporary cements, mucins, and blood will prevent quality adhesion and polymerization/set of resins and will lead to microleakage under any restoration. Preparations must be thoroughly cleaned using a firm air/water spray and/or pumice or Consepsis scrub.
5. ViscoStat Clear must be thoroughly washed from the preparation site with a firm air/water spray to avoid reaction with polyether materials and thereby compromising the surface set of the impression.
6. When using self-etch bonding agents, the tooth/preparation surface must be scoured with pumice or Consepsis Scrub and thoroughly washed before application. This is not necessary when using a phosphoric etch bonding system or when using conventional glass ionomer, zinc phosphate, or similar cements.
7. Do not combine with other hemostatic agents or chemistries without first thoroughly cleansing tooth and surrounding tissue.
8. ViscoStat Clear is designed for intraoral use.
9. Verify flow of all syringes prior to applying intraorally. If resistance is met, replace tip and re-check.
10. Use only recommended tips.
11. Dispose of used tips and empty syringes properly.
12. To avoid cross contamination, do not re-use tips.
13. Do not use after expiration date noted on containers.
14. All syringe tips and empty syringes are disposable product and for single use only to avoid cross-contamination. Fill a new empty syringe with the amount of material needed for the individual patient. Dispose of syringe after use.
15. Prefilled syringes can be used several times, when protected during each use by syringe covers. Please note the instructions for use of the Syringe Covers. Re-cap syringe with the Luer Lock cap and disinfect syringe with an intermediate level disinfectant.

16. Do not allow product to be ingested.
17. Keep products out of direct heat/sunlight.
18. Use protective clothing and eye shield when loading and handling ViscoStat Clear.
19. Keep out of reach of children.

NOTE: For MSDS and additional information about using ViscoStat Clear or related products, please go to www.ultradent.com

(b) (4)

(b) (4)

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Section 14: Sterilization and Shelf Life

Sterilization: ViscoStat Clear is not a sterile or sterilizable product. Therefore, the sterilization section does not apply to this 510(k).

(b)(4) Testing

[redacted]

Section 15: Biocompatibility

(b)(4) Testing

[redacted]

(b) (4)

Section 16: Software

ViscoStat Clear, used for tissue management in dental procedures, contains no software, electrical components or any power source; therefore, this section is not applicable.

Section 17: Electromagnetic Compatibility/ Electrical Safety

ViscoStat Clear, used for tissue management in dental procedures, contains no software, electrical components or any power source; therefore, this section is not applicable.

Section 18: Performance Testing - Bench

(b)(4) Testing

[redacted]

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

Section 19: Performance Testing – Animal

No animal testing was conducted using ViscoStat Clear; therefore, this section is not applicable.

Section 20: Performance Testing – Clinical

ViscoStat Clear was tested against the identified predicate in comparison testing (reported in Section 18). No clinical testing was conducted for this 510(k) submission; therefore, this section is not applicable.

Appendix A : Clinical Literature

CLINICAL SUMMARY

Viscostat Clear

I. Introduction:

The following summary provides a documented review of clinical data collected with respect to the involved device as part of the conformity assessment procedure required by the Medical Device Directive (93/42/EEC), using the 'literature route.' The following clinical literature evaluation demonstrates safety and efficacy of the device, and provides a basis for clinical evaluation and assessment of the risk to benefit for the intended use and claims as required.

A. **General details:** Viscostat Clear is a 25% aluminum chloride material manufactured by Ultradent Products Inc.

B. **Description of the device and its intended application:** Viscostat Clear is a 25% Aluminum Chloride gel in a viscous, aqueous vehicle which leaves no residue or stain and makes it ideal for use in the esthetic zone. The product is contained within a 30mL or 1.2mL plastic syringe. The 30mL syringe is a bulk container and prior to application, will be dispensed into a provided, empty 1.2mL plastic syringe. Dento-Infusor application tips are used to apply the product to the prepared area.

C. **Intended use and/or diagnostic indications and claims:** Viscostat Clear is intended for sulcus retraction prior to impression making and to control bleeding and gingival oozing in restorative and operative dentistry used with gingival retraction cord and/or the Dento Infusor. The gel facilitates the insertion of the cord into the sulcus.

II. Evaluation Background:

The control of sulcular fluids and minor bleeding is often a problem for the clinician during dental procedures and endodontic surgery. Since the 1970's, aluminum chloride has been an accepted soft tissue management agent used to control both sulcular fluids and minor bleeding in the dental practice. Additionally, aluminum chloride is commonly used in gingival retraction because of its ability to cause contraction and shrinkage of tissue. It has been used in the dental industry for many years with successful results.

Tissue management and gingival retraction are integral elements in successful dental restorations. One of the keys to fabricating well-fitting crowns is the quality of the impression. Without a clean treatment field, the restoration may be unsuccessful or fail and cause the need for re-treatment. Agents, such as ViscoStat Clear, aid in the success of the restoration.

A documented review of clinical data has been collected, with respect to the involved device, as part of the conformity assessment procedure required by the Medical Device Directive (93/42/EEC). ViscoStat Clear contains no special design features that pose special performance or safety concerns, as documented in the Risk Analysis of this technical file. ViscoStat Clear does not incorporate new technology or new clinical applications. The clinical data used to support the safety and efficacy of the product is based off of similar devices with nearly identical or similar clinical applications and indications for use. The predicate for Viscosat Clear, Racegel, as manufactured by Septodont, was researched via PubMed and Google search engine. Due to the minimum amount of literature available, 25% aluminum chloride in dental applications was used as a general search. Current articles that also used Expa-syl, an aluminum chloride paste currently approved and released on the market, were also used because of the relevance to the safety and efficacy of its active ingredient and not necessarily the mode of application. Each of the articles relevant has been chosen because of the use of aluminum chloride as its active ingredient.

Table Viscostat Clear: Substantial equivalence comparison among similar devices on market:

This table is an illustration of similarities of the competitive product found in the literature search to Viscostat Clear. This will show that the articles found do represent Viscostat Clear and its safety and efficacy in patient use.

Characteristic	Comparison Product (Racegel™ K093711)	Comparison Product (Expa-syl K050180)	Viscostat Clear
Intended Use	Racegel is a gel containing aluminum chloride which is intended for sulcus retraction prior to impression taking; control of bleeding and gingival oozing, particularly in restorative dentistry; and, if using a gingival retraction cord, the gel facilitates the insertion of the cord into the sulcus	Expa-syl is a paste containing aluminum chloride which is intended to be used for the temporary retraction and hemostasis of the gingival margin during dental procedures such as, but not limited to, dental impressions, seating of temporary and permanent restorations, restorations of cavities and placement of rubber dam.	Viscostat Clear is intended for sulcus retraction prior to impression making and to control bleeding and gingival oozing in restorative and operative dentistry used with gingival retraction cord and/or the Dento Infusor. The gel facilitates the insertion of the cord into the sulcus.
Intended user	Dental professional	Dental professional	Dental professional

Chemical characteristics	Aluminum chloride gel	Aluminum chloride paste	Aluminum chloride gel
Recommended contact time	2 minutes	1-2 minutes	1-3 minutes
Delivery system	Pre-filled syringe with applicator tip	Pre-filled plastic cartridge with applicator	1.2ml pre-filled syringe with applicator tip, 30ml Indispense syringe with 1.2ml empty syringe and applicator tip
Physical properties	Orange, odorless gel 24 month shelf life	Blue paste	Clear gel 42 month shelf life
Biocompatibility	Acute oral toxicity Sensitization Oral Mucosa Irritation Cytotoxicity	Unknown	Cytotoxicity

III. Summary of Clinical Literature Evaluation:

Eight keyword searches were performed on PubMed or via Google to obtain articles relevant to Viscostat Clear and the safety and efficacy of aluminum chloride when used in dental applications. However, due to the lack of published material in regards to Viscostat Clear, the search was expanded to include similar product that contain aluminum chloride and aluminum chloride dental applications so that relevant safety and efficacy issues are addressed as appropriate:

"Retraction cord with Aluminum Chloride 25%" via Google Sep 2012:

Two articles were chosen from the search results for credit to the use of retraction cords with 25% Aluminum Chloride. One of the articles was excluded because it was retrieved in a previous search and included in the summary.

"Aluminum Chloride" AND "In-Vitro" AND "Dental" via PubMed Aug 2012:

This search returned six articles, of which one was found not to be relevant as it discusses the concern of bond strengths. The remaining five articles were omitted because they did not discuss the safety and efficacy of aluminum chloride or there was a different system of mechanism for aluminum chloride.

"Aluminum Chloride" AND "Hemostasis" via PubMed Aug 2012:

This search returned three articles, of which one was considered to be relevant to the safety and effectiveness of Viscostat Clear. The remaining two articles were

excluded because they did not pertain to the use of aluminum chloride in a dental application and instead focused on other medical procedures.

"Aluminum Chloride" AND "Efficacy" AND "Bleeding" via PubMed Aug 2012:

This search returned two articles, of which one was considered to be relevant. This article; however, was a duplicate to a previous search. The other article was not within the scope of use for aluminum chloride and was excluded.

"25% Aluminum Chloride" AND "Dental" via PubMed Aug 2012:

Two articles were returned with this search. Both articles were considered relevant and included in the summary.

"Folia Biologica" AND "Nowakowska" via PubMed Single Citation Search Aug 2012.

Two articles were retrieved and one was considered relevant. The other article was excluded because the study did not include Aluminum Chloride in the materials being studied.

"Aluminum Chloride" AND "Dental" and "Efficacy" via Google Aug 2012:

Five articles were chosen from the search results that were considered to be relevant to the safety and efficacy of Viscostat Clear.

"Hemostatics" and "ADA" via Google Aug 2012:

One publication was desired and retrieved in this search. The target was to access the ADA guidelines for Dental Hemostatics and all other articles were excluded.

"(Hemostatics" [Mesh] OR "Hemostatics [Pharmacological Action] OR "Hemostatic Techniques [Mesh])" AND "Dental" AND "Impression" via PubMed Sep. 2010:

This search returned thirty-eight articles. Seven articles were selected to be relevant. Articles excluded were omitted because they were over 10 years old. One article that was published in 1998 was chosen because of its relevance to Ultradent Products, Inc. The remaining articles were excluded because they did not pertain to hemostatics, the safety and efficacy of hemostatic, or they were not available in English.

"Aluminum Chloride" AND "Dental" AND "Hemostat" via PubMed Sep. 2010:

This search returned eight articles, of which three were considered to be relevant to the safety and effectiveness of the product. Articles excluded were omitted for the

following reasons: duplicate articles retrieved from the previous search, no reference to Aluminum Chloride, or no relevance to the safety or efficacy of aluminum chloride solution.

III. Safety Literature:

A. *In Vivo* Studies

1. KQ Al Hamad, et al. A clinical study on the effects of cordless and conventional retraction techniques on the gingival and periodontal health. J Clin Periodontal 2008; 35:1053-1058.
AIM: To investigate the influence of two cordless techniques on the periodontium in comparison with conventional cords. MATERIALS and METHODS: Dental students (n=60 with healthy gingival conditions were recruited – an expanding poly vinyl siloxane material (Magic Foam Cord®), a paste-like material (Expasyl®), and a conventional retraction cord (Ultrapak®) were applied on the buccal aspects of three premolars of each subject. Probing depth, clinical attachment level, gingival index, mobility, bleeding, and sensitivity were assessed at baseline, and at 1 and 7 days after application. Data were analyzed using Kruskal-Wallis and Mann-Whittney tests ($\alpha = 0.05$). RESULTS: The periodontal parameters were not statistically significant among the groups at all time intervals except for the GI, which was increased for all groups after 1 day. The highest was Expasyl ($p=0.011$). After 7 days, the GI returned to a non-significant level compared with baseline except for Expasyl, which was still significant ($p=0.044$). Expasyl induced sensitivity in four subjects. Bleeding was only induced by Ultrapak in 28.3% and 26.7% during and after retraction, respectively. CONCLUSIONS: All techniques caused a temporary gingival inflammation; the greatest was in Expasyl, which also showed slower recovery. Cordless techniques did not induce bleeding during or after retraction.

2. Arx T von, et al. Hemostatic agents used in periradicular surgery: an experimental study of their efficacy and tissue reactions. International Endodontic Journal 2006;39:800-808.

AIM: To evaluate the hemostatic efficacy and the histologic tissue responses after the application of different hemostatic agents used in periradicular surgery. METHODOLOGY: The study was conducted in the calvarium of six rabbits. Standardized bone defects (diameter 4 mm) were tephined, and different hemostatic agents were applied and compared with control defects: bone wax (left for 10 min), Stasis® (ferric sulphate, left for 5 s), Expasyl™ (aluminum chloride, left for 2 min and left permanently *in situ*), and a combination of Expasyl™ and Stasis® (5s). The sites were photographed before the application and after the removal of the hemostatic agents. Three independent examiners judged the initial and final bleeding (on the photographs) using a bleeding score for each site and treatment. The results were compared using Wilcoxon's signed rank test. For the histologic analysis, three animals were killed after 3 weeks and three animals after 12 weeks. Transverse, nondecalcified sections were stained with combined basic fuchsin and toluidine blue for descriptive histology.

RESULTS: The most efficient hemorrhage control was by Expasyl™ alone, whereas bone wax had the weakest bleeding reduction effect. The histologic analysis after 3 weeks demonstrated an inflammatory and foreign body tissue response towards all hemostatic agents. At 12 weeks, this tissue response was less pronounced but still present in sites treated with bone wax or Expasyl™. In general, the inflammatory tissue reactions were limited to the bone defects, and never extended into the surrounding tissues. CONCLUSIONS: Expasyl™ alone or in combination with Stasis® appeared to be the most efficient of tested agents to control the bleeding within the bony defects created in rabbit calvarium model.

3. Kopac I, et al. Gingival Inflammatory Response Induced by Chemical Retraction Agents in Beagle Dogs. Int J Prosthodont 2002;15:14-19.

PURPOSE: The aim of this in vivo study on dogs was to investigate and compare the inflammatory potential of four different retraction agents on the gingival connective tissue. MATERIALS and METHODS: All procedures on eight beagle dogs were performed under general anesthesia; taking oral hygiene measures, placing retraction cords medicated with four chemical agents into the gingival sulci, and taking tissue biopsies. The specimens were evaluated after a 10-minute exposure to chemical agents. The inflammatory response of the connective tissue underlying the sulcular and junctional epithelium triggered by retraction agents was assessed quantitatively. Microscopic images of tissue specimens were morphometrically analyzed using a computer-assisted morphometric method. RESULTS: The most intense inflammatory response in the connective tissue underlying the sulcular epithelium was triggered by astringent retraction agents – Racestyptine in specimens taken after 1 day and 1 week and rastringent after 1 day (P<.05). Tetrahydrozoline-sympathomimetic vasoconstrictor (Visine) was found to have the lowest inflammatory potential. Retraction chemicals produced no significant effects on the connective tissue subjacent to the junctional epithelium. The ratio of the connective tissue area to that of the inflammatory infiltrate showed that 25% aluminum chloride (Racestyptine) was the most aggressive and tetrahydrozoline the least aggressive retraction agent used. CONCLUSION: All the retraction chemicals tested increased the infiltration with inflammatory cells in the gingival connective tissue.

B. *In Vitro* Studies

4. Kopac I, et al. Electron microscopic analysis of the effects of chemical retraction agents in cultured rat keratinocytes. J Prosthet Dent 2002;87:51-6.

Chemical retraction agents used in fixed prosthodontics for temporary displacement of free gingival tissue before impression making can cause injury to the gingival tissue cells. PURPOSE: This study evaluated changes in cultured rat keratinocytes treated with 2 chemical agents used for gingival retraction. Treated cultures were compared with untreated cultures. MATERIAL and METHODS: Keratinocytes of rat gingiva were grown

in a specific medium for 10 days. After treating 1 group of specimens with 0.05% tetrahydozoline and another group with 25% aluminum chloride, both for 10 minutes, the cultured cells were examined with scanning and transmission electron microscopy and compared with control specimens. RESULTS: Twenty-five percent aluminum chloride produced a significantly greater extent of cellular damage than 0.05% tetrahydrozoline, which caused only mild changes in the cultured cells. CONCLUSION: On the basis of the morphologic and ultrastructural changes in primary cell cultures of rat keratinocytes observed in this study, it was concluded that 25% aluminum chloride was significantly more aggressive than 0.05% tetrahydrozoline.

5. Nowakowska E, et al. Dynamic Oxidoreductive Potential of Astringent Retraction Agents. Folia Biologica. 2010;56(6):263-8.

   ABSTRACT: The aim of this study was to evaluate the dynamics of the cytotoxicity of gingival margin retraction astringents based on aluminum chloride, aluminum sulphate, and ferric sulphate (solutions and gels) in human fibroblasts isolated from the gingiva. The cytocompatibility of ten astringent-based chemical retraction agents: Gingiva Liquid, Alustin, Racestypine, Orbat sensitive, Astringedent®, Alustat, Hemostat, Racecord, Gelcord and Viscostat®, in dilutions of 1:10 and 1:20, with human gingival fibroblasts was investigated. The MTT assay was performed to determine oxidoreductive mitochondrial function after 3, 5, 10 min and 24 h of incubation. Cell viability was determined according to the chemical group, concentration, exposure time, and the clinical form of the gingival retraction agents. Ferric sulphate-based agents were the most cytotoxic, followed by aluminum chloride and aluminum sulphate. The form of the astringents influenced cell viability. The evaluated astringents may have cytotoxic potential for gingival margin tissues under clinical conditions.

C. Review Articles

6. Donovan T, et al. Current concepts in gingival displacement. Dent Clin N Am 2004;48:434-444.

   SUMMARY: Gingival displacements an important procedure with fabricating indirect restorations. Gingival displacement is relatively simple and effective when dealing with healthy gingival tissues and when margins are properly placed a short distance into the sulcus.
   The most common technique used with gingival displacement is use of gingival retraction cords with hemostatic medicament. Retraction cords of sufficient diameter should be used to provide adequate lateral displacement to create a mean sulcular width of 0.2mm. Epinephrine containing retraction cords should be avoided.
   Several techniques have proven to be relatively predictable, safe, and efficacious. No scientific evidence has established the superiority of one technique over the others, so the choice of technique depends on the presenting clinical situation and operator preference.

V. **Efficacy Literature:**

A. *In Vivo* Studies

7. Elledge, D. Effective Hemostasis and Tissue Management. Dent Today. 2010;29(10):150,152-3.

INTRODUCTION: A common clinical challenge dentists face with restorative procedures is blood contamination. There are a variety of reasons that the gingiva can bleed, including from plaque, trauma, and/or an encroached biologic width. Plaque causes gingivitis, caries, and periodontitis. Trauma that happens during the restorative procedure can cause bleeding. Wedges can press laterally and aggressively against the gingival papilla, and metal or plastic matrix bands' sharp edges can cut healthy/inflamed tissue during the isolation of the cavity. Burs are used to excise the caries, excise inflammatory tissue, and widen the gingival sulcus. Cords are packed to deflect or retract the gingiva in attempt to expose the cavity margin. Any of these events can result in blood contaminating the restorative field, thus negatively affecting impressions, cavity preparation, restorative materials, and cementation.
There is an association between restorative care and periodontal health. An encroachment of the biologic width happens when the restorative margins are placed too deep within the sulcus. Inadequate restorations can have ledges or areas that are not cleansable, which can contribute to plaque accumulation. Adolescents and geriatrics alike can have poor oral hygiene. New restorations are often needed because plaque control has been compromised. In addition, a high-carbohydrate (sugary, carbonated beverages) and nutrient-poor (refined foods) diet is a primary contributing factor in the patient examples presented in this article.
With case examples, this article will demonstrate how one can improve the quality of one's indirect restorative work by changing his or her technique protocol (system) to effectively control bleeding and manage the soft tissues.

8. Phatale S, et al. Effect of retraction materials on gingival health: A histopathological study. J Indian Soc Periodontal. 2010; 14(10):35-39. As taken from www.ncbi.hlm.nih.gov on August 21, 2012.
http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2933527/

BACKGROUND: Gingival retraction methods are used in dentistry for impressions of subgingival crown margins, such as, mechanical, chemical, chemicomechanical, and surgical. These methods may injure the gingival sulcular epithelium. Hence, the present study is carried out to evaluate the effect of different retraction materials, such as Expasyl, Magic Foam Cord, and impregnated retraction cord on the gingival sulcular

epithelium. MATERIALS and METHODS: This study included 30 cases of bilateral premolar extraction patients with Loe and Silness gingival index zero. Retraction materials were kept in the dry, isolated labial gingival sulcus for the required time. The retraction materials were removed by rinsing with water. Retracted gingiva of 2 – 3 mm from the gingival margin along with the tooth was extracted and the decalcified sections were microscopically studied. Data analysis: Data were analyzed by applying the chi-square test. RESULTS: This study showed better results with retraction paste as compared to the retraction cord, and there was a significant association between retraction materials and the relative degree of injury to the sulcular epithelium. CONCLUSION: There is a significant association between retraction materials and gingival sulcular epithelium. It can be stated that impregnated retraction cord, may be used commonly but it need proper tissue manipulation and is technique sensitive. Newly advanced material in the form of retraction paste like Expasyl or Magic Foam Cord was found to be better than cord as assessed histologically, it respects periodontium.

B. *In Vitro* Studies

9. Harnirattisai C, et al. Bond Strengths of Resin Cements to Astringent-contaminated Dentin. Operative Dentistry, 2009, 34-4, 415-422.

   SUMMARY: The current study evaluated the micro-shear bond strength of two resin cements to astringent-contaminated dentin. Twelve occlusal dentin discs were prepared from extracted caries-free human molars and divided into two groups subjected to two types of resin cements, Panavia F (PF) and Variolink II (VL). Each disc was ground 600 grit SiC paper and sectioned into two semi-discs, one for the normal dentin surface and the other for the contaminated dentin surface. For contaminated dentin, an astringent containing aluminum chloride was applied for two minutes and rinsed before the bonding procedures. A micro tygon tube was placed on the dentin surface following the bonding application and then filled with a resin cement. After the resin was polymerized, the specimen was kept in water for 24 hours before the micro-shear bond strengths evaluation. The micro morphology of the treated surfaces and resin-dentin interfaces were observed under a scanning electron microscope (SEM). Aluminum content under different dentin conditions was also examined. No significant differences were found between the dentin bond strengths to normal dentin and contaminated dentin surfaces in both the PF and VL groups ($p>0.05$). PF showed similar bond strengths to VL on normal and contaminated dentin ($p>0.05$). SEM observations of the VL groups revealed no differences in the treated dentin surfaces and the resin-dentin interfaces between normal and contaminated dentin. However, for the PF group, an inconsistent etching pattern of the self-etching primer and gap formation at the interface of resin cement to contaminated dentin were observed.

10. Kuphasuk W, et al. Bond Strengths of Two Adhesive Systems to Dentin Contaminated with a Hemostatic Agent. Operative Dentistry, 2007, 32-4, 399-405.

RP019.1

SUMMARY: This study evaluated the bond strength of a total-etch and a self-etch adhesive to dentin contaminated with a hemostatic agent containing aluminum chloride ($AlCl_3$). Eighteen occlusal dentin discs were prepared from human molars. Each disc was ground and sectioned into two halves, one for normal dentin and the other for contaminated dentin. The specimens of both normal and contaminated dentin were randomly divided into three groups and treated with the following materials: 1) Excite (EX); 2) Clearfil SE Bond with 20-second primer application time (DB-20) and 3) Clearfil Se Bond with 40-second primer application time (CB 40). The microshear bond strength specimens were prepared using the resin composite Clearfil APX. The bond strengths were evaluated on a universal testing machine. Statistical analysis was performed at α=0.05. The surface micromorphology and aluminum content of the different dentin conditions were also examined. In EX, no significant difference was found between the bond strengths of normal dentin and contaminated dentin. The bond strength of CB20 to contaminated dentin was significantly lower than that to normal dentin. The extension of primer application time from 20 to 40 seconds significantly increased the bond strength of CB to contaminated dentin.

11. O'Mahony A, et al. Effect of 3 medicaments on the dimensional accuracy and surface detail reproduction of polyvinyl siloxane impressions. Quintessence Int 2000;31:201-206.
OBJECTIVE: The purpose of this study was to determine the effect of retraction cord medicaments (aluminum chloride, ferric sulfate, and ferric subsulfate/sulfate) on the dimensional accuracy and surface detail reproduction of polyvinyl siloxane impressions. METHOD and MATERIALS: Polyvinyl siloxane impressions were made of standardized metal dies (American Dental Associate [ADA] specification No. 19) treated with 1 of the 3 retraction cord medicaments. Dimensional accuracy was evaluated by comparing the average length of a line in the impressions to the standard die. Surface detail reproduction was evaluated by viewing the impressions under low-angle illumination at x10 magnification. Reproduction was considered satisfactory if 2 of 3 horizontal lines were reproduced continuously. The dies were also evaluated under the microscope before the impression was made. RESULTS: The medicaments did not significantly effect the dimensional accuracy; mean shrinkage was within ADA guidelines in the treatment groups. All of the medicaments had an adverse effect on surface detail reproduction. These effects were statistically significant compared to the untreated control. CONCLUSION: Although the changes in dimensional accuracy were within ADA guidelines, the surface detail reproduction was modified such that the impression would be considered clinically unacceptable. For optimal results, care must be taken to remove all traces of these retraction cord medicaments prior to recording polyvinyl siloxane impression.

12. Land M, et al. Smear layer instability caused by hemostatic agents. J Prosthoet Dent. 1996 Nov;76(5):477-82.

The effect of hemostatic agents, other than a 15.5% $Fe_2(SO_4)_3$ solution, on prepared tooth structure is unknown. The purpose of this study was to (1) compare the effect of six commonly used hemostatic solution and two nondental astringents on the dentinal smear layer and (2) determine whether different responses caused by product and/or time could be established. Standardized dentinal smear layers were exposed to eight astringent solutions for 30, 120, and 300 seconds (n=6). A total of 144 SEM photographs at x2400 magnification were ranked according to predetermined criteria for five categories of smear layer removal and etching of underlying tooth structure. There were significant differences ($p<0.001$) caused by the solution, exposure time, and their interaction. Greatest smear layer removal was observed with 21.3% $AlCl_3$-6 hydrate, 8% racemic epinephrine HCl, and 15.5% $Fe_2(SO_4)_3$ solutions at longer exposures. These caused significantly more removal than did almost pH neutral tetrahydrozoline or oxymetazoline ($p<0.05$).

C. Review Studies

13. Mohan M, et al. Pharmacological Agents in Dentistry: A Review. British Journal of Pharmaceutical Research. 2011;1(3):66-87. As taken on August 14, 2012 from http://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=11&ved=0CGIQFjAAOAo&url=http%3A%2F%2Fwww.sciencedomain.org%2Fdownload.php%3Ff%3D1307275882-Published_Parolia_2011BJPR272.pdf&ei=Y74qUNKHLom9igKIuYGAAg&usg=AFQjCNFJ0j1VaTkw-sfW4HCTXB1zm4TJew&sig2=uoKKw41oEv5dyy2fZRIRfg.

    ABSTRACT: All clinicians should be fully aware of the recent trends in their specialty to enable them to provide effective and successful treatment to their patients. One vital aspect of the treatment is that the clinician should constantly update his knowledge on the drugs being administered during the course of treatment and their interactions. The purpose of this article is to review the current pharmacological agents being used in Prosthodontics along with their interactions and indications. This paper mainly focuses on Therapeutic drugs and drugs that aid in prosthodontics treatment. Therapeutic drugs include local anesthetics, antiseptics, steroids, analgesics, antimicrobials, antifungals, antianxiety drugs, centrally acting muscle relaxants. Drugs that aid in prosthodontics treatment include astringents, vasoconstrictors, hemostatic agents, sialogogues, anti-sialogogues, denture cleansers, gum paints, denture adhesives, ORAL protective agents and demulcents. An ondontologist should have sound knowledge of the benefits and drawbacks of all these agents. This will enable the clinician to provide a safe and predictable treatment to the patients.

14. Radz G. Soft-Tissue Management. The key to the perfect impression. Compend Contin Educ Dent. 2010 Jul-Aug;31(6):463-5.

    In the ideal world, excellent soft-tissue health would be a pre-requisite for predictable impressions. Inflamed tissues will bleed more readily and exhibit increased crevicular

fluid flow, rendering moisture control more difficult. Despite having less than ideal conditions, the capture of an excellent impression is still possible. The use of a retraction cord is the first line of defense to control fluid flow. When placed in the gingival sulcus, the retraction cord will physically block crevicular fluids from the preparation margin. Most commonly, bleeding is managed chemically. Ferric sulfate, aluminum chloride, and epinephrine are the most common options. These materials will cause constriction of peripheral blood vessels, resulting in a transient shrinkage of the surrounding tissues. Aluminum chloride, while not quite as effective as ferric sulfate, is a popular option for controlling localized bleeding. Its benefit is that no dark residue remains on the restoration. This makes aluminum chloride the chemical of choice when the final restoration is made of an all-ceramic or indirect composite material.

15. Strassler H. Tissue Management, Gingival Retraction and Hemostasis. Benco Dental ADA/CERP. 2009-2013. As taken on August 14, 2012 from http://d3e9u3gw8odyw8.cloudfront.net/ie2_ce_tissue_management.pdf.

    CONCLUSION: There are a variety of techniques and materials that allow the clinician to manage the gingival tissues during restoration and when making an impression. These include gingival retractions cords, chemical reagents, electrosurgery, laser tissue sculpting, copper tube impressions, hydraulic impressions and non-invasive, atraumatic displacement/hemostatic materials. In most cases, gingival retraction cord is the most effective method for retracting tissue to the depth of the sulcus. The other methods have their advantages and indications. In any case, the control of the soft tissue for exposing the margins of the tooth preparation for restoration and impressioning is critical. It would be worthwhile for the clinician to understand all the choices available.

16. Boghosian A. Clinical and Material Factors in Achieving the Ideal Impression. PennWell ADA/CERP. 2008. As taken on August 14, 2012 from http://www.ineedce.com/courses/1424/PDF/ClinicalandMaterialFactors.pdf.

    ABSTRACT: Clinicians report that the impression-taking process is the most stressful restorative procedure. Key factors involved in producing clinically acceptable impressions include managing soft tissue, appropriately selecting tray and impression material, and enabling impression material to flow predictably. Managing soft tissue is the most critical step in obtaining a perfect impression. Tray selection also plays a significant role with tray choice depending on the clinical situation and on the impression material and technique used. The most commonly used elastomeric impression materials are polyether (PE) and vinyl polysiloxane (VPS) chemistries. Appropriate use of either will produce a clinically accurate impression. The material must have an adequate working time and flowability, and have sufficient tear strength to prevent tearing at thin areas at the margin. Using a hydrophilic impression material and a surface modifier will permit enhanced flow and result in a more accurate and detailed impression. In addition, the impression must be dimensionally stable for a

reasonable time until it is cast. Achieving clinically acceptable impressions requires clinical expertise and appropriate materials, trays, and techniques.

17. Poss, S. Minimally Invasive tissue Management for Restorative Procedures. PennWell ADA/CERP. www ineedce.com. 2007. As taken from on August 14, 2012. http://www.kerrdental.com/index/cms-filesystem-action?file=KerrDental-Products-Articles/poss-minimallyinvasive-ce.pdf

ABSTRACT: The clinical success and longevity of restorations depend on a number of factors, including the initial accuracy of the restoration. Factors attributed to restoration accuracy have included the degree of clinical expertise; properties of impressions, stone and die, and restorative materials; and the conditions under which impressions are taken and restorations completed. When restorations are placed with sub-gingival margins, it is essential that the operative site is clear of debris, dry and that the margins are accessible. This requires gingival retraction, which can be carried out using a number of methods, including retraction cord, copper bands, rubber dams, electrosurgery, and lasers, as well as polymers and pastes. Selection of the appropriate method depends on clinical demands and preferences, the individual patient, and consideration of the potential advantages and disadvantages. Ideally, gingival retraction should be quick, user-friendly, patient friendly, painless, and inexpensive. The use of modern techniques and materials has made possible minimally-invasive and tissue-friendly gingival retraction that preserves periodontal health while enabling clear, dry access to sub-gingival margins.

18. Belozerskaya GG, et al. Local Hemostatics (A Review). Pharmaceutical Chemistry Journal 2006;40(7):353-359.

This review is intended to generalize data concerning the use of drugs with various structures and mechanisms of action, as well as their combinations for the arrest of local bleeding. Local hemostatics can be, albeit quite conditionally, classified into the following groups: (1) Agents producing vasoconstrictive and proaggregant effects; (2) Compounds inducing the transition of blood proteins into solid state and reducing vessel permeability by means of protein denaturation; (3) Compounds stimulating the aggregation and adhesion of formed elements and accelerating fibrin formation; (4) Plasma coagulation factors; (5) Fibrinolysis inhibitors; (6) Combined preparations. The international pharmaceutical market offers a number of mineral hemostatics, which are widely used in dentistry for the arrest of bleeding, including rasestiptin or septodont (containing aluminum chloride and hydroxyquinoline sulfate), imodent (containing 21.3% aluminum chloride) rastrigent (25% aluminum sulfate solution), and stasis (aqueous iron sulfate solution).

To summarize, there are many single-component and combined preparations possessing hemostatic activity and intended for local application. All such products have certain limitations and are intended for use in various clinical conditions. The

specific pharmacological activity was tested under various conditions (in patients with different experimental models, and in various organs and tissues). We believe that, along with the developmental of new products, it would be expedient to perform comparative evaluation of various local hemostatics under identical experimental model conditions. Such comparative tests would provide useful information concerning the character of action of the existing preparations and indicate the promising directions of further search for effective local hemostatics.

19. Stewardson D. Trends in Indirect Dentistry: 5. Impression Materials and techniques. Dent Update. 2005 Sep;35(7):374-6, 379-80, 382-4 passim.

    ABSTRACT: A fundamental pre-requisite for the construction of satisfactory indirect restorations is the ability to record an accurate and detailed impression of the dental structures. Knowledge of the key properties of the available impression materials and their handling behavior is necessary if they are to be used effectively. A variety of techniques can be employed in different situations, each of which can be highly successful, but only if attention is paid to the detail of their execution and the clinician is aware of their individual limitations and pitfalls. Where imperfections occur, an appreciation of how they have been caused, and the strategies to take to prevent them, will lead to greater success in impression taking.

20. Poss S. An Innovative Tissue-Retraction Material. Compendium. 2002 Jan;23(1):13-17.

    ABSTRACT: One of the most challenging problems of fixed prosthodontics is tissue control. Gingival retraction before a final impression can be very frustrating and time consuming. Many different techniques have been developed over the years to accommodate the clinician's struggle to obtain tissue control and achieve an ideal impression. This article discusses several of those techniques and how the new, innovative product Expa-syl™ can be incorporated into these techniques. Expa-syl™ is an injectable retraction and hemostatic agent that can cause little trauma to the tissue as well as save the dentist time and money. The author elaborates on the multiple uses of Expa-syl™ and the correct techniques for making this material a successful took in any dental office.

21. Ch. 5. Hemostatics, astringents and gingival retraction products. ADA guide to dental therapeutics / American Dental Association. Chicago, Ill. : ADA Pub., c2003

    This publication summarizes different bleeding disorders and different types of hemostatics and astringents used in the dental office to control bleeding. As noted throughout, "An understanding of hemostasis, identification of patients with excessive bleeding tendencies, and interventions to stop abnormal bleeding is essential to the provision of safe and appropriate dental care. For slow blood flow and oozing, a combination of hemostatics can be used. The three kinds of hemostatics to be noted here are absorbable hemostatic agents, agents that modify blood coagulation and

vasoconstrictors. Aluminum chloride is an astringent that causes contraction or shrinkage of tissues, making it useful in retracting gingival tissue. It also reduces secretions and minor hemorrhage."

22. Fischer D. Tissue Management Needs for Adhesive Dentistry Now and in the Future. Esthetic Dentistry. 1998;42(4):595-605.

    This article discusses dental impressions, direct restorative dentistry, and the current and future needs for tissue management. Hemostasis and other tissue control are important for proper impression making. A bonding procedure should never be performed in the presence of blood, and with astringent hemostatics such as alum, aluminum chloride and ferric sulfate, there is seldom a need for bonding procedures to be compromised.

23. Strassler H, et al. Tissue Management, Gingival Retraction and Hemostasis. www.oralhealthgroup.com. 2007. Retrieved 26 Sep 2012 from http://www.oralhealthgroup.com/news/tissue-management-gingival-retraction-and-hemostasis/1000519731/.

    One of the most challenging aspects of crown and bridge is management of the gingival tissues when making an impression. Tissue management includes placing the gingival tissues away from the preparation margins so they can be impressed combined with proving for hemostasis when the gingival tissues are susceptible to bleeding. The rationale for tissue management is a critical aspect of impression making whether the impression is made with a conventional impression material or by a digital impression technique so that all tooth preparation margins are captured in the impression to assure an excellent marginal fit of a laboratory fabricated restoration.

24. Thomas M, et al. Nonsurgical Gingival Displacement in Restorative Dentistry. Compendium of Continuing Education in Dentistry. June 2011. As taken from www.cdeworld.com on 26 Sep 2012. http://www.cdeworld.com/courses/4521-nonsurgical-gingival-displacement-in-restorative-dentistry.

    ABSTRACT: Gingival displacement is critical for obtaining accurate impressions for the fabrication of fixed restorations, especially when the finish line is at or just within the gingival sulcus. Displacement of the gingival tissue is also important when dealing with the restoration of cervical lesions due to their proximity to the periodontal tissue. The methods of gingival tissue displacement can be broadly classified as nonsurgical and surgical techniques, with nonsurgical being the more commonly practiced method. Dentists must alter their armamentarium and gingival displacement techniques to meet specific demands and obtain predictable results. Hence, the purpose of this article is to describe the different means by which nonsurgical gingival displacement can be achieved effectively under a variety of clinical situations.

VI. Literature Summary

A. Efficacy:

Aluminum Chloride has been used to control bleeding and sulcular fluids during dental procedures for over twenty-five years. Current, available literature provides evidence of its reliability as an effective material in retracting gingival tissue and reducing secretions and minor bleeding (7,13,16,18,20,21) with multiple articles discussing the use of 20-25% aluminum chloride being the most common and effective (11, 15, 18, 23, 24). ViscoStat Clear, with a 25% total aluminum chloride value, hits this standard of practice and thus proves to be an effective product for dental tissue management procedures. Gingival retraction, using a retraction cord soaked in an astringent or vasoconstrictor, is a common and popular procedure in dentistry (1, 5, 12,15-17) with the cord commonly soaked in an aluminum chloride or ferric sulfate solution prior to placement (11,15). It is noted that retraction cord methods can damage the gingival epithelial tissue (8) because of tissue manipulation, but this can be mitigated with proper technique (8,14). Without proper control of fluids, dental impressions can be negatively affected (7,15-17,22) because of poor margin definition (19,22). A concern lies within the accuracy of the impression when using this technique. One study investigated the effect of retraction cord with aluminum chloride had on the dimensional accuracy of an impression material (11). This study showed that the accuracy was within ADA guidelines. In addition to impression accuracy, there is a concern that the bond strength of the restorative material can be affected when the dentin surface is contaminated with dental hemostatic agents. Both in-house testing, and literature show that bond strength is not negatively affected by Viscostat Clear (in-house testing) or other hemostatic agents containing aluminum chloride (9,10).

The use of retraction cords and aluminum chloride agents such as those currently approved and released on the market (Racegel and Expasyl) and the proposed Viscostat Clear prove to be a benefit to the dental practitioner because of their ability to control sulcular fluids and minor bleeding throughout the restoration process. Each of the articles above presents the efficacy of aluminum chloride in this field. Viscostat Clear utilizes aluminum chloride, an established dental hemostatic, and will provide another option to the licensed dental practitioner.

B. Safety:

The safety of Viscostat Clear has been previously established through biocompatibility testing and clinical research illustrating the long historical use of aluminum chloride in the dental field. There is no new technology introduced in Viscostat Clear and there are multiple, similar devices released and used in the dental arena that utilize aluminum chloride as the active ingredient to control sulcular fluids and control bleeding during dental procedures. Current literature studies reflect this (6). Multiple studies

investigate Expasyl®, a 15% aluminum chloride paste. The first compares Expasyl® to gingival retraction cord (1) and another to Stasis®(2). Although both showed gingival inflammation, the cordless technique did not induce bleeding during or after retraction (1) and the inflammatory reactions were limited to the bone defects in the second study (2). ViscoStat Clear will be used in conjunction with the retraction cord so bleeding will be controlled and all procedures, cordless and corded; will promote some sort of inflammation as tissues are being manipulated outside of their normal function. Other studies on a 25% aluminum chloride device also conclude that the produce induces significant inflammatory response on gingival tissue (3) or in cultured cells (4,5). However, each of these includes a protocol where the product was left in contact for 10 minutes or longer. The study by Nowakowska (5) included a 3 and 5 minute time interval as well which shows 40-70% cell viability after exposure. Viscostat Clear instructions recommends a contact time of 1-3 minutes, which will help reduce the inflammatory response.

In addition to the studies presented for safety, there are numerous studies available which demonstrate the safe use of dental hemostatic agents (6). Significant research has been performed which indicate that aluminum chloride is safe when used as directed by a dental professional.

C. Product Literature and Instructions for Use:

The labeling, literature and instructions for use (IFU) for Viscostat Clear are consistent with the clinical data and predicate devices. All hazards and other clinically relevant information that may impact the use of the device or safety of the patient are included within these.

VII. Conclusions

These studies and reviews, in conjunction with the product risk analysis, supporting biocompatibility test result, and complaint history demonstrate that the safe and effective use of Viscostat Clear when used as directed by licensed dental professionals. The use of ViscoStat Clear, as compared to similar product already approved and released on the market, does not pose any undue risks to patients when used as directed. The risks associated with the use of Viscostat Clear are acceptable when weighed against the benefits to the patient.

VIII. Clinical Literature Evaluator(s)

Refer to attached CVs for each evaluator

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RP019.1

Journal of Clinical Periodontology

J Clin Periodontol 2008; 35: 1053–1058 doi: 10.1111/j.1600-051X.2008.01335.x

Journal of Clinical Periodontology

A clinical study on the effects of cordless and conventional retraction techniques on the gingival and periodontal health

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Al Hamad KQ, Azar WZ, Alwaeli HA, Said KN. A clinical study on the effects of cordless and conventional retraction techniques on the gingival and periodontal health. J Clin Periodontol 2008; 35: 1053–1058. doi: 10.1111/j.1600-051X.2008.01335.x.

Abstract

Aim: To investigate the influence of two cordless techniques on the periodontium in comparison with conventional cords.

Material and Methods: Dental students ($n = 60$) with healthy gingival conditions were recruited – an expanding poly vinyl siloxane material (Magic Foam Cord®), a paste-like material (Expasyl®), and a conventional retraction cord (Ultrapak®) were applied on the buccal aspects of three premolars of each subject. Probing depth, clinical attachment level, gingival index (GI), plaque index, mobility, bleeding, and sensitivity were assessed at baseline, and at 1 and 7 days after application. Data were analysed using Kruskal–Wallis and Mann–Whitney tests ($\alpha = 0.05$).

Results: The periodontal parameters were not statistically significant among the groups at all time intervals except for the GI, which was increased for all groups after 1 day. The highest was in Expasyl ($p = 0.011$). After 7 days, the GI returned to a non-significant level compared with baseline except for Expasyl, which was still significant ($p = 0.044$). Expasyl induced sensitivity in four subjects. Bleeding was only induced by Ultrapak in 28.3% and 26.7% during and after retraction, respectively.

Conclusions: All techniques caused a temporary gingival inflammation; the greatest was in Expasyl, which also showed slower recovery. Cordless techniques did not induce bleeding during or after retraction.

Key words: cordless techniques; gingival displacement; gingival health; retraction cord

Accepted for publication 7 September 2008

Introduction

Management of the gingival tissues is essential for obtaining accurate impressions for the fabrication of fixed restorations, particularly when the finish line is at, or just within, the gingival sulcus (Goldberg et al. 2001, Rosenstiel et al. 2006, Hansen et al. 1999, Perakis et al. 2004, Donovan & Chee 2004). This is also true when dealing with procedures for the restoration of cervical lesions due to their proximity to the periodontal tissue (Meraner 2006).

Gingival displacement is defined as the deflection of the marginal gingiva away from the tooth (Glossary of prosthodontics; The Academy of Prosthodontics, 2005). This is performed to create sufficient lateral and vertical space between the preparation finish line and the gingival tissue to allow the injection of adequate bulk of impression material into the expanded gingival crevice (Nemetz et al. 1984, Weir & Williams 1984, Benson et al. 1986, Cassidy & Gutteridge 1994). It is especially critical when using hydrophobic impression materials that do not displace the gingival tissues (Wassell et al. 2002). Numerous forces act to return the tissues to their original position, such as the elasticity of the gingival cuff around the tooth and the rebound forces of the compressed adjacent attached gingiva during retraction (Livaditis 1998). The critical sulcular width has been reported to be approximately 0.15–0.2 mm at the level of the finish line. Impressions with less sulcular width have higher incidences of voids, tearing of impression materials, and reduction in marginal accuracy

Conflict of interest and source of funding statement

The authors declare that they have no conflict of interests.

No external funding, apart from the support of the authors' institution, was available. Magic Foam Cord® was supplied free of charge by Coltene Whaledent AG, Altstätten, Switzerland.

(Laufer et al. 1996, 1997, Baharav et al. 2004, Donovan & Chee 2004).

Retraction techniques can be classified as mechanical, chemical or surgical, and are often used in combination. The use of retraction cords as a mechanical or chemo-mechanical technique is well established in practice due to their relative predictability, effectiveness, and safety compared with rotary gingival curettage and electrosurgery (Benson et al. 1986, Hansen et al. 1999). However, the use of retraction cord can be laborious, time-consuming, can cause gingival bleeding, uncomfortable for patients in the absence of anaesthesia, and when inappropriately manipulated, can lead to direct injury and gingival recession (Ruel et al. 1980, de Gennaro et al. 1982, Azzi et al. 1983, Feng et al. 2006). Various haemostatic agents with varying degrees of safety and effectiveness are available such as aluminium potassium sulphate (Alum), aluminium chloride, epinephrine, zinc chloride, ferric sulphate and sympathomimetic amines. Recently, cordless techniques have been introduced with several claimed advantages, such as time-savings and enhanced patient comfort while being minimally invasive. Expasyl® (Kerr Corp., Orange, CA, USA) is a paste-like gingival retraction material that depends on the haemostatic properties of aluminium chloride and the hygroscopic expansion of kaolin upon contact with the crevicular fluid, to provide mild displacement of the gingiva in about 2 min. (Lesage 2002). Aluminium chloride has been reported to be irritant in moderate concentrations and caustic in high concentrations. It is sold in a stable acidic buffer, resulting in an etched dentine (Donovan et al. 1985, Felpel 1997, Polat et al. 2007).

Magic Foam Cord® (Coltène Whaledent AG, Altstatten, Switzerland) is an expanding poly vinyl siloxane material designed for easy and fast retraction of the sulcus without the potentially traumatic and time-consuming packing of retraction cord.

Most studies on cordless techniques are demonstrations of their clinical use; their effects on the gingival and periodontal tissues are not well documented (Poss 2002, Shannon 2002, Smelltzer 2003).

Yang et al. (2005) investigated two cordless techniques: Expasyl and Korlex-GR® (Biotech-one, San-Chung, Taiwan) and compared them with Ultrapak® cords (Ultradent Products Inc., South Jordan, Utah). The authors reported no significant difference in achieving gingival deflection, but reported that the use of Ultrapak appeared to be more painful and produced more gingival recession than the cordless technique(s).

This study was conducted to investigate the influence of Expasyl and Magic Foam Cord on the gingival and periodontal tissues in comparison with conventional retraction cord.

Material and Methods

Fourth and fifth year dental students at the Jordan University of Science and Technology were recruited for the study on March 2007, according to the following inclusion criteria: currently enrolled student with no relevant medical history; non-smoker or quit smoking for at least 6 months before the study; with at least three premolars in one of the two arches. The selected premolars were screened for periodontal health and teeth included in the study were those with a gingiva not expressing a highly scalloped margin and at least 2 mm of keratinized tissues, non-fibrotic gingival tissues, no recession, probing depths of $\leq$3 mm, no evidence of significant loss of attachment, no bleeding on probing, and scored 0 or 1 according to the gingival and plaque indices (Löe 1967, Palmer & Floyd 1995).

The study protocol was approved by the health and safety committee for research on humans at Jordan University of Science and Technology, and by the college of dentistry-related committees. The selected participants gave their consent after they were informed about the purpose, procedures, and duration of the study.

The study was performed at the periodontal clinics of the dental health teaching centre, Jordan University of Science and Technology. Probing depth (PD), clinical attachment level (CAL), gingival index (GI), plaque index (PI), and mobility were recorded for the buccal aspects of the selected teeth before gingival retraction was initiated. Subjects were also asked to report the presence or absence of sensitivity (subjective reporting). Cold air test for sensitivity was also performed on the selected teeth through a one second application of cold air from a dental unit syringe (at 20 ± 3°C at 60–65 psi). The same measurements were again recorded on the first and seventh days post-retraction (Löe 1967, Holland et al. 1997). Periodontal probing to the bottom of the sulcus was conducted on the buccal aspect of every selected tooth with Williams probe (Hu-Friedy Manufacturing Inc., Chicago, IL, USA). This probe had a tapered tip with a diameter of 0.5 mm, and markings consisted of milled grooves and were situated at 1, 2, 3, 5, 7, 8, 9, and 10 mm from the tip. The probe was held with a light grasp and pointed towards the apex buccally while being parallel to the long axis of the tooth. Each measurement was rounded to the lowest whole millimetre. Clinical attachment loss measurement was then recorded as the distance from the CEJ to the base of the probable crevice.

The GI was recorded for every selected premolar based on the modification of the method of Löe & Silness (1963). Bleeding also was observed within 15 s after probing, or if there was any tendency to spontaneous bleeding.

For purposes of calibration, a pilot study was conducted during which an experienced periodontist measured the periodontal parameters for selected quadrants on four subjects. The principal investigator randomly repeated the measurements 30 min. later on the same subjects, and subsequently. Duplicate measurements were obtained to measure the reliability of the examination using percent agreement, Kappa test, which revealed more than 95% agreement in parameter assessment.

The following gingival deflection techniques were used on the buccal aspect of the premolars: Ultrapak knitted non-impregnated retraction cord (Ultradent Products Inc., Ref. No. BØ456, LOT UP131), Magic Foam Cord (Coltene Whaledent AG, Art. No. 6735, LOT 0078546), and Expasyl (Kerr Corp., Ref. No. 261030, LOT 3104). Each technique was applied to the buccal gingival sulcus along the distance from the mesial to the distal papilla of the selected premolar.

Three premolars were selected in one arch for each subject to receive the three retraction techniques. Each tooth was assigned a number from 1 to 3 starting from the most distal premolar in the right side of the subject. The middle premolar was assigned number 2 and the last premolar number 3. Each tooth received one retraction technique. Maxillary premolars were chosen in half of the subjects and mandibular premolars were chosen for the other. The sequence of application was chosen taking in consideration the recommended time

Table 1. Subject distribution for periodontal parameters at the three visits for each technique (E, Expasyl®; M, Magic Foam®; R, Ultrapak® Cords)

Parameter	Subjects distribution, $n = 60$								
	before retraction			1 day post-retraction			7 days post-retraction		
	E	M	R	E	M	R	E	M	R
PD (mm)									
1	10	11	9	8	10	9	12	11	13
2	37	30	29	33	31	34	30	32	33
3	13	19	22	19	19	17	18	17	14
4	0	0	0	0	0	0	0	0	0
Mean ± SD	2.05 ± 0.62	2.13 ± 0.70	2.22 ± 0.69	2.2 ± 0.68	2.15 ± 0.68	2.13 ± 0.65	2.1 ± 0.70	2.1 ± 0.68	2.02 ± 0.67
GI									
0	36	34	35	18	25	26	29	36	34
1	24	26	25	18	28	24	20	21	20
2	0	0	0	24	7	10	11	3	6
PI									
0	46	45	47	47	48	48	45	43	45
1	12	15	12	11	10	10	13	16	14
2	2	0	1	2	2	2	2	1	1
Sensitivity									
− ve	60	60	60	56	60	60	56	60	60
+ve	0	0	0	4	0	0	4	0	0
Mobility									
0	60	60	60	60	60	60	60	60	60
CAL (mm)									
0	60	60	60	60	60	60	60	60	60

PD, probing depth; GI, gingival index; PI, plaque index; CAL, clinical attachment level.

of placement for each technique. Ultrapak was applied first as it has the longest possible time of application (10 min.) (Löe & Silness 1963), followed by the Magic Foam Cord (5 min.), and then by Expasyl (2 min.). The sequence of retraction techniques allocation was in the order of teeth number 1, 2, 3. In the next subject the order was changed to 2, 3, 1 and then to 3, 1, 2. The order was changed in the next subject back to 1, 2, 3 and so on. The whole procedure was practised before starting the study.

Tissue displacement was preceded with isolation and drying of the area. Appropriate Ultrapak cord size and length was chosen and wetted with water, and was packed gently in the buccal gingival sulcus with a plastic instrument without anaesthesia and kept in the gingival sulcus no more than 10 min.; during that time, the other two materials were applied on the remaining premolars. A suitable Comprecap size was selected and adjusted proximally to allow its placement and Magic Foam was syringed into the buccal sulcus around the premolar and the Comprecap was placed for 5 min. Expasyl was extruded into the buccal sulcus using the gun at even pressure, the tip was perpendicular to the axis of the tooth, and then it was pressed against the tooth and angled until it contacted the sulcus lining of the gingival margin (Lesage 2002). Expasyl was left in place for 2 min. All materials were removed at the same time; the cord was removed manually, while cordless materials were copiously irrigated with water until no traces of materials were left. The same procedure was repeated in every eligible subject.

The presence or absence of bleeding during and after the procedure was recorded for each technique.

The whole study was carried out by two researchers: one was responsible only for the application of the retraction materials, and the other carried out the rest of the study. The researcher who recorded the periodontal parameters was unaware of the technique applied on the tooth. The data were analysed using Statistical Package for Social Sciences software (version 15.0; SPSS Inc., Chicago, IL, USA). Kruscal–Wallis and Mann–Whitney tests were used to analyse the differences of the periodontal parameters among the three materials and the differences among the three visits within each material applied ($p \leq 0.05$). With regard to sensitivity and evaluation of bleeding within and after the procedure, simple descriptive statistics were computed using the frequency and descriptive procedures of SPSS.

Results

One hundred and eighty premolars in 60 subjects free of clinical signs of gingivitis participated in this study. The sample size was determined in consultation with a statistician. The participants were between 20 and 29 years of age with a mean of (22.32 ± 1.900). Most subjects (93.3%) were between 21 and 26 years, with 56.7% females and 43.3% males. Premolars were equally distributed between the two arches.

Mobility and CAL measurements were not different among the three groups. Sensitivity was only induced by Expasyl in four subjects at the 1 and 7 days period (Table 1). Means of PD for all techniques are presented in Table 1. Mean ranks of PD, GI, and PI are presented in Tables 2–4 for the Expasyl, Magic Foam Cord, and Ultrapak, respectively. Kruskal–Wallis test was used to compare the mean ranks between the three groups at the three times intervals ($p = 0.05$). Mann–Whitney test was used for two-way comparisons and the significant difference is presented in the tables by superscripts. The GI, PD, and PI values at the baseline measurements were homogenous among the three groups. The PD and PI values were not significantly different among the groups at all time intervals.

Table 2. Mean ranks of probing depth (PD), gingival index (GI), and plaque index (PI) for the Expasyl® group (*p*-value using Kruskal–Wallis test)

Parameter	Time	*n*	Mean rank	*p*
PD	Before retraction	60	85.81	0.918
	1 day after retraction	60	95.84	
	7 days after retraction	60	89.85	
GI	Before retraction	60	71.00[a]	0.001
	1 day after retraction	60	112.15[b]	
	7 days after retraction	60	88.35[c]	
PI	Before retraction	60	90.50	0.496
	1 day after retraction	60	89.05	
	7 days after retraction	60	91.95	

Mean ranks with different superscripts are significantly different ($p \leq 0.05$ using Mann–Whitney test).

Table 3. Mean ranks of probing depth (PD), gingival index (GI), and plaque index (PI) for the Magic Foam Cord® group (*p*-value using Kruskal–Wallis test)

Parameter	Time	*n*	Mean rank	*p*-value
PD	Before retraction	60	90.98	0.917
	1 day after retraction	60	92.02	
	7 days after retraction	60	88.51	
GI	Before retraction	60	84.83[a]	0.046
	1 day after retraction	60	102.54[b]	
	7 days after retraction	60	84.13[a]	
PI	Before retraction	60	90.63	0.614
	1 day after retraction	60	86.93	
	7 days after retraction	60	93.94	

Mean ranks with different superscripts are significantly different ($p \leq 0.05$ using Mann–Whitney test).

Table 4. Mean rank of probing depth (PD), gingival index (GI), and plaque index (PI) for the Ultrapak® group (*p*-value using Kruskal–Wallis test)

Parameter	Time	*n*	Mean rank	*p*-value
PD	Before retraction	60	97.29	0.256
	1 day after retraction	60	91.08	
	7 days after retraction	60	83.13	
GI	Before retraction	60	82.67[a]	0.076
	1 day after retraction	60	101.27[b]	
	7 days after retraction	60	87.57[ab]	
PI	Before retraction	60	89.90	0.83
	1 day after retraction	60	88.77	
	7 days after retraction	60	92.83	

Mean ranks with different superscripts are significantly different, while mean ranks with "ab" superscript are at no significant difference with those with "a" or "b" superscripts ($p \leq 0.05$ using Mann–Whitney test).

The use of Ultrapak resulted in a slight decrease in the mean of the PD values after 1 day (2.13 mm) and a further decrease after 7 days (2.02 mm) compared with the baseline (2.22 mm). The mean of the PD for the Magic Foam group almost had the same values (2.13, 2.15 mm, 2.10 at baseline, 1, and 7 days, respectively). The values of the PD for the Expasyl group showed a slight increase from 2.05 mm at baseline to 2.2 and 2.1 mm at 1 and 7 days after retraction.

All techniques resulted in a significant increase in the GI values (Table 1). Mann–Whitney tests demonstrated that the increase in GI means after 1 day by all techniques was significant compared with their baseline measurements (Tables 2–4). The highest increase was induced by Expasyl and was also significantly different from the other groups. After 7 days, the GI for the three retraction techniques decreased to a non-significant level compared with their baseline measurements except the Expasyl group (Table 4).

Bleeding during and after each retraction material was encountered only with the use of Ultrapak. Bleeding during placement happened in 28.3% and after removal in 26.7% of the subjects.

Discussion

A narrow young age range group was studied and teeth were equally distributed between maxilla and mandible, which eliminated age/gender influence and ensured little variation in gingival thicknesses. This allowed using the same size of Ultrapak cord in all subjects (size one) to minimize differences among the groups. Only buccal aspects of premolars with comparable features in terms of periodontal clinical features were selected, also because premolars offered good visibility and accessibility.

The sequence of applications was selected taking in consideration the recommended time of placement for each technique. Ultrapak has the longest possible time of application (10 min.). Retraction cords have been reported to cause necrosis of the crevicular epithelium when placed longer than 10 min. (Löe & Silness 1963). This allowed the application of Magic Foam Cord for 5 min., and then Expasyl for 2 min. as recommended by the respective manufacturers.

This study investigated the effects of different retraction techniques on gingival and periodontal health and did not test the effectiveness of gingival displacement. The use of unprepared teeth was beneficial, because the adverse effects of preparation and provisionlization steps on the gingival tissue were avoided. This provided the study with a homogenous group, as shown by the periodontal baseline measurement (Table 1). On the other hand, because the retraction materials were applied to structurally healthy teeth, in which no crown preparation was performed, one could argue that the results may not be extrapolated to the clinical reality. In order to minimize the possible effects of this on the results, every attempt was made by the expert prosthodontist to apply these materials in the same way as they would be used with prepared teeth. The technique and time of application was strictly followed according to the manufac-

turer's instructions and the relevant literature on conventional retraction cords. The Comprecaps were adjusted proximally to allow a proper placement over the unprepared teeth.

Clinical diagnostic indicators including PD, CAL, GI, PI, mobility, and sensitivity were used to evaluate periodontal health in this study. These indices have been developed to identify the degree of severity of gingival and periodontal disease by analysing the degree of gingival inflammation in gingivitis and the degree of connective tissue destruction in periodontitis. They are easy to perform, cost-effective, and relatively non-invasive. Clinical probing is the most commonly used parameter both to document loss of attachment and to establish a diagnosis of periodontitis. There are, however, some sources of error inherent to this method which contribute to the variability of the measurements. These include the tip of the probe, probing force, placement and angulations of probing, and the crudeness of the measurement scale (Lang & Corbet 1995). In this study, a 0.5 mm probing tip was used in a light force and the placement and angulation was standardized to minimize the variability in measurements. Probing depth is generally assessed to the nearest millimetre (Glavind & Löe 1967). It is evident that even a measurable loss of attachment of 0.5 mm accepts a high incidence of false negative values, which, in turn, means that "true" disease progression may actually occur, but only to a small extent which is not revelled by the crudeness of the measurement scale (Lang & Corbet 1995). Ultrapak use caused PD reduction (about 0.1 mm in 1 day and about 0.2 mm after 7 days). Such reduction is possibly of some clinical importance because it might imply gingival recession. It may have occurred as result of low-grade trauma due to impaction of foreign bodies (retraction cord) on the gingival tissue. Direct injury to the gingiva through mechanical procedures often shows obvious and immediate changes (de Gennaro et al. 1982, Feng et al. 2006). Previous studies reported that gingival retraction with cord caused destruction of the junctional epithelium that took 8 days to heal and caused gingival recession of about 0.2–0.1 mm (Ruel et al. 1980, Wassell et al. 2002). This study did not demonstrate that at a significant level, due probably to the crudeness inherent in the PD measurement. The fact that no anaesthesia was used could have resulted in reduction of the force of impaction. Dentists tend to increase the force of cord placement in the absence of pain. None of the other materials caused any significant changes on PD mean after 1 or 7 days. As mentioned previously, the use of structurally healthy teeth may imply that the retraction techniques could have been used in a different way, causing a different packaging force in the sulcus. Nevertheless, similar results were reported by Yang et al. (2005), who found that the greatest amount of gingival recession was demonstrated by the use of epinephrine-impregnated cord while the recession observed in the cordless techniques was too small and clinically insignificant.

The GI is a valuable tool in assessing gingival condition (Löe & Silness 1963). This index is probably the most widely used index in clinical trials, and provide a more objective assessment of gingivitis than do indices which rely solely on visual criteria (Lang & Corbet 1995).

All techniques caused gingival injury after the first day as shown by the significant increase of GI. This may be explained by the reaction of the inflammatory cells to the mechanical or chemical trauma (de Gennaro et al. 1982). However, when the three groups were compared after the first day, the greatest increase was significantly evident in the Expasyl group, while Ultrapak and Magic Foam groups showed similar increase. Expasyl contains 15% aluminium chloride, which has been reported to result in local tissue damage and transient ischemia in concentrations higher than 10% (Donovan et al. 1985, Felpel 1997, Polat et al. 2007). All groups showed tissue recovery after 7 days. Magic Foam showed the best healing followed by Ultrapak. Expasyl group showed slower healing, and was still significantly different from the baseline measurements. The results for the Ultrapak group in this study were similar to those reported by Feng et al. (2006) who reported that GI was the highest in the first and second day after placement of retraction cord, but it appeared clinically to reverse itself in 2 weeks.

Dentine sensitivity is dependent on exposure and patency of the dentinal tubules (Addy 2002, Banfield & Addy 2004). Expasyl induced sensitivity in four subjects. This might be attributed to its acidity, which may have affected the patency of the dentinal tubules (Baharav et al. 1997). In addition, it was noticed that Expasyl caused a degree of dryness, which although was a desirable characteristics for making successful impressions, it may have resulted in sensitivity.

Bleeding during and after application was only observed with the use of the non- impregnated Ultrapak cord. Retraction cord is usually used in combination with local anaesthesia and a haemostatic agent to provide better control over bleeding. Homeostasis was controlled by the aluminium chloride in the Expasyl group, while the Magic Foam was only applied with little pressure on the gingiva. This was similar to the findings reported by Yang et al. (2005) who found that less bleeding and pain was observed with the cordless techniques compared with the use of traditional retraction cord.

This study did not investigate the efficiency in achieving gingival deflection among the three techniques. This area requires further research to provide the clinicians with valuable clinical information on the efficiency of the cordless techniques.

Each type of retraction appears to possess desirable characteristics. It is imperative to match positive characteristics to a particular challenge presented by each unique patient, clinical condition, and specific abutment.

Conclusions

This study showed that all retraction techniques caused an acute injury after 1 day of retraction, which took 1 week to heal in the Ultrapak and the Magic Foam groups. The Expasyl group had the highest GI compared with others, and showed slower healing. Its use might cause sensitivity in a small number of cases. The use of cordless techniques did not require haemostatic agent to control bleeding during retraction.

Acknowledgements

The authors thank Dr. Dierk Lübber, Coltene Whaledent AG, Altstatten, Switzerland, for providing the Magic Foam Cord® in this study.

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Clinical Relevance

Scientific rationale for the study: The present study is the first to investigate the effects of using cordless techniques on the gingival and periodontal health in comparison with conventional retraction cords.

Principal findings: The data indicated that all retraction techniques caused a temporary inflammation, measured through the gingival index. The recovery at 7 days was slower for Expasyl.

Bleeding during or after retraction was only encountered with the use of conventional retraction cords.

Practical implications: This study showed that none of the techniques tested seems to harm the tissues in the long term; however, clinicians should be aware that Expasyl use is less friendly to the gingival tissues. Cordless techniques do not require haemostatic agents to control bleeding.

In vivo safety & efficacy

(2)

doi:10.1111/j.1365-2591.2006.01152.x

Haemostatic agents used in periradicular surgery: an experimental study of their efficacy and tissue reactions

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Abstract

von Arx T, Jensen SS, Hänni S, Schenk RK. Haemostatic agents used in periradicular surgery: an experimental study of their efficacy and tissue reactions. *International Endodontic Journal*, **39**, 800–808, 2006.

Aim To evaluate the haemostatic efficacy and the histologic tissue responses after the application of different haemostatic agents used in periradicular surgery.

Methodology The study was conducted in the calvarium of six rabbits. Standardized bone defects (diameter 4 mm) were trephined, and different haemostatic agents were applied and compared with control defects: bone wax (left for 10 min), Stasis® (ferric sulphate, left for 5 s), Expasyl™ (aluminium chloride, left for 2 min and left permanently *in situ*), and a combination of Expasyl™ (2 min) and Stasis® (5 s). The sites were photographed before the application and after the removal of the haemostatic agents. Three independent examiners judged the initial and final bleeding (on the photographs) using a bleeding score for each site and treatment. The results were compared using Wilcoxon's signed rank test. For the histologic analysis, three animals were killed after 3 weeks and three animals after 12 weeks. Transverse, nondecalcified sections were stained with combined basic fuchsin and toluidine blue for descriptive histology.

Results The most efficient haemorrhage control was provided by Expasyl™ in combination with Stasis® and by Expasyl™ alone, whereas bone wax had the weakest bleeding reduction effect. The histologic analysis after 3 weeks demonstrated an inflammatory and foreign body tissue response towards all haemostatic agents. At 12 weeks, this tissue response was less pronounced but still present in sites treated with bone wax or Expasyl™. In general, the inflammatory tissue reactions were limited to the bone defects, and never extended into the surrounding tissues.

Conclusions Expasyl™ alone or in combination with Stasis® appeared to be the most efficient of tested agents to control the bleeding within the bony defects created in a rabbit calvarium model.

Keywords: aluminium chloride, bone wax, ferric sulphate, haemorrhage control, periradicular surgery.

Received 23 January 2006; accepted 28 March 2006

Introduction

One of the objectives of periradicular surgery following root-end resection is to hermetically seal the root canal system, thereby enabling healing by forming a barrier between the irritants within the confines of the affected root and the tissues surrounding the root. Haemorrhage control is an essential step in periradicular surgery, allowing adequate intra-operative diagnostic evaluation of the root-end, of the resected surface, and of the root-end preparation (Witherspoon & Gutmann 1996). In addition, it is a prerequisite for placement and setting of most root-end filling materials. Inadequate visibility due to copious bleeding at the surgical

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site can be frustrating and time-consuming to control (Kim & Rethnam 1997).

Various agents and techniques have been promoted for haemorrhage control during periradicular surgery. Locally applied haemostatic agents can be classified by their mechanism of action: mechanical, vasoconstrictive, intrinsic and extrinsic. A number of studies have described the tissue reactions of haemostatic agents (Ibarrola *et al.* 1985, Alberius *et al.* 1987, Haasch *et al.* 1989, Finn *et al.* 1992, Solheim *et al.* 1992, Jeansonne *et al.* 1993, Lemon *et al.* 1993, Allison 1994). Other studies have evaluated the systemic aspects following the use of haemostatic agents or have evaluated the clinical efficacy of haemostasis in periradicular surgery (Vickers *et al.* 2002, Vy *et al.* 2004).

While bone wax is relatively easy to use, and is generally considered as both a haemostatic agent and a debris collector in periradicular surgery, wax residues may produce severe tissue reactions. As an alternative haemostatic agent, the authors have used ferric sulphate. Although the application of this haemostatic solution is very simple, oozing of blood may occur prematurely, and repetitive application results in a creamy substance making working within the bony crypt more difficult than easier. In 2001, the principle author started to use a paste containing aluminium chloride that clinically appeared to be very efficient to control bleeding in periradicular surgery. In certain situations, aluminium chloride and ferric sulphate were combined synergistically to control recurrent bleeding.

The objective of this study was to assess the haemostatic effect and to evaluate the tissue responses after application of these mentioned haemostatic agents in the standardized bone defects in the calvarium of rabbits.

Material and methods

Study design

The study protocol was approved by the authorities of the Canton of Berne (Department of Agriculture, Section Veterinary Service, Experimental Animal Studies, study number 51/03). The experimental study was conducted in six adult Burgundy rabbits, each at least 5 months old and weighing between 4 and 5 kg. Histologic analysis was conducted after healing periods of 3 weeks (three animals) and 12 weeks (three animals).

Medication of animals

All surgery was performed under intravenous general anaesthesia. The animals were premedicated with ketamine, 65 mg kg^{-1} (Narketan®; Vétoquinol, Berne, Switzerland) and xylazine, 4 mg kg^{-1} (Xylapan®; Vétoquinol), mixed and injected intramuscularly into the hind leg. Subsequently, a cannula was placed into the lateral ear vein and general anaesthesia was maintained with an intravenous infusion of ketamine and xylazine (double quantity of premedication dosage) in 100 mL physiologic saline. Each animal was given 100 000 IU benzylpenicilline intramuscularly (Duplocillin LA®; Intervet BV, Boxmeer, the Netherlands). Postoperatively, the animals were given analgesics for 3 days (Novalgin®; Aventis, Zurich, Switzerland; 50 mg kg^{-1}, once a day intramuscularly).

Surgical protocol

The animals were shaved on the top of the head between the eyes and the ears. The skin was disinfected using an iodine-polyvinylpyrrolidone solution (Betadine®; Mundipharma, Basel, Switzerland). After the subcutaneous administration of a local anaesthetic (1 mL Ultracain DS®; Aventis Pharma, Frankfurt a.M., Germany), a midline incision was made and the skin and periosteum were reflected to expose the vault of the skull. Using a bone trephine, circular bone defects (diameter 4 mm, depth 1.5 mm) were drilled into the outer cortex (tabula externa). It was attempted to avoid perforating the inner cortex (tabula interna) and thereby contacting the 'dura mater', but avoiding contact was not always possible. A total of six bony defects were created, three on each side of the sagittal suture. After the removal of the outer cortical bone plate, the six defects received one of the following treatments in a randomized sequence (concealed envelopes) (Fig. 1a):

- Control site: no haemostatic agent was placed.
- Bone wax site: bone wax (Johnson & Johnson AG, Spreitenbach, Switzerland) was placed into the bone defect with a spatula, flush with the adjacent outer cortex; after 10 min the bone wax was removed with a dental curette.
- Expasyl™ site (temporary): Expasyl™ (Pierre Rolland, Merignac, France) was placed into the bone defect with a spatula, flush with the adjacent outer cortex; after 2 min the paste was removed with a dental curette.

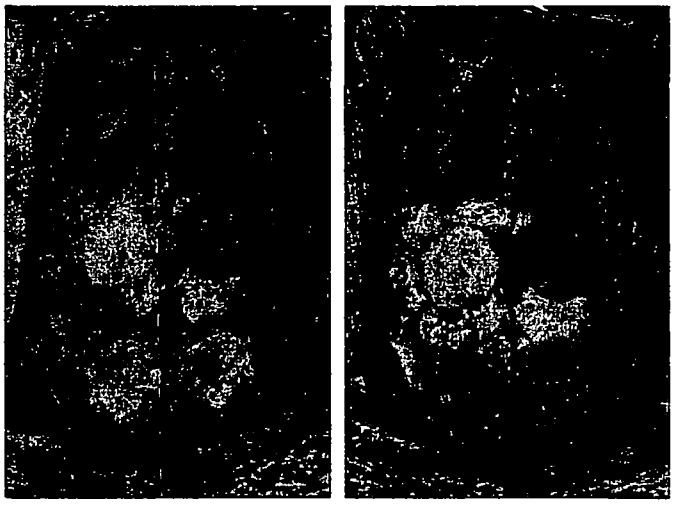

Figure 1 (a) Circular bone defects in the rabbit calvarium following placement of haemostatic agents: site 1, bone wax for 10 min; site 2, control site; site 3, expasyl™ left *in situ*; site 4, Stasis® for 5 s; site 5, Expasyl™ for 2 min and Stasis® for 5 s; site 6, Expasyl™ for 2 min. (b) Assessment of bleeding after removal of the haemostatic agents.

- Expasyl™ site (permanent): Expasyl™ was placed into the bone defect with a spatula, flush with the adjacent outer cortex; the material was left *in situ* throughout the study period.
- Stasis® site: a small foam pellet (3 × 4 × 3 mm) saturated with Stasis® (Belport Co., Camarillo, CA, USA) was placed for 5 s into the bone defect; then the sponge was removed.
- Expasyl™ and Stasis® site: Expasyl™ was placed into the bone defect with a spatula, flush with the adjacent outer cortex; after 2 min the paste was removed with a dental curette. Subsequently, a small sponge soaked with Stasis® was placed for 5 s into the bone defect, and then the sponge was removed.

Following the removal of the test agents with the dental curette (Fig. 1b), no additional bone freshening with drills was performed. The sites were rinsed with saline and wound closure was accomplished in a two-layer technique. The periosteum (galea aponeurotica) was closed using expanded polytetrafluoroethylene (ePTFE) – suturing material (Gore-Tex® Suture CV-5; W.L. Gore & Associates Inc., Flagstaff, AZ, USA). This suture material was chosen to avoid tissue reactions, as ePTFE is an inert and biocompatible material. The skin was closed with single interrupted sutures (Vicryl® 5-0; Ethicon, Johnson & Johnson, Brussels, Belgium).

Sacrifice

Following premedication with ketamine, 65 mg kg^{-1} (Narketan®; Vétoquinol) and xylazine, 4 mg kg^{-1} (Xylapan®; Vétoquinol), a cannula was placed into the lateral ear vein. Death was induced with 1.4 mL kg^{-1} pentobarbital (Nembutal®; Abbott Laboratories, Chicago, IL, USA). After a rectangular skin incision, the calvarium was removed with an oscillating autopsy saw. The retrieved specimens were immediately immersed in a solution of 4% formaldehyde and 1% calcium.

Histological analysis

The nondecalcified specimens were embedded in methyl-methacrylate and stained with combined basic fuchsin and toluidine blue. Transverse sections with a thickness of approximately 80 μm were obtained for descriptive histology (Schenk *et al.* 1984).

Visual analysis of haemorrhage control

Photos were taken before and after the application of the haemostatic agents. The amount of blood per site was assessed on a scale from 0 (completely dry defect) to 7 (profuse bleeding from the defect) (Fig. 2). Three evaluators independently examined the photos and determined the bleeding score per site. A mean bleeding score was calculated per treatment for the different sites before (=initial score) and after (=final score) the application of the haemostatic agents. The difference between the two scores determined the mean haemostatic effect per agent (reduction of bleeding).

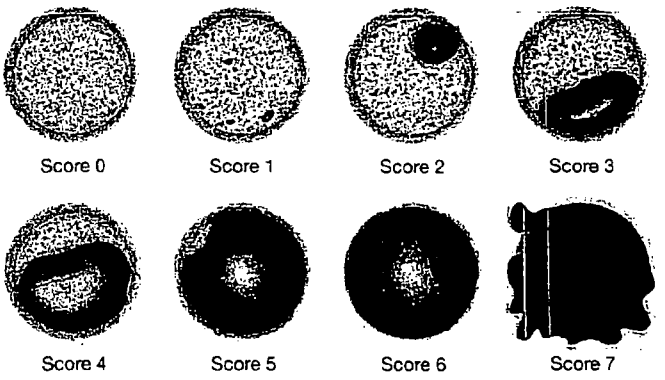

Figure 2 Schematic illustrations of bleeding scores used for visual determination of haemorrhage.

Table 1 Mean bleeding scores (±standard errors of the mean) and mean bleeding reduction (±standard errors of the mean) per treatment ($n = 6$)

Treatment[a]	Initial bleeding score	Final bleeding score	Calculated bleeding reduction[b]
Control	4.22 (±0.82)	5.50 (±0.66)	−1.28 (±0.62)
Bone wax	4.00 (±0.41)	2.72 (±0.57)	1.28 (±0.43)
Stasis®	5.28 (±0.64)	3.28 (±0.57)	2.00 (±0.69)
Expasyl™	4.11 (±0.32)	0.78 (±0.39)	3.50 (±0.41)
Expasyl™ + Stasis®	5.34 (±0.73)	0.56 (±0.25)	4.78 (±0.69)

[a]One treatment (Expasyl™ left *in situ*) not applicable to bleeding assessment.
[b]Positive values represent decrease of haemorrhage and negative values represent increase of haemorrhage.

Table 2 Pairwise comparisons of initial bleeding scores using Wilcoxon's signed rank test ($n = 6$, exact two-sided P-values)

Treatment	Control	Bone wax	Stasis®	Expasyl™
Bone wax	1.00	–	–	–
Stasis®	0.56	0.12	–	–
Expasyl™	1.00	0.41	0.12	–
Expasyl™ + Stasis®	0.31	0.31	1.00	0.12

P-value adjustment method: none.

Table 3 Pairwise comparisons of final bleeding scores using Wilcoxon's signed rank test ($n = 6$, exact two-sided P-values)

Treatment	Control	Bone wax	Stasis®	Expasyl™
Bone wax	0.094	–	–	–
Stasis®	0.125	0.656	–	–
Expasyl™	0.031	0.125	0.031	–
Expasyl™ + Stasis®	0.031	0.062	0.031	0.750

P-value adjustment method: none.

Statistics

The results were compared using Wilcoxon's signed rank test for paired samples. Exact two-sided P-values were computed to detect differences between the various treatment options. As pairwise comparisons were done on the same data, the P-values were adjusted to compensate the multiple testing situation. However, due to the explorative nature of the study and the small sample size, no adjustment was carried out. With regard to the interobserver variation, Cohen's *kappa* values were computed.

Results

All animals healed uneventfully and were killed as scheduled. The visual analysis of the haemorrhage control showed the highest effect for the combined Expasyl™ and Stasis® application (Table 1). All initial and final bleeding scores as well as the calculated bleeding reduction per treatment are summarized in Table 1. No differences were found for the initial bleeding scores per treatment (Table 2). With regard to the final bleeding scores, Expasyl™ and Expasyl™ in combination with Stasis® performed better than the control or Stasis® alone (Table 3). Bleeding reduction was more pronounced for Expasyl™, Stasis® and for Expasyl™ in combination with Stasis® compared with the control, as well as for Expasyl™ and Expasyl™ in combination with Stasis® compared with bone wax (Table 4). The calculated *kappa* values of the pairwise comparisons (three examiners) were 0.56, 0.51 and 0.62. These values indicated fair to strong concordance between the three

Table 4 Pairwise comparisons of calculated bleeding reduction using Wilcoxon's signed rank test ($n = 6$, exact two-sided *P*-values)

Treatment	Control	Bone wax	Stasis®	Expasyl™
Bone wax	0.094	–	–	–
Stasis®	0.031	0.438	–	–
Expasyl™	0.031	0.031	0.188	–
Expasyl™ + Stasis®	0.031	0.031	0.094	0.188

P-value adjustment method: none.

observers. As there were eight possible scores, one might interpret a difference of one as agreement. In this case, *kappa* values increased to 1.00, 0.92 and 0.95 showing that a difference of two or more occurred very rarely. The histological analysis is reported separately for each treatment option.

Control sites/3 weeks

Two of the three defects were bicortical. In those, woven bone formation could be observed on the defect walls without bridging the defects. The third defect showed woven bone formation to the level of the original cortex. In one of the sections, a small area with foreign body reaction was observed in the soft tissue covering the defect. Otherwise, the soft tissue presented without inflammatory reactions.

Control sites/12 weeks

Almost complete osseous healing with woven bone, reinforced with parallel-fibred bone was observed in all defects. In between the bone trabeculae, both fatty and haematopoietic bone marrow could be observed. One minor area of chronic infection could be seen in the top of one of the defects.

Bone wax sites/3 weeks

Bone formation was limited or nonexistent in all three defects. At the bottom of the defects large empty vacuoles, representing bone wax remnants (dissolved during the embedding procedure) could be observed surrounded by a soft tissue with chronic inflammatory changes and many foreign body giant cells.

Bone wax sites/12 weeks

A little more bone formation was seen after 3 weeks, but a slight to severe foreign body and chronic inflammatory reaction consistently surrounded bone wax remnants (Fig. 3).

Expasyl™ sites (temporary)/3 weeks

Sparse woven bone formation could be observed in two of the defects, none in the third. Varying amounts of foreign material were seen in the defects, and all showed abundant chronic inflammation including giant cells and phagocytes containing Expasyl™ remnants.

Expasyl™ sites (temporary)/12 weeks

No or very little bone formation could be seen (Fig. 4). The inflammatory reaction was reduced. There was a small amount of residual foreign material and an

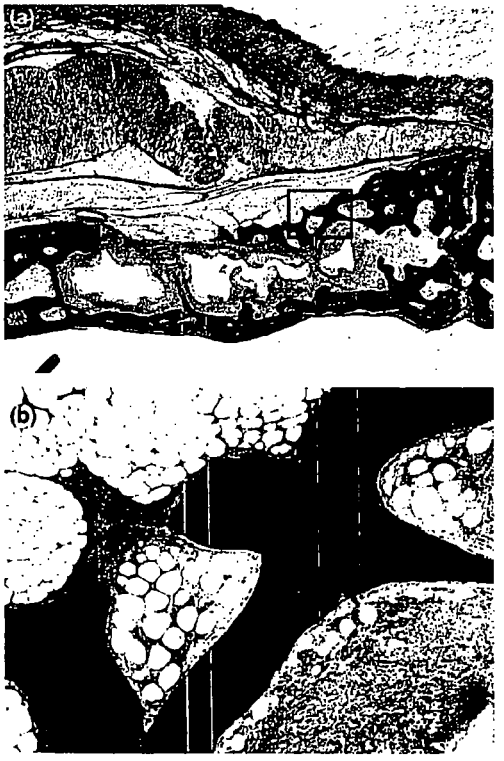

Figure 3 Histology after 12 weeks of defect treated with bone wax for 10 min (basic fuchsin and toluidine blue). A severe foreign body reaction with chronic inflammation is found around bone wax remnants in the centre of the bone (a, original magnification ×10). The enlargement shows the severe inflammatory response on the right side of the picture (b, original magnification ×90).

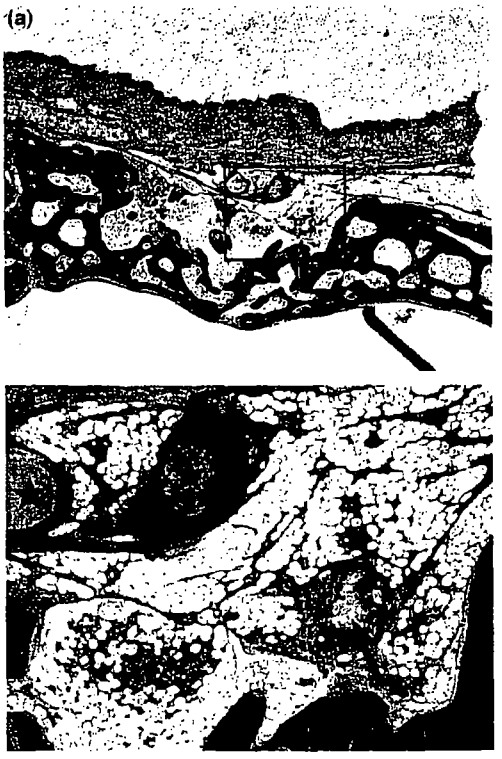

Figure 4 Histology after 12 weeks of defect treated with Expasyl™ for 2 min (basic fuchsin and toluidine blue). New bone formation is limited to the lower portion of the original defect (a, original magnification ×10). The enlargement shows an inflammatory reaction around Expasyl™ remnants (arrow), and in the upper left the cPTFE-suture (asterisk) (b, original magnification ×90).

increasing volume fraction of fatty bone marrow. A moderate amount of phagocytes and foreign body giant cells were identified.

Expasyl™ sites (permanent)/3 weeks

A more or less dense mass of foreign material occupied the main part of all three defects. No bone formation could be observed in any of the defects. Pronounced inflammation and foreign body reaction in the overlying soft tissue was a uniform finding.

Expasyl™ sites (permanent)/12 weeks

There was a limited bone formation on the defect walls. The amount of foreign material was clearly reduced in comparison with the 3-week specimens. Most of the defects were occupied by chronic inflammatory tissue containing giant cells and phagocytes, with Expasyl™ remnants in the cytoplasm.

Stasis® sites/3 weeks

Three unicortical defects showed 0%, 50% and almost 100% bone fill respectively. Areas with brown/yellow discoloration containing a variable amount of foreign material and foreign body giant cells were uniformly found. The overlying soft tissue showed slight to severe chronic inflammation.

Stasis® sites/12 weeks

All three defects showed almost complete osseous regeneration with woven bone, reinforced with parallel-fibred bone (Fig. 5). Apart from one small nidus of chronic inflammation, and one small area of discoloration (as seen in the 3-week specimens), the bone marrow was mature and free of inflammatory reactions.

Expasyl™ and Stasis® sites/3 weeks

The defects were dominated by the presence of chronic inflammation, with multiple multinucleated giant cells around remnants of the materials. Almost no new bone formation could be observed on the defect walls.

Expasyl™ and Stasis® sites/12 weeks

Moderate amounts of new bone formation could be seen. Mature fatty and haematopoietic bone marrow could be seen between areas with remnants of foreign material, chronic inflammation and multinucleated cells.

In general, the observations above were restricted to the defect sites. No chronic or acute tissue reactions could be observed in the marrow spaces surrounding the defects.

Discussion

This experimental study evaluated the immediate haemostatic effect of five different treatment options, and analysed histologically the tissue reactions to them. Both aspects are of clinical interest for surgical management of root structures and associated tissue lesions during periradicular surgery. While effective

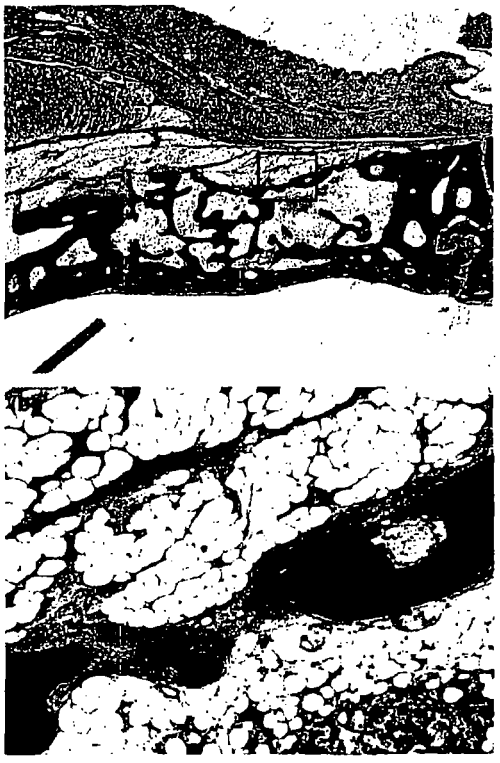

Figure 5 Histology after 12 weeks of defect treated with Stasis® for 5 s (basic fuchsin and toluidine blue). New bone formation is almost complete (a, original magnification ×10). Apart from a small area of chronic inflammation (lower right corner), the enlargement demonstrates mature bone marrow (b, original magnification ×90).

haemostasis is important during surgery for intraoperative diagnostic evaluation and root-end treatment, adverse tissue reactions to the agents applied for haemostasis might negatively influence the healing of the surgical site.

Two human studies have evaluated the haemostatic efficacy during periradicular surgery (Vickers *et al.* 2002, Vy *et al.* 2004). Vickers *et al.* reported adequate haemostasis in all 17 cases when racemic-epinephrine cotton pellets were used, and adequate haemostasis was achieved in 15 of 16 cases following the application of 20% ferric sulphate. Vy *et al.* reported complete haemostasis in 39 of 42 cases in which collagen sponges saturated with racemic epinephrine were applied. In contrast, haemorrhage control was not achieved in five of six cases that were treated with collagen sponges saturated with saline.

In the present study, the degree of bleeding was judged before and after the application of the haemostatic agents by three examiners independently using a score from 0 (no bleeding) to 7 (profuse bleeding) and schematic illustrations. Mean scores of bleeding reduction and the mean final bleeding scores showed that Expasyl™ alone or in combination with Stasis® was efficient in achieving good haemostasis of the surgical site.

Expasyl™, a paste containing aluminium chloride and kaolin, has been advocated for gingival retraction to ensure separation of the marginal gingiva and drying of the sulcus before impression-taking and insertion of restorations (Pescatore 2002, Shannon 2002). However, it has been shown that aluminium chloride elicits inflammatory tissue reactions. In a clinical comparative study on gingival retraction, aluminium chloride (25%) showed slower healing and more inflammatory reactions compared with a Nd:YAG-laser treatment (Abdel Gabbar & Aboulazm 1995). A dermatologic report on four cases demonstrated that aluminium chloride could cause a proliferative histiocytic reaction when used as a topical cauterizing agent (Barr *et al.* 1993). In an experimental study in eight beagle dogs evaluating four different retraction agents, racestyptine containing 25% aluminium chloride showed the most aggressive inflammatory infiltrate in gingival connective tissue (Kopac *et al.* 2002). In the present study, Expasyl™, alone or in combination with Stasis®, demonstrated a typical foreign body reaction including giant cells and inflammatory tissue response after 3 and 12 weeks. In contrast to control sites, new bone formation was minimal and clearly delayed in sites treated with Expasyl™. Although Expasyl™ is hydrophilic and easily washed out with saline, there may be a risk of leaving behind residues in the cancellous bone. It is therefore recommended to clean the surgical site with a bone curette and to freshen the walls of the bony crypt with a round bur before wound closure. In the present study, no attempts were made to completely remove the Expasyl™ employing such procedures. As no chronic or acute tissue reactions could be observed in the marrow spaces in the vicinity of the defects, it can be speculated that the adverse effects of Expasyl™ could be avoided by freshening the bony crypt as mentioned above.

In the present study, ferric sulphate (Stasis®) was found to be less effective than aluminium chloride (Expasyl™) in controlling the bleeding. Vickers *et al.* (2002) reported in their clinical study that in one-third

of the cases where ferric sulphate was used, some oozing of blood occurred in the bony crypt, requiring suctioning to maintain the dryness of the root-end preparation. Ferric sulphate has been used for more than a century in medicine. Ferric sulphate acts by agglutination of blood proteins resulting in plugs that occlude the capillary orifices (Lemon *et al.* 1993). When adequately curetted and irrigated from the surgical site prior to closure, ferric sulphate appears not to cause persistent inflammation or delay osseous repair (Jeansonne *et al.* 1993). In contrast, when ferric sulphate was left *in situ* for maximum exposure, an intense inflammatory response including foreign body reaction and delayed osseous healing were reported histologically after 18 and 46 days (Lemon *et al.* 1993). Interestingly, similar findings were seen in the present study for the shorter healing group of 3 weeks, whereas after 12 weeks, sites treated with ferric sulphate showed osseous regeneration and were free of any inflammatory reaction.

Bone wax containing purified beeswax, paraffin wax and isopropyl palmitate as a softening agent, has been recommended as an effective haemostatic agent in periradicular surgery since 1970 (Selden 1970). However, several reports have shown that bone wax residues are not resorbed and produce a foreign body giant cell reaction and inhibit bone reformation (Ibarrola *et al.* 1985, Alberius *et al.* 1987, Finn *et al.* 1992, Solheim *et al.* 1992, Allison 1994). From a clinical point of view, bone wax (after it was removed from the site) did not provide sufficient reduction in bleeding in the present study. Taking into consideration its adverse effects on tissue healing, it should no longer be used for haemostasis control in periradicular surgery.

Conclusions

- This explorative study in the rabbit calvarium clinically and histologically assessed the effect of various haemostatic agents.
- The key findings were: the visual analysis of pre- and post-application photographs demonstrated excellent bleeding reduction within trephined bony defects using Expasyl™ (aluminium chloride) alone or in combination with Stasis® (ferric sulphate). Histologic analysis showed a marked inflammatory tissue response towards Expasyl™ and bone wax within the immediate site of application, but no adverse tissue reactions were seen in the vicinity of the bone defects.
- Although not assessed directly in the study it is recommended that before wound closure of sites treated with such haemostatic agents, the bony crypt must be curetted to remove any foreign material, or preferably, freshened using rotary instruments.
- A future study should be performed to evaluate whether complete removal of Expasyl™ would prevent an inflammatory foreign body reaction and would allow for complete bone regeneration.

Acknowledgements

The authors gratefully acknowledge the assistance of Dr med. vet. Daniel Mettler and the veterinarian team of the Department of Experimental Surgery, University Hospital, Inselspital, Berne. We also thank Mrs Britt Hoffmann, Department of Oral Surgery and Stomatology, University of Berne, for the histologic preparation of the specimens. The schematic illustrations were provided by Ueli Iff, medical illustrator, School of Dental Medicine, University of Berne. We also thank Dirk Klingbiel and Stefanie Hayoz, Institute of Mathematical Statistics and Actuarial Science, University of Berne, for the statistical analysis. This study was funded by the Foundation for Dental Research and Education (FDR), Basle, Switzerland (grant 1-03/16).

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Safety ... 37

Gingival Inflammatory Response Induced by Chemical Retraction Agents in Beagle Dogs

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Erika Cvetko, DDS, PhD[b]
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Purpose: The aim of this in vivo study on dogs was to investigate and compare the inflammatory potential of four different retraction agents on the gingival connective tissue. **Materials and Methods:** All procedures on eight beagle dogs were performed under general anesthesia: taking oral hygiene measures, placing retraction cords medicated with four chemical agents into the gingival sulci, and taking tissue biopsies. The specimens were evaluated after a 10-minute exposure to chemical agents. The inflammatory response of the connective tissue underlying the sulcular and junctional epithelium triggered by retraction agents was assessed quantitatively. Microscopic images of tissue specimens were morphometrically analyzed using a computer-assisted morphometric method. **Results:** The most intense inflammatory response in the connective tissue underlying the sulcular epithelium was triggered by astringent retraction agents—Racestyptine in specimens taken after 1 day and 1 week and Rastringent after 1 day ($P < .05$). Tetrahydrozoline-sympathomimetic vasoconstrictor (Visine) was found to have the lowest inflammatory potential. Retraction chemicals produced no significant effects on the connective tissue subjacent to the junctional epithelium. The ratio of the connective tissue area to that of the inflammatory infiltrate showed that 25% aluminum chloride (Racestyptine) was the most aggressive and tetrahydrozoline the least aggressive retraction agent used. **Conclusion:** All the retraction chemicals tested increased the infiltration with inflammatory cells in gingival connective tissue. *Int J Prosthodont 2002;15:14–19.*

Temporary displacement of free gingival tissue was introduced in fixed prosthodontic procedures and impression making using elastomeric materials for cast fixed restorations. The procedure allows an accurate recording of preparation finish line and also of uncut tooth surface apically from the tooth preparations.

A 0.2- to 0.4-mm horizontal displacement of the free marginal gingiva provides sufficient space for an adequate bulk of impression material at the apical aspect under the chamfer or shoulder, thereby preventing distortion or disruption on removal of the impression.[1] The impression of the uncut portion of the tooth in the vertical direction apically under the preparation finish line should measure at least 0.5 mm if the die is to be properly trimmed.[2] Identification of the preparation line is a prerequisite for the accurate modeling of the gingival margins of crowns that afford a proper relationship to the gingiva and therefore help to maintain the health of periodontal tissue. This aim can only be attained by the dilation of the gingival sulcus.

Several clinical methods are available for adequate tissue retraction prior to impression making, including mechanical retraction, chemical-mechanical retraction, electrosurgery, and rotary gingival curettage. The gingiva is most commonly retracted by a chemical-mechanical technique that involves the use of cotton cords impregnated with chemical retraction agents.[3] As demonstrated by experimental animal and human studies,[4–6] retraction chemicals used in prosthodontic treatment are potentially harmful to the gingiva. These agents are reported to produce

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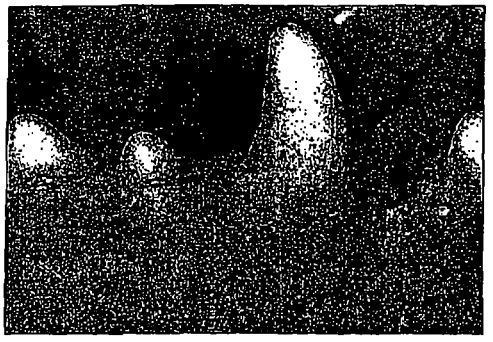

Fig 1a Slight gingival inflammation and plaque accumulation is present.

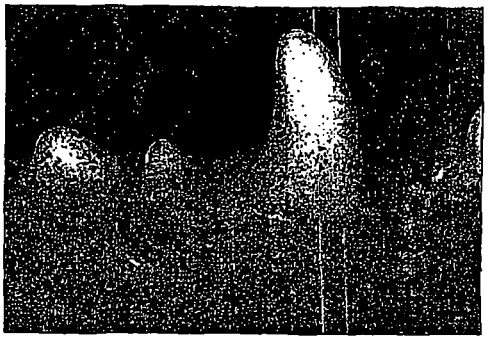

Fig 1b After the oral hygiene phase, the gingiva is clinically healthy.

injury to the sulcular epithelium. In addition, inflammatory cells may also infiltrate the gingival connective tissue underlying the epithelium.[7]

The new retraction agents are sympathomimetic vasoconstrictors with pH values more physiologic than those of standard retraction chemicals.[8] They allow for sufficient gingival retraction and constitute an effective alternative to the standard agents.[9] Their untoward systemic effects have been documented only with excessively high doses.[10] Local inflammatory potential and dynamic of gingival tissue restitution into clinically healthy gingiva following the use of retraction chemicals are still unknown. The authors' in vitro study using fibroblast tissue cultures demonstrated differences in their toxicity.[11]

This in vivo study on dogs was undertaken to evaluate the inflammatory response occurring in the gingival connective tissue treated with four different chemical retraction agents used in fixed prosthodontics.

Materials and Methods

Eight 2-year-old beagle dogs weighing 13 to 15 kg were selected for the study. They exhibited moderate amounts of sub- and supragingival concrement and plaque accummulation, and some parts of the gingivae were slightly inflamed (Fig 1a). Therefore, the following oral hygiene procedures were applied: removal of hard and soft plaque deposits with an ultrasonic cleaner; scaling and planing of dental surfaces, followed by polishing; and daily teeth brushing and application of 0.12% chlorhexidine gel. After 10 days of the hygienic procedures, the clinically healthy gingiva was demonstrated by periodontal parameters: Plaque Index (PI), gingival index (GI), and probing depth (PD) (Fig 1b).

Application of Retraction Agents

A total of 128 twined cotton cords (Reatracto, Roeko) impregnated with selected retraction agents were packed into the gingival sulci at the buccal aspect of lateral incisors, canines, posterior premolars, and first molars. The untreated gingival tissue on the buccal aspects of the second or the third premolar in each quadrant served as controls (32 specimens).

Each dog was treated with all four retraction agents under the following protocol:

- Left superior quadrant: Gingiva Liquid (Roeko), 10% aluminum chloride, pH 1.8
- Right superior quadrant: Racestyptine (Septodont), 25% aluminum chloride, pH 0.8
- Left inferior quadrant: Rastringent Two (Pascal), 20% aluminum sulphate, pH 2.6
- Right inferior quadrant: Visine (Pfizer), 0.05% tetrahydrozoline, pH 5.6

The cords were inserted very carefully and gently to avoid damaging the gingival tissue and were left in place for 10 minutes. The greatest diameter of each cord was placed at the level of the free gingival margin or just slightly below it.

Biopsies for Histologic Studies

Two parallel vertical incisions were made with a scalpel in the buccal gingiva, and one horizontal incision was made at the level of the alveolar bone crest. Tissue specimens of approximately 3 mm × 5 mm were carefully excised from the apical direction using a raspatory.

The first series of gingival specimens (n = 43) was obtained 1 hour after removal of the medicated retraction

Fig 2a Histologic specimen of a clinically healthy gingiva in the control group shows a smooth surface of the sulcular epithelium and minimal inflammatory infiltration of the underlying connective tissue; *arrowheads* = connective tissue cells (original magnification × 340).

Fig 2b Gingival tissue after 10 minutes of treatment with a Racestyptine-medicated retraction cord. The epithelial surface shows desquamation. Connective tissue is infiltrated with inflammatory cells *(arrowheads)* (original magnification × 340).

cords; the second series (n = 43) was taken 24 hours after cord removal; and the third series (n = 42) was taken 1 week after cord removal. Tissues were placed into 10% buffered formalin and stored in 70% ethyl alcohol. Specimens were dehydrated in alcohols of increasing concentrations, ending in xylene; they were then embedded in paraffin, cut into 4-μm-thick sections, and stained with hematoxylin–eosin.

Figure 2a shows a healthy gingiva from the control group, with minimally infiltrated connective tissue. By contrast, the gingivae treated with tested agents exhibited as a rule various degrees of inflammatory infiltration, and the epithelium was usually desquamated (Fig 2b).

Morphometric Analysis

Microscopic images of tissue specimens were morphometrically analyzed using System for Image Processing and Analysis Lucia 4.1 (Laboratory Imaging). Gingival inflammatory infiltration induced by retraction agents was assessed separately for the connective tissue underlying the sulcular epithelium and underlying the junctional epithelium. The surface area of inflammatory connective tissue infiltration (mm^2) was measured, and the ratio (%) of the inflammatory infiltration surface area underlying both epithelia to the total connective tissue surface area was determined (Fig 3). Statistical significance was tested by analysis of variance (ANOVA).

Results

Morphometric measurements showed that the clinically healthy gingivae that served as controls exhibited minimal connective tissue inflammatory infiltration under sulcular and junctional epithelia (Fig 2a). Specimens of gingivae treated with different retraction agents showed epithelial damage and different degrees of inflammatory infiltration.

One hour after cord removal, all treated gingival tissues demonstrated small and nonsignificant changes in the mean area of inflammatory infiltration relative to the control group (Fig 4). At 1 day after cord removal, the inflammatory infiltration area was significantly larger in tissue specimens treated with Racestyptine, Rastringent, and Gingiva Liquid compared to the control group and Visine ($P < .05$). Among specimens taken at 1 week, those treated with Racestyptine demonstrated the largest area of connective tissue inflammatory infiltrate, differing significantly ($P < .05$) from the degree of inflammation in

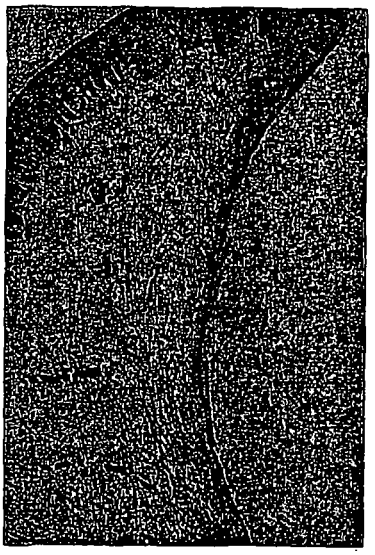

Fig 3a Relatively small inflammatory infiltration area in the connective tissue subjacent to the sulcular and junctional epithelia (green) (original magnification × 40).

Fig 3b Total area of healthy and inflamed connective tissue subjacent to the sulcular and junctional epithelia in the control specimen (green). The *arrow* indicates the transition between the sulcular and junctional epithelia (original magnification × 40).

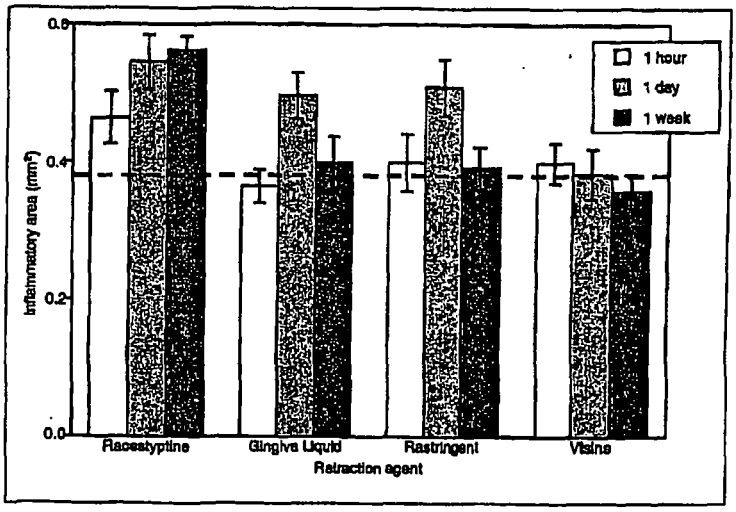

Fig 4 Inflammatory infiltrated area of treated specimens in the connective tissue underlying the sulcular epithelium relative to the control values; dashed line = 0.38 ± 0.03 mm². The areas were measured at three different time intervals after cord removal.

the controls and in specimens treated with the other retraction agents.

Racestyptine-treated tissue showed the largest area of inflammatory infiltration in the connective tissue underlying the junctional epithelium 1 hour, 1 day, and 1 week after cord removal. However, there were no statistically significant differences between specimens treated with Racestyptine and the controls, or specimens treated with the other retraction chemicals.

Discussion

Retraction agents were placed 10 days after the hygienic phase, although morphometric measurements of control specimens showed that there still existed 8.6% ± 0.5% connective tissue infiltrated with inflammatory cells. According to Page and Schroeder,[12] the obtained percentage lies between clinically healthy gingiva and initial gingivitis. Clinically healthy gingiva may contain up to 5% inflammatory cells in the connective tissue, while in early gingivitis this figure may increase up to 15%. After the hygienic phase, clinically healthy gingiva was achieved in the study dogs. Similarly, in clinical practice, prosthodontic treatment should start when clinically healthy periodontal tissues are demonstrated by clinical parameters (PI, GI, PD), without any information about tissue infiltration on the histologic level.

In our study, we applied retraction agents in intact sulci where no crown preparation was performed. This decision was based on the prerequisite that we must not in principle injure the gingiva during clinical preparation of teeth. Mechanical trauma per se may induce an inflammatory response of the gingiva during prosthodontic procedures, and so comparative results regarding the inflammatory effects of agents would not be realistic.

Semiquantitative evaluation of gingival inflammatory infiltration induced by a 10-minute exposure to a single aluminum chloride retraction agent at different concentrations in beagle dogs has been reported in the literature. Tissue specimens were obtained at 30 minutes, 1 day, 3 days, and 14 days after the treatment.[7] A comparable experimental procedure was used in our study, but histologic analysis of specimens was greatly improved due to computer-assisted morphometric measurement of the inflammatory response.

Studies dealing with the effects of retraction agents have mainly dealt with the evaluation of clinical parameters, such as the hemostatic effect following the removal of cords from sulci,[13] clinical effects exerted by different retraction agents and cords,[14] video recording of the rate of closure of the gingival crevice,[15] and assessment of the retraction times necessary for adequately dilated sulci.[16] Our experiment, however, was focused on a comparison of the inflammatory response triggered in the connective tissue, which was assessed morphometrically.

The occurrence of subepithelial inflammatory cell infiltrate was described in a study that compared the effects of a copper band, medicated retraction cords, and electrosurgery on human periodontal tissues. A 5-minute exposure of gingiva to an adrenalin-impregnated retraction cord was reported to trigger an inflammatory response, which declined to the values of control specimens in 8 days.[17] A similar dynamic of inflammatory response was observed in our study for all tested agents, except the 25% aluminum chloride.

Contrary to the above-citied experiment, a semiquantitative study of the effects of three different retraction chemicals on healthy human periodontal tissue showed no significant difference between specimens treated with different retraction agents or between the treated and control specimens at 1 day or 1 week after treatment. The diversity of the results was attributed to physiologic differences among the individuals studied.[6] Beagle dogs with similar genetic characteristics were used in our study to increase the homogeneity of the group studied. The small standard deviations of the data confirm similar gingival response of the treated animals to the applied stimuli.

The retraction agents tested provoked a transitory inflammatory response in the gingival tissues that persisted for more than 1 week only in tissue specimens treated with Racestyptine.

Acknowledgments

The authors acknowledge Prof Zlatko Pavlica, Veterinary Clinic, University of Ljubljana for help with experimental animals, and Mr Marko Slak and Mr Milan Števanec for technical assistance.

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Literature Abstracts

Denture base polymer Alident Sinomer: Mechanical properties, water sorption and release of residual compounds.

This study evaluated a new paste-type denture base polymer, Alident Sinomer, in terms of its flexural properties, water sorption, solubility, and release of residual compounds. The study compared the denture base polymer with or without reinforcement using a preimpregnated continuous glass fiber (Stick). Four groups were included: *(1)* unreinforced, stored dry; *(2)* unreinforced, stored in water for 7 days; *(3)* reinforced with one Stick fiber; and *(4)* reinforced with three Stick fibers. Both reinforced groups were stored in water for 7 days. The flexural strength and flexural modulus were measured using the three-point bending test, and the data were analyzed with one-way ANOVA. Water sorption and solubility were tested according to the ISO 1567 standard. The release of residual compound was determined with the high-performance liquid chromatography method. There were no significant differences in the flexural properties among the first three groups ($P < .05$). The group reinforced with three Stick fibers showed significantly higher flexural strength and modulus compared to the other groups. The released compounds were determined to be methyl(methacrylate) monomer. It was concluded that the mechanical properties, water sorption, and solubility values of the polymer Sinomer are acceptable according to ISO requirements.

Lassila LVJ, Vallittu PK. *J Oral Rehabil* 2001;28:807–813. References: 17. Reprints: Dr L. V. J. Lassila, Institute of Dentistry & Biomaterials Project, University of Turku, Lemminkäisenkatu 2, FIN-20520 Finland. e-mail: lippo.lassila@utu.fi—*Swee-Chian Tan, Iowa City, Iowa*

The relationship between non-working-side occlusal contacts and mandibular position.

The aim of this study was to test the hypothesis that the nonworking-side contact pattern varies with the mandibular position. Occlusal contacts of 86 young adults were examined using shim stock (10- to 15-μm-thick occlusal registration strips) in standardized lateral positions: 0.5, 1, 2, and 3 mm from maximum intercuspation. The 3-mm position was an edge-to-edge position. The frequency of nonworking-side contacts was significantly greater in the 0.5- and 1-mm positions than in the 3-mm position. Nonworking-side occlusal contacts occurred in nearly half of the 0.5-mm positions. There were fewer nonworking-side contacts with canine protection than with group function for the 0.5- and 1-mm positions. It was concluded that the nonworking-side contact pattern varied with the mandibular position. Based on these results, it was suggested that clinical examination should include contact patterns both in a position close to maximum intercuspation and in an edge-to-edge position, ie, in functional and parafunctional ranges. Data from occlusal contact research should also include a standardized definition of mandibular position.

Ogawa T, Ogimoto T, Koyano K. *J Oral Rehabil* 2001;28:976–981. References: 28. Reprints: Dr Takahiro Ogawa, The Weintraub Center for Reconstructive Biotechnology, Division of Advanced Prosthodontics, UCLA School of Dentistry, 10833 Le Conte Avenue (B3-068 CHS), Box 951668, Los Angeles, California 90095-1668. e-mail: tack@dent.kyushu-u.ac.jp—*AW*

in vitro

Electron microscopic analysis of the effects of chemical retraction agents on cultured rat keratinocytes

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Statement of problem. Chemical retraction agents used in fixed prosthodontics for temporary displacement of free gingival tissue before impression making can cause injury to the gingival tissue cells.
Purpose. This study evaluated changes in cultured rat keratinocytes treated with 2 chemical agents used for gingival retraction. Treated cultures were compared with untreated cultures.
Material and methods. Keratinocytes of rat gingiva were grown in a specific medium for 10 days. After treating 1 group of specimens with 0.05% tetrahydrozoline and another group with 25% aluminum chloride, both for 10 minutes, the cultured cells were examined with scanning and transmission electron microscopy and compared with control specimens.
Results. Twenty-five percent aluminum chloride produced a significantly greater extent of cellular damage than 0.05% tetrahydrozoline, which caused only mild changes in the cultured cells.
Conclusion. On the basis of the morphologic and ultrastructural changes in primary cell cultures of rat keratinocytes observed in this study, it was concluded that 25% aluminum chloride was significantly more aggressive than 0.05% tetrahydrozoline.() Prosthet Dent 2002;87:51-6.)

CLINICAL IMPLICATIONS

In this animal study, 0.05% tetrahydrozoline had fewer adverse effects on epithelial cells than the astringent 25% aluminum chloride. Tetrahydrozoline can be recommended for clinical use in fixed prosthodontics.

The use of quality impression materials, proper impression techniques, and temporary displacement of free gingiva before impression making are essential to the accuracy of fixed prosthodontic impression procedures. This is especially the case in shoulder or chamfer preparations with the preparation finish-line located slightly subgingivally or at the level of the free gingiva.

The use of retraction cords impregnated with various chemical retraction agents is one of the most widely adopted techniques for temporary gingival tissue displacement.[1] The optimum retraction agent will enable satisfactory gingival retraction and have as few local or systemic adverse effects as possible. Retraction agents are classified by their chemical composition in a group of commonly used agents, which include aluminum chloride, aluminum sulphate, ferric sulphate, and epinephrine, and in a group of sympathomimetic vasoconstrictors such as tetrahydrozoline.[2] These new agents are supposed to produce only slight local damage and to have no systemic adverse effects.[3]

All standard chemical retraction agents are acidic solutions with pH values from 0.8 to 3.0, and all are potentially harmful to cut dentin and periodontal tissues. In vivo animal and human studies have shown that these chemicals tend to damage the sulcular and junctional epithelium, and the most aggressive among them damage even the connective tissue.[4,5] Toxic effects of chemical agents in clinical studies, corroborated by histologic evidence, have been reported by several authors.[6-9] Recently, cell cultures have been used to determine the irritation potential and toxicity of various agents,[10] whereas in the past, these investigations were performed in vivo with the Draize rabbit eye irritability test.[11] In vitro tests are used for preliminary screening of all chemical agents, which significantly reduces the number of animals required for in vivo tests. In vitro tests therefore constitute a more cost-effective option, provide for greater accuracy and reproducibility, and correlate well with in vivo studies.[12]

Most in vitro cytotoxicity assays use cell lines that are less differentiated (diploid fibroblasts) or permanent (He-La cells).[13,14] A previous study with V-79 fibroblasts indicated that individual chemical retraction agents differ significantly in their degree of cytotoxicity.[15] The greatest proportion of cultured cells were damaged by 25% aluminum chloride (Racestyptine; Septodont, Saint-Maur-des-Fosses

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Cedex, France), and the least proportion by 0.05% tetrahydrozoline (Visine; Pfizer, Arnprior, Ontario, Canada). The same tests are feasible on tissue cells that are more differentiated, yet culturing these cells for experimental work is more laborious.[13]

The purpose of this study was to investigate, with scanning and transmission electron microscopy (SEM and TEM), the potentially destructive effects of 0.05% tetrahydrozoline and 25% aluminum chloride on cultured rat keratinocytes. Rat tissue specimens were used because of the similarity between the histologic patterns of human and rat gingiva[16] and because a large number of specimens was needed for measurements. Although Land et al[17] used SEM to examine cut dentin treated with retraction agents, and although the harmful effects of such agents have been extensively documented, the use of both SEM and TEM for evaluation purposes has not been described in the literature. The use of these complimentary methods and high magnification allowed even subtle morphologic changes in cell surface and ultrastructure to be identified.

MATERIAL AND METHODS

Explants were derived from the gingiva of adult male white Wistar rats that weighed approximately 200 g each. Gingival specimens were obtained from the anterior gingival region buccally and lingually to the maxillary and mandibular incisors and palatally to the maxillary molars. The specimens were cut into 2- to 3-mm^2 pieces and then transferred to a Cyclopore membrane culture support (Falcon, Becton Dickinson, Franklin Lakes, N.J.). The pieces, 3 in each tissue culture well, were spread over the porous bottom of the membrane insert, which provided close contact with the tissue. The total number of pieces was 246.

Culture medium was added and replaced every 3 days. The cultures were incubated at 37°C in a humidified 5%–CO_2 atmosphere for 10 days. One day after the gingival explant attachment to the porous membrane, keratinocytes began to migrate over the membrane, and at 10 days, they formed a culture 4 to 6 layers thick. In this study, only keratinocytes growing over the porous membrane were used.

Retraction agents were applied directly to the cell cultures after removal of the culture medium; this procedure mimicked the clinical use of these chemicals. Thirty-six cultured pieces served as controls. Half of the remaining cultures (N = 105) were treated with 0.05% tetrahydrozoline; the other half (N = 105) were treated with 25% aluminum chloride for 10 minutes and then washed with phosphate-buffered saline solution.

Culture medium

Cell cultures were grown in a differentiated medium consisting of MCDB 153 (Sigma Chemical Co, St. Louis, Mo.) and Dulbecco's modified Eagle's medium (Gibco, Paisley, Scotland) at a ratio of 1:1, supplemented with 0.1 mmol/L ethanolamine, 0.1 mmol/L phosphoethanolamine, 15 μg/mL adenine, 0.5 μg/mL hydrocortisone, 5 μg/mL insulin, 20 ng/mL epidermal growth factor (EGF), 0.7 mmol/L $CaCl_2$, 100 μg/mL streptomycin, 100 U/mL penicillin, and 0.1 mmol/L nystatin. To the epithelial cell culture medium, 10% fetal calf serum (FCS) comprising amino acids needed for culture growth was added. (All cell culture supplements were obtained from Sigma-Aldrich, Diesenhofen, Germany).

Scanning and transmission electron microscopy

All specimens were fixed with 2.5% glutaraldehyde and 4% paraformaldehyde in 0.1M cacodylate buffer (pH 7.4) with 0.05% calcium chloride and 4% saccharide at 20°C for 2 hours. The specimens were rinsed with 0.1M cacodylate buffer, postfixed with buffered 1% OsO_4, and dehydrated with ethanol at increasing concentration. The porous membrane with cultured cells was cut into small pieces. The pieces were dried at a critical point and spattered with gold. The specimens then were examined at 15 kV under an electron microscope (JSM840A; JEOL Ltd, Tokyo, Japan).

The fixation procedure for transmission electron microscopy was the same as described above. The specimens were rinsed with 0.1M cacodylate buffer and postfixed in 1% OsO_4 at 40°C for 1 hour. After dehydration at increasing alcohol concentration, the specimens attached to the porous membrane were cut into small pieces and embedded in epoxy resin (Epon 812; Serva, Heidelberg, Germany). Ultra-thin sections (40 nm) were contrasted with lead citrate and uranyl acetate and examined under a transmission electron microscope (100 CX; JEOL Ltd).

RESULTS

Control group. Flattened polygonal superficial cells were covered with microvilli, which sometimes formed short microcrests and expanded from the cell periphery toward the center. Occasionally, the whole cellular surface was covered with crests (Fig. 1, *A*). Morphologically, cells at the periphery differed significantly from cells contained in layers. The stellate cells were 1-layer thick, were covered with microvilli, and had long and thin protrusions resembling filopodia (Fig. 1, *B*).

The multilayered epithelium-like structure was visible under the transmission electron microscope as well. All cultured cells, from basal to superficial, were markedly flattened and contained large oval nuclei. Numerous mitochondria and a well-developed endoplasmic reticulum were discernible in the basal cell layers. Junctions between cellular basolateral mem-

branes were provided by numerous desmosomes. Tonofilament bundles were present in the cytoplasm, predominating in the intermediate and superficial cell strata. Occasionally, intermediate type filaments were present in the form of intertwined tonofibrils (Fig. 1, *C*).

Cell culture treated with 0.05% tetrahydrozoline. No relevant changes were noted in the superficial structure of the epithelial cells after a 10-minute treatment with 0.05% tetrahydrozoline compared with that of the control specimens. Superficial cells remained flat and polygonal in shape and were covered with numerous microvilli. They were mostly connected (Fig. 2, *A*), yet some cell surfaces were without close contact to adjacent cells and were only sparsely covered with microvilli, which gave them a smoother appearance than the control cells. Stellate cells at the periphery were 1-layer thick and had a number of filopodia-like protrusions that were shorter than those in the control group. The cells bore large numbers of microvilli on their surface (Fig. 2, *B*).

Under the transmission electron microscope, several (6 or fewer) layers of cells were seen; their ultrastructure was similar to that in the control group. Intercellular junctions were provided by desmosomes or long protrusions, separated by large intercellular spaces, which were discernible mostly in the superficial layer cells (Fig. 2, *C*).

Flattened cells of the basal layers contained large oval nuclei and a well-developed endoplasmic reticulum. There was an increase in the number of tonofilament bundles and a decrease in the number of cellular organelles from the base to the surface of the multilayered culture. The superficial cell layers were separated from the lower ones and had numerous cytoplasmic elongations. In the superficial layer cytoplasm, no cellular organelles but rather a variety of vacuoles and large numbers of tonofilaments were noted.

Analysis by means of the scanning and transmission electron microscopes showed no significant differences in terms of shape, surface, or ultrastructure between treated and control cells, which confirmed the relatively mild effect of 0.05% tetrahydrozoline.

Cell culture treated with 25% aluminum chloride. Structural features of cells exposed to 25% aluminum chloride for 10 minutes differed significantly from those of the control group. The cells remained flattened, but there was no contact between them. The extent of cellular damage was notably greater than that in the control group and in the 0.05% tetrahydrozoline group. As a result of exposure to 25% aluminum chloride, not only superficial intercellular junctions but also lower cell layers were destroyed. Microvilli on the cell surface were less distinctive than in the control group (Fig. 3, *A*). Among numerous flattened cells without

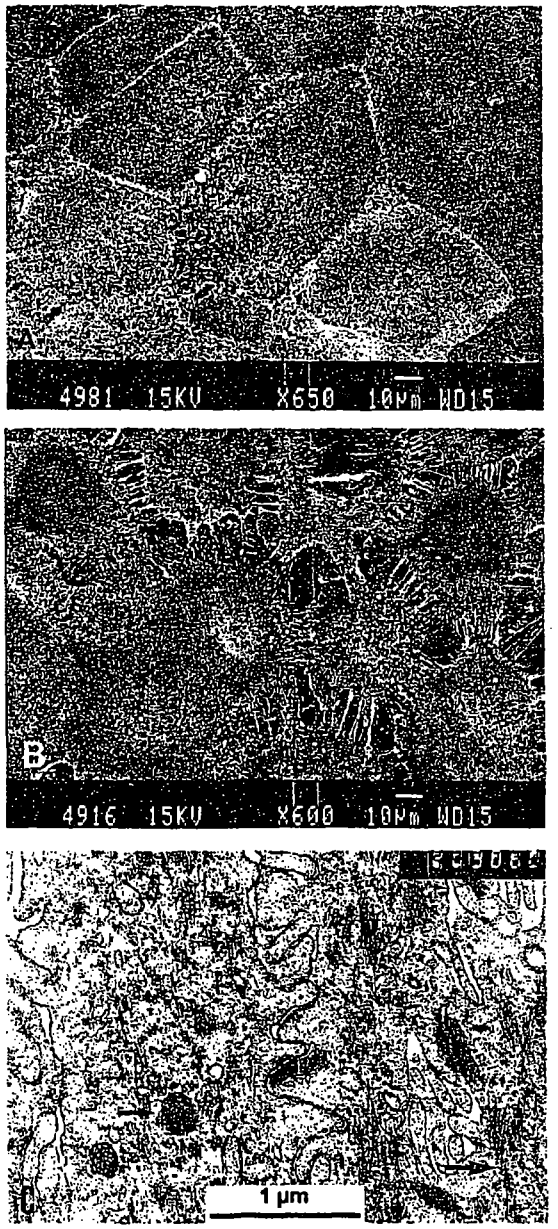
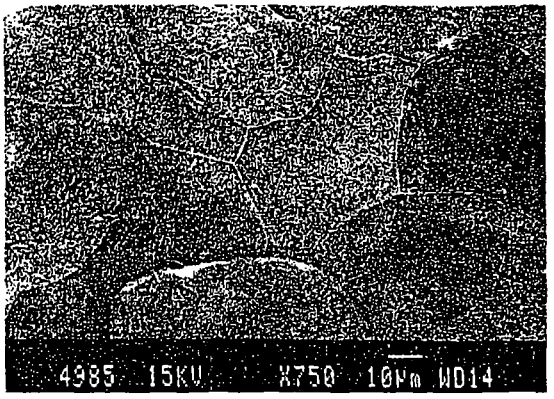
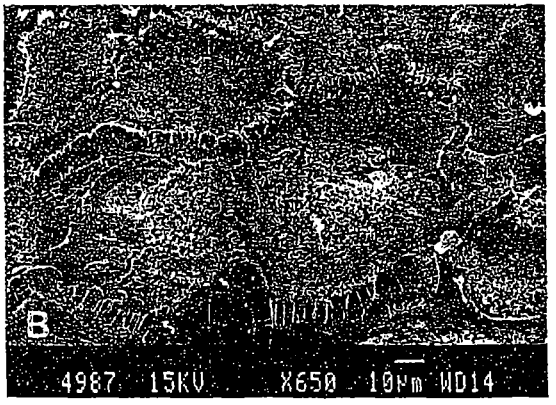


Fig. 1. A, Tight adhesion between polygonal cells of superficial keratinocyte layers in control group. Cellular surface was covered with large number of microcrest-forming microvilli (SEM, original magnification ×650). **B,** One-layer-thick epithelial cells at periphery of explant culture. Numerous long structures resembling filopodia grew from cell surface (SEM, original magnification ×600). **C,** Cells in intermediate layer were connected with numerous desmosomes and contained tonofilament bundles (large arrow), intensely staining dense granules (small arrow), and sparse mitochondria (TEM, original magnification ×20,000).





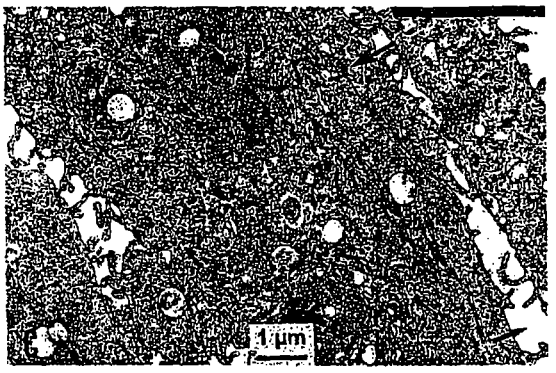
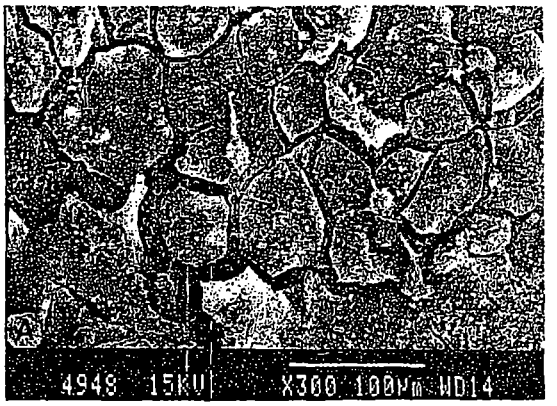
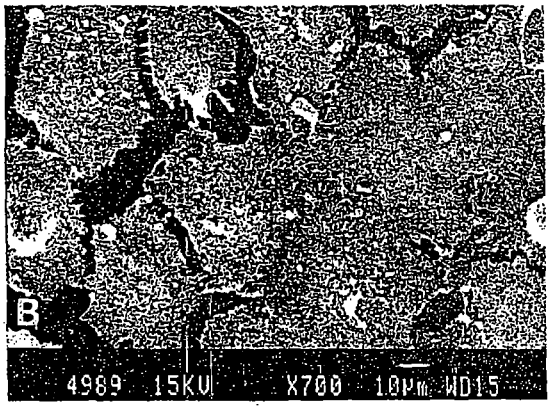


Fig. 2. A, Surface of explant culture central area after 10-minute treatment with 0.05% tetrahydrozoline. Flattened polygonal cells resembled cells in control samples, were closely connected, and bore numerous microvilli on surface (SEM, original magnification ×750). B, Epithelial cells from periphery of explant culture after 10-minute treatment with 0.05% tetrahydrozoline. Stellate cells had short filopodia that provided junction with adjacent cells (SEM, original magnification ×650). C, Cell cultures maintained for 10 days and treated with 0.05% tetrahydrozoline were connected by desmosomes *(large arrow)*, yet there was loss of adherence between superficial and basal layers *(small arrow)*. Various vacuoles were present in intermediate layer cells (TEM, original magnification ×6600).





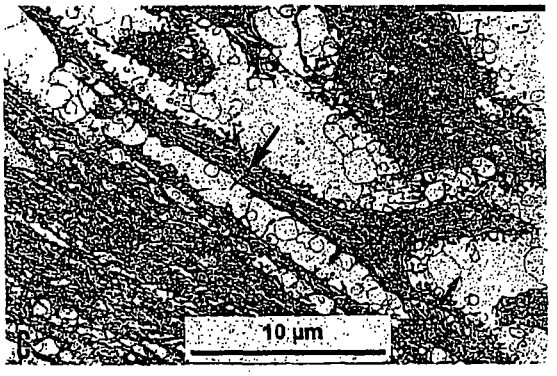


Fig. 3. A, Epithelial cells after 10-minute exposure to 25% aluminum chloride were flattened, polygonal in shape, and separated from each other (SEM, original magnification ×300). B, Cells at periphery of explant culture were extremely flattened and polygonal in shape and had very short, filopodia-like protrusions. Occasional spherical cells were discernible between individual polygonal cells (SEM, original magnification ×700). C, Cross section of epithelial cell layers after 10-minute exposure to 25% aluminum chloride disclosed notable changes in all cell layers compared with those of control samples. No organelles were discernible in cytoplasm. Cell layers were separated by large intercellular spaces *(small arrow)*. Chromatin was condensed at nuclear lining *(large arrow)* (TEM, original magnification ×3300).

regions of cell junctions, sparse spherical, flattened, and elongated cells were seen at the periphery. They were 1-layer thick and had no filopodia (Fig 3, *B*).

Electron microscopic images indicated that cultures exposed to 25% aluminum chloride demonstrated a considerably greater extent of cell damage than cells treated with 0.05% tetrahydrozoline and control samples. The most evident change was a nearly complete destruction of cell junctions in the studied group of specimens.

Under the transmission electron microscope, multilayered keratinocyte cultures formed long threads of cells, which in some areas were completely separated from each other. Between the cells joined by long and thin projections, there were large intercellular spaces. Desmosomes were discernible only in the cells of the basal strata. Cell ultrastructure was notably altered. Mitochondria, ribosomes, and endoplasmic reticulum were no longer discernible in the cells. The nuclei were notably flattened and contained condensed chromatin clusters at the nuclear envelope. Cell separation extended into deeper layers of the explant culture. The cytoplasm had a fine-grained texture and contained no cell organelles. Sparse electron-dense areas and a number of vacuoles were noted (Fig. 3, *C*). Alterations caused by the harmful effects of 25% aluminum chloride involved even the basal cell layers of the explant culture. The aggressiveness of this chemical relative to 0.05% tetrahydrozoline was confirmed by the observed loss of intercellular junctions and notable changes in the cellular ultrastructure.

DISCUSSION

The effects of retraction chemicals on keratinocytes may differ from those induced in fibroblasts. Since healthy gingival epithelium forms a barrier to physical and chemical insults,[18] it is supposed to reduce direct harmful effects exerted by retraction chemicals. In clinical practice, agents are placed directly on the sulcular epithelium in their original concentrations by means of cotton cords. By analogy, the retraction agents in this assay were applied directly to the cell cultures. If they had been added to the culture medium, their concentrations would not have been the same as those used clinically.

Terminal differentiation of the surface cells of the sulcular epithelium can be established experimentally in human beings only after supervised, meticulous daily plaque control for several weeks. Keratinocytes in the culture did not reach terminal differentiation, which leads to the speculation that the effects of retraction agents are more pronounced in in vitro conditions. In clinical practice, the action of chemical retraction agents may be less intense because they are diluted by gingival fluid. Despite incomplete differentiation, epithelial cell cultures provided a suitable model for this kind of study given that, in normal clinical conditions, the sulcular epithelium does not reach the terminal stage of cytodifferentiation.

It may be that cell differentiation in the superficial layers of the explant culture did not reach the stage of differentiation observed in rat gingival keratinocytes in vivo. This observation accords with the results of another study on long-term cell culture.[19] In the process of differentiation, immature cells acquire morphologic and functional characteristics of mature cells. Compared with lower cell layers, superficial keratinizing layers of the differentiated oral epithelium contain an increased number of desmosomes, keratin-containing cytoplasm, and intermediate filaments (cytokeratins), which is characteristic of the terminal stage of cell differentiation.[20]

The absence of intercellular junctions in cell cultures treated with 25% aluminum chloride probably was the result of protein denaturation. Specific characteristics of astringens have been described by Felpel.[21] Nonselective protein denaturation seems to be responsible for the loss of intercellular junctions, which are provided by transmembranous proteins. Changes in the number and arrangement of microvilli on the epithelial cell surface most likely were caused by the direct denaturation effect of the chemical agents as well. These changes were characteristic of cells treated with 25% aluminum chloride, whereas cultures exposed to 0.05% tetrahydrozoline showed greater similarity to control cell specimens. In view of the small differences in both the superficial structure and ultrastructure of tetrahydrozoline-treated and control cells, it can be concluded that the treated specimens retained the essential functions characteristic of epithelial cells.

The marked morphologic changes in the aluminum chloride-treated specimens seemed to be reflected in altered cellular and, consequently, epithelial functions. The disappearance of cell organelles results in a loss of ability to maintain and provide energy for metabolic function and growth. Intercellular junctions are disconnected, which leads to cellular separation and desquamation; these, in turn, cause a breakdown of epithelial integrity. Typically, chromatin condenses next to the nuclear membrane, which suggests that the concentration of aluminum chloride used in this study causes apoptotic cell death.

Morphologically altered cells with impaired basic cellular functions cannot perform their original roles. A healthy epithelium has a protective function, but the action of aggressive agents causes desquamation and cell death, advancing deep into the culture and reaching even the most inferior layers. Viewed from the clinical aspect, the damaged epithelium not only loses its protective role but exposes the gingiva even more to harmful effects from the environment.

The described methodology and results obtained

show promise for further investigations into the harmful effects of retraction agents used in dental care.

CONCLUSIONS

Scanning and transmission electron microscopy were used to evaluate ultrastructural changes in keratinocytes after treatment with chemical agents. The results disclosed that the effect of 25% aluminum chloride on primary cultures was significantly more adverse than that of 0.05% tetrahydrozoline. The latter agent can be recommended for clinical use in fixed prosthodontics.

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0022-3913/2002/$35.00 + 0. 10/1/119681

doi:10.1067/mpr.2002.119681

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Dynamic Oxidoreductive Potential of Astringent Retraction Agents

(gingival margin retraction agents / cytotoxicity / human gingival fibroblasts). Abstract. The aim of this study was to evaluate the dynamics of the cytotoxicity of gingival margin retraction astringents based on aluminium chloride, aluminium sulphate, and ferric sulphate (solutions and gels) in human fibroblasts isolated from gingiva. The cytocompatibility of ten astringent-based chemical retraction agents: Gingiva Liquid, Alustin, Racestypine, Orbat sensitive, Astringedent®, Alustat, Hemostat, Racécord, Gel cord and ViscoStat®, in dilutions of 1 : 10 and 1 : 20, with human gingival fibroblasts was investigated. The MTT assay was performed to determine oxidoreductive mitochondrial function after 3, 5, 10 min and 24 h of incubation. Cell viability was determined according to the chemical group, concentration, exposure time, and the clinical form of the gingival retraction agents. Ferric sulphate-based agents were the most cytotoxic, followed by aluminium chloride and aluminium sulphate. The form of the astrigents influenced cell viability. The evaluated astringents may have cytotoxic potential for gingival margin tissues under clinical conditions.

Previous article: La Bataille du rail

Next article: Corrections

Publication: Folia Biologica
Author: Nowakowska, D
Date published: November 1, 2010

Introduction

Gingival margin retraction is a commonly accepted procedure in modem restorative dentistry. Providing visibility and easy access to a clean and dry gingival sulcus, it creates optimal conditions for performing direct and indirect tooth restoration. This is especially important for subgingival finish-line imaging using conventional impression materials or CAD/CAM digital/ optical techniques, for fixed dental restoration, and for adhesive methods very useful in aesthetic dentistry (Bennani et al., 2008).

Gingival retraction agents (GRAs) are used in clinical practice in the form of gingival retraction fluids (GRFs) or gingival retraction gels (GRGs) (Nowakowska and Panek, 2007). With respect to the pharmacological effects of the active substance, they belong either to class 1 (vasoconstrictors, adrenergics) or class 2 (haemostatics, astringents) (Nowakowska, 2008). Chemical retraction agents based on aluminium chloride, aluminium sulphate, ferric sulphate, and, less frequently, zinc chloride and aluminium potassium sulphate are astringents (Shillingburg et al., 1980). The above-mentioned survey demonstrated that over 80 % of dentists applied astringents for gingival margin retraction in clinical practice (Donovan et al., 1985; Hansen et al., 1999, Nowakowska et al., 2006b). Chemically, all the retraction agents containing astringents are characterized by a relatively high level of acidity, with their original concentrations ranging from pH 1 to pH 3 for solutions (Woody et al., 1993; Land et al., 1994, 1996; Ayo-Yusuf et al., 2005). Our previous study of the pH levels of commonly used astringents in solution and gel form found that the pH values of these agents both in the original concentrations and in dilutions of 1 : 10 and 1 : 20 were surprisingly low (Nowakowska and Raszewski, 2009).

Astringents containing conventional non-injectable (packing) materials and the newly developed injectiontype retraction materials to be placed in the gingival sulcus remain in direct contact with free gingival margin tissues for some time and are also in contact with mineralized tooth structures prepared

by cutting. The practical application time of these substances reported in clinical studies were from 2 to 30 min (De Gennaro et al., 1982; Akca et al., 2006).

In numerous studies, the effectiveness of astringents under clinical conditions was evaluated positively. However, in vivo and/or in vitro observations showed that they induce undesirable local side effects on gingival margin tissues (De Gennaro et al., 1982; Azzi et al., 1983; Nemetz et al., 1984; Weir and Wiliams, 1984; Benson et al., 1986; Kopac et al., 2002a,b,c; Akca et al., 2006; Kumbuloglu et al., 2007; Al-Hamad et al., 2008). These authors demonstrated studies with human and animal models using various research methods that confirmed inflammatory response of the surrounding soft tissues. This was demonstrated by different methods: histomorphometric (De Gennaro et al., 1982; Kopac et al., 2002b,c; Akca et al., 2006), gingival crevicular fluid (GCF) flow measurements (Feng et al., 2006; Wöstmann et al., 2008), and of GCF analysis, for example TNF-a proinflammatory cytokine levels (Feng et al., 2006). The inflammatory response was normally transitory and its severity depended on the type and concentration of the retraction agent. Results obtained by SEM-EDX techniques reported an altered morphology of prepared human dentine surface after exposure to conventional astringents containing gingival retraction fluids (Land et al., 1994, 1996; Ayo-Yusufet al., 2005).

Cytotoxicity evaluation of human cell colonies is one of the most objective methods for assessing the biocompatilibity of dental materials and agents (Phillips, 1973; Mosman, 1983). Only Kopac et al. (2002a) studied this on Chinese hamster diploid lung fibroblasts (V-79-379 A) and Lodetti et al. (2004) evaluated keratinocyte viability after treatment with astringent-based agents. In an attempt to determine the safety level of retraction agents by human fibroblast viability evaluation, a newly developed method by Saczko et al. (2008) seems most valuable and appropriate.

The aim of this in vitro study was to evaluate the dynamic cytotoxic effects of different gingival retraction astringents, both solutions and gels, on human fibroblasts isolated from patients' gingival tissues.

Material and Methods

Retraction astringents

Ten gingival retraction agents from three different chemical groups (aluminium chloride, aluminium sulphate, and ferric sulphate), including five solutions and five gels, were selected for this study. Experiments with the original concentrations of all the gingival astringents, cell culture viability from 0 to 2 % were determined. The commercially available agents were diluted 1:10 and 1 : 20 with deionized water. Their characteristics and pH values are presented in Table 1 .

Cell cultures

The tissue cultures of human gingival fibroblasts (Fig. 1) were obtained from patients with healthy periodontium undergoing tooth extraction. The gingival biopsies were provided by the Department of

Dental Surgery of Wroclaw Medical University. The cells were isolated from the healthy gingival tissues according to the procedure described by Saczko et al. (2008). The cells were grown routinely in Dulbecco's Modified Eagle's medium (DMEM). DMEM (Sigma, St. Louis, MO) supplemented with 10% FBS and glutamine with penicillin/streptomycin (Sigma) in 25-cm2 flasks (Falcon, Franklin Lakes, NJ). The cells were maintained in a humidified atmosphere at 37 oC and 5% CO,. For experimental purposes, the cells were removed by trypsinization (0.25% Trypsin-EDTA, Sigma).

Cytotoxicity test

The MTT (3-(4,5-dimethyl-2-thiazollyl)-2,5-diphenyl-2H tetrazolium bromide) assay (Sigma) was used to evaluate the cytotoxicity of the gingival retraction astringents. Cells were seeded onto 96-well plates at a concentration of 5 ? 10"' cells/well. For the viability assay the cells were exposed to different gingival retraction agents. Following incubation for 3, 5, and 10 min and 24 h at 37 oC, the cells were washed twice in phosphate-buffered saline (PBS) (Invitrogen, Carlsbad, CA) and treated according to the manufacturer's protocol. The absorbance was determined using a multi-well scanning spectrophotometer at 570 nm (Multiscan MS, Helsinki, Finland). The results were expressed as the percentage of untreated control cells.

Statistics

The significance of differences between the mean values of different groups of cells compared with the control group (untreated cells) was assessed by Student's /-test, with values of $P < 0.05$ taken to imply statistical significance.

Results

The influence of three retraction astringent groups on gingival fibroblasts was investigated. Oxidoreductive mitochondrial function is shown in Fig. 2. In the group of retraction astringents that contained aluminium chloride (solution- and gel-based), the oxidative mitochondrial function of the fibroblasts was similar at a dilution of 1:10. After 3 min of incubation, the levels of viability were about 100 %, i.e. comparable to that of the control cells (Fig. 2 A). The 10% aluminium chloride agent (Gingiva Liquid) was the least cytotoxic of all the agents in the 1 : 20 dilution. Cells treated for 5 min with these compounds displayed significantly lower oxidative mitochondrial function at both dilutions than the control cells (1 : 10, 1 : 20) (Fig. 2 A), whereas after 10 min of incubation an increase in oxidative mitochondrial function in Gingiva Liquid-treated cells was observed, higher than in the control cells. The level of viability was comparable to that of the control cells for cells incubated with 20% (Alustin) and 25% aluminium chloride (Racestypine) at both dilutions (Fig. 2 A). The greatest damage to mitochondrial function was observed in cells treated with 25% aluminium chloride in gel form (Racécord gel). The results for the 20% aluminium chloride gels (Hemostat and Alustat) indicated cell viability (40

to 70 %) for both 3 and 5 min incubation (Fig. 2 B). Twenty-four-hour incubation with the retraction astringents resulted in the highest level of damage to mitochondrial function (Fig. 2 B).

For the agents containing aluminium sulphate we noted a significant increase in mitochondrial function compared with those based on aluminium chloride. Oxidative mitochondrial function was 1 10% for the 1:10 dilution and 140% in the cells treated with 25% aluminium chloride in liquid form (Orbat sensitive) and from 1 20% (1 : 1 0) to 1 30% (1 : 20) in the gel form (Gel cord) (Fig. 2 C). The level of viability decreased significantly in cells after 5 min of incubation and was similar to that of the cells after 10 min (Fig. 2 C). The levels of fibroblast viability were higher with the 1 : 20 dilutions and increased similarly to the control cells for sulphate aluminium, but were on the same level as that of sulphate aluminium in the gel form. Both forms of the astringents were cytotoxic after 24 h of incubation.

The agents based of ferrous sulphate demonstrated the statistically significant lowest level of viability (Fig. 2 D). After 3 min of incubation, oxidative mitochondrial function was below 50 % in the 1:10 dilution and at 1 : 20 viability increased to 90 %. Oxidative mitochondrial function decreased to below 50 % after 5 min and was on the same level for both dilutions, but after 1 0 min it rose to above 50 % for both ferrous sulphate retraction agents (Astringedent" solution and ViscoStaf gel, Ultradent Product, South San Francisco, CA).

Discussion

According to the guidelines of the American National Standards Institute (ANSI) and the Technical Report ISO-TR 7405 of the ISO Technical Committee concerning dentistry (TC 1 06), in vitro cytotoxic screening investigations of different cell cultures is commonly accepted as adequate for dental devices for the primary determination of their biocompatibility (Kopac et al., 2002a). In clinical practice, retraction agents are applied with retraction materials or incorporated in retraction materials directly into the gingival sulcus. They remain there until effective shrinkage and displacement of free gingiva away from tooth structures and haemostasis is obtained. Hence they remain in direct contact with the thin monolayer of epithelial cells in the gingival sulcus and the connective epithelium (epithelial attachment) at the bottom of the sulcus. Many authors observed an inflammatory response or even necrosis of the sulcular epithelium and subepithelial connective tissue induced by gingival margin retraction agents with an astringent base (De Gennaro et al., 1982; Azzi étal., 1983;Nemetz et al., 1984; Weir and Wiliams, 1984; Benson et al., 1986; Akca et al., 2006; Kumbuloglu et al., 2007; Al Hamad et al., 2008). Under these conditions, chemical agents influence the gingival connective tissues directly. The choice of primary cells cultured from fibroblasts obtained from patients with healthy periodontal tissue undergoing tooth extraction seems to be the most appropriate for constructing an adequate in vitro study model.

Only Kopac et al. (2002a) and Lodetti et al. (2004) studied the cytotoxic effects of gingival retraction fluids on cell cultures using the MTT assay. Kopac et al. (2002a) evaluated the viability of fibroblasts

obtained from Chinese hamster diploid lung (V-79-379 A) treated with astringents based on aluminium chloride and sulphate. After 1 min of exposure, all chemical agents in the original concentrations caused stronger cytotoxic effects than in 1 : 10 dilution. At a 1 : 10 dilution of the agents, the viability of Chinese hamster lung fibroblasts treated with 25% aluminium chloride was significantly lower than that of fibroblasts incubated with 10% aluminium chloride and 20% aluminium sulphate. The study of Lodetti et al. (2004) demonstrated the cytotoxic effects of astringent retraction solutions on human oral keratinocytes. The most damaging was the agent Astringedent X", which contains ferric sulphate and ferric subsulphate.

Kopac et al. (2002c) also observed changes in primary cell cultures of rat keratinocytes after 1 0 minutes of treatment with 25% aluminium chloride used for gingival retraction. The cells, examined by scanning and transmission electron microscopy, differed significantly from those of a control group.

Chemo-mechanical methods based on two-element systems may pose the additional danger of accumulation of the cytotoxic effects of the gingival retraction agent and material. Liu et al. reported that even non-impregnated cords were cytotoxic for human gingival fibroblasts cultured from gingival expiants. Evaluation after 1 0 min and 24 h of exposure to retraction cords impregnated with aluminium sulphate also demonstrated a significant potential for gingival toxicity (Liu et al., 2004).

In clinical conditions, the duration of the chemo-mechanical retraction procedure should range from 3 to 10 min (Nowakowska et al., 2006c). Our experiments took place in four time intervals: from 0 to 3 min, 3 to 5 min, 5 to 10 min, and 10 min to 24 h after treatment with three chemical groups of astringents in different concentrations and clinical forms. The results after 3 min showed that aluminium sulphate-based retraction agents and aluminium chloride-based fluids and gels ensure a relatively high oxidoreductive potential of fibroblasts. The statistically significant lower oxidoreductive functions of cells cultured with ferric sulphate-based astringents in the first 3 min of incubation suggest limitations in their use in clinical practice. The cytotoxic effects on fibroblasts after 5 min incubation to all evaluated retraction astringents exhibited the lowest viability. The increase of the viability of fibroblasts after 10 min of exposure to all of the evaluated chemical groups provided the interesting insight that oxidoreductive mitochondrial potential was activated, which may suggest a reactive defensive action of the cells to the impact of the retraction agents. The observation after 24 h showed that all the retraction agents (except for the ferric sulphate agents) caused a cytotoxic effect. According to the results it can be stated that cell viability increases with decreasing concentration of the astringents and decreases with increasing exposure time. Retraction agents composed of ferric sulphate proved to be the most cytotoxic, followed by aluminium chloride and aluminium sulphate. It seems that the lower pH of the agent, the higher the cytotoxicity.

The agent's form proved to have a significant influence on human gingival fibroblast viability. This experiment is most probably the first examination of the cytotoxic effects of gel-based retraction

astringents on gingival cells. The results obtained at the shortest exposition, i.e. 3 min, on fibroblasts (except for the ferric sulphate gel-based agent) revealed that the agents do not induce any significant increase of the cells' mitochondrial oxidoreductive functions. The use of gel-type astringents allows reducing the area of gingival tissue exposure to the effect of the retraction agent. Additionally, gel type agents diminish the scratching effect involved when applying and removing the retraction material into and from the gingival sulcus (Nagler et al., 2002; Nowakowska et al., 2006a).

Our results can be directly extrapolated to clinical conditions, but they are predictive of the probability of the behaviour of these agents under in vivo conditions. Healthy gingival epithelium and epithelial attachment constitute a natural barrier protecting the connective gingival tissues and reducing the level of damage. Additionally, the aggressive clinical action of chemical retraction agents may be less intense because their concentration is diluted by water spray, human saliva, and natural gingival fluids (Edgar, 1990; Nagler et al., 2002). A systematic in vivo review of the impact of retraction astringents on gingival margin tissues reported that the healing period after retraction with chemical agents in their original concentrations was from seven to ten days (Nowakowska, 2009).

The presented results may also suggest the need for reducing the use of retraction astringents in their original concentrations, especially ferric sulphates. This is particularly important when damage to the gingival margin tissues occurs during mechanical tooth preparation. In this case, retraction with the use of chemical retraction agents should be postponed until the tissues have recovered in order to reduce the potential cytotoxic effect on human gingival fibroblasts. These investigations suggest that the evaluated chemical retraction agents can have cytotoxic potential towards gingival tissues under clinical conditions. It can be concluded that there is a need to obtain oxidoreductive stress markers and determine the type of cell death induced by the retraction agents.

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Received May 14, 2010. Accepted September 5, 2010.

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Abbreviations: ANSI - American National Standards Institute, DMEM - Dulbecco's Modified Eagle's medium, GCF - gingival crevicular fluid, GRA - gingival retraction agent, GRF - gingival retraction fluid, GRG - gingival retraction gel, MTT - 3-(4,5-dimelhyl-2-thiazollyl)-2,5-diphenyl-2H tetrazolium bromide, PBS - phosphate-buffered saline.

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Dent Clin N Am 48 (2004) 433–444

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Current concepts in gingival displacement

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Indirect restorations, including cast gold inlays, onlays, partial veneer restorations and complete crowns, metal-ceramic and all-ceramic crowns, and bonded ceramic inlays and onlays are routinely used to restore defective teeth. These restorations frequently have cervical margins that are intentionally placed in the gingival sulcus for esthetic or functional reasons. In these situations, the clinician must make impressions that accurately capture the prepared cervical finish lines and permit the fabrication of accurate dies on which the restorations are fabricated.

There is evidence that inadequate impressions are frequently forwarded to commercial laboratories, and the chief deficiency seen in such impressions is inadequate recording of the cervical finish lines [1,2]. The primary reason for not adequately capturing marginal detail is deficient gingival displacement technique.

The procedure used to facilitate effective impression making with intracrevicular margins is gingival "displacement" as opposed to gingival "retraction" [3]. The goal of the procedure is to reversibly displace the gingival tissues in a lateral direction so that a bulk of low-viscosity impression material can be introduced into the widened sulcus and capture the marginal detail (Fig. 1) [4,5].

A bulk of impression material is required to obtain maximum accuracy and to improve the tear strength of the material so that it can be removed from the mouth intact with no tearing [6,7]. The critical sulcular width in this regard seems to be approximately 0.2 mm. A width of less than 0.2 mm results in impressions that have a higher incidence of voids in the marginal area, an increase in tearing of the impression material, and a reduction in marginal accuracy [8]. It is imperative that a small amount of impression material flows beyond the prepared margin (Fig. 2). This permits accurate trimming of the recovered die (Fig. 3).

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doi:10.1016/j.cden.2003.12.012

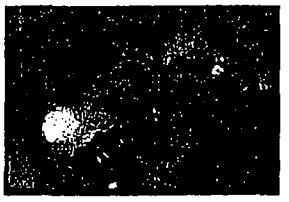

Fig. 1. The gingival tissues need to be displaced laterally to permit injection of a bulk of low-viscosity impression material into the sulcus.

Many clinicians have difficulty with gingival displacement procedures primarily because they have not mastered effective soft tissue management procedures [9,10]. One critical factor in this regard is to ensure that the gingival tissues are in an optimum state of health before making the impression [11]. Making impressions with inflamed marginal gingival tissues can be difficult and requires aggressive procedures that may result in gingival recession.

Quality provisional restorations are essential to establish an improved environment to facilitate oral hygiene procedures to improve and maintain gingival health [12,13]. The location of the prepared cervical margin within the sulcus is critical to long-term gingival health and to impression making. The optimum position of the margin is 0.5 mm from the healthy free gingival margin or 3.0 to 4.0 mm from the crest of the alveolar bone and must follow the natural scalloped form of the attachment and alveolar housing [14,15].

If the gingival tissues are healthy and the cervical margin is placed in the appropriate position, gingival displacement is a relatively simple, atraumatic procedure. Most of the difficulties with gingival displacement result from attempting to make impressions when the tissues are clinically inflamed, when clinically there is inadequate attached gingiva, or when prepared margins are placed too deep in the sulcus.

Techniques for gingival displacement have been classified as mechanical, chemical, surgical, and combinations of the three [16,17]. The method of gingival displacement used by the majority of practitioners is a combination of mechanical-chemical displacement using gingival retraction cords along with specific hemostatic medicaments [18]. A small number of dentists use

Fig. 2. A definite amount of impression material must flow beyond the prepared margin to facilitate trimming of the gypsum die.

Fig. 3. Trimming of gypsum die is a simple procedure when effective gingival displacement procedures result in excellent impressions.

surgical methods, including rotary gingival curettage and electro-surgery, but these are generally used as ancillary procedures in conjunction with mechanical-chemical techniques.

There are three main variations of the mechanical-chemical technique for gingival displacement. They include the single cord technique, the double cord technique, and the infusion method of gingival displacement [19–21]. Each of these techniques can be used effectively and are described in detail below. Before describing these techniques, a discussion of differences in retraction cords and medicaments may be useful.

Retraction cords are supplied in three basic designs, including twisted cords, knitted cords, and braided cords. There is little scientific evidence to differentiate one type of cord from another; thus, the selection of which design of cord to use is determined by operator preference. The authors prefer to use braided or knitted cords [22].

One key to effective displacement is to use a cord of sufficient diameter to provide adequate displacement so that adequate bulk of impression material can be introduced into the sulcus. The largest cord that can be atraumatically placed in the sulcus should be used (Fig. 4) [5,16]. The primary error made by inexperienced dentists is to use a cord that is too small in diameter. These small-diameter cords are placed with minimal trauma; however, they do not provide adequate lateral displacement of the gingival tissues.

There are numerous hemostatic medicaments that have been advocated for use with gingival retraction cords, and some of these medicaments have been extensively studied [23–33]. A review of the literature demonstrates that four medicaments seem to provide adequate displacement and fluid control and seem to be "safe" in that they do not produce iatrogenic soft tissue damage when used appropriately [18]. These medicaments include aluminum potassium sulfate, aluminum sulfate, aluminum chloride, and epinephrine.

The local use of epinephrine as a gingival displacement medicament has the potential to cause significant systemic side effects. The systemic effects of epinephrine have been studied extensively, and most researchers have concluded that epinephrine should not be used for routine gingival displacement [34–47].

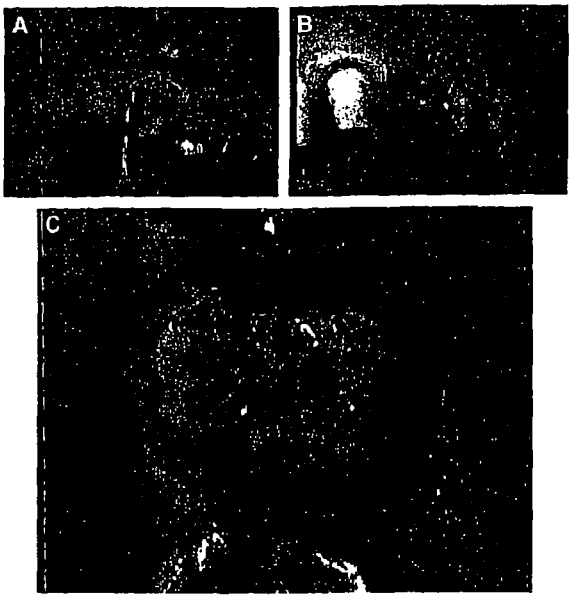

Fig. 4. The largest diameter cord that readily fits into the gingival sulcus should be used.

The literature on the absorption and effects of epinephrine from gingival retraction cords is somewhat contradictory. In correlating data from various studies, it is safe to conclude that under certain conditions epinephrine from retraction cords is absorbed systemically. Conditions that limit absorption are not clear, but increased absorption seems to occur with increased exposure of the vascular bed and with an increase in the total amount of epinephrine used. Increased doses may occur with the use of stronger concentrations of the medicament or with the use of multiple cords when making impressions of multiple prepared teeth.

Other factors related to the total dose of epinephrine received by a patient include the epinephrine administered in the local anesthetic solution and any endogenous epinephrine that may be secreted by the patient in reaction to stress or discomfort associated with the dental procedures. Epinephrine is contraindicated in patients with hyperthyroidism and in patients taking monoamine oxidase inhibitors or tricyclic antidepressants for depression, β-blockers, or cocaine. It also is contraindicated in diabetics and cardiovascular patients.

Determining which patients may be classified as cardiovascular patients can be difficult. Although many patients are clearly identified as a result of taking a careful medical history, many patients are unaware of incipient problems. Even though the majority of dentists routinely take blood pressure

and pulse records, resting pulse rates, resting blood pressure records, and resting electrocardiograph records miss approximately 45% of latent cardiovascular problems [48].

Clinicians should avoid using epinephrine for gingival displacement because of the significant number of contraindications for the use of epinephrine and the uncertainty of any given patient's cardiovascular status. Other equally effective medicaments have no systemic manifestations and are preferred. Fortunately, the use of epinephrine for routine gingival displacement has decreased over the years. In 1985, 79% of dentists routinely used epinephrine for retraction [18]. A recent article indicated that routine use had declined to 25% of respondents [49].

Techniques for gingival displacement

Gingival displacement can be accomplished using several different techniques. Common to all of them is the use of a retraction cord along with a chemical medicament. No clinical study has demonstrated the superiority of one technique over another, so the choice of which procedure to use depends upon the presenting clinical situation and operator preference.

The single cord technique

The single cord technique is indicated when making impressions of one to three prepared teeth with healthy gingival tissues. It is relatively simple and efficient and is probably the most commonly used method of achieving gingival displacement.

1. Tooth preparation is accomplished and cervical margins are dropped carefully to their pre-determined intra-crevicular position.
2. A length of gingival retraction cord is selected to specifically match the anatomy of each individual gingival sulcus. The largest-diameter braided (First String; Clinician's Choice Dental Products, London, Ontario) or knit cord (Ultrapack Cord; Ultradent Dental Products, Salt Lake City, Utah) that fits in the sulcus should be used.
3. The cord is soaked in the medicament of choice (eg, Hemodent; Premier Dental Products, Norristown, Pennsylvania).
4. Excess medicament is blotted from the soaked cord with a sterile cotton sponge. The cord is carefully packed into the sulcus in a counterclockwise direction.
5. After the cord is in place, the tooth preparation is carefully inspected to ascertain that the entire cervical margin can clearly be visualized and that there is no soft tissue impediment to easy injection of the impression material to capture all of the cervical margin detail (Fig. 5). If there is excess soft tissue blocking easy access, it can be displaced with an additional small section of cord or excised with an electro-surgery unit or soft tissue laser (Fig. 6).

Fig. 5. After the cord is in place, the prepared tooth should be carefully examined to determine that the entire cervical margin can be visualized.

6. At this point it is critical to wait 8 to 10 minutes before removing the cord and making the impression. The cord needs time to effect adequate lateral displacement, and the medicament needs time to create hemostasis and crevicular fluid control.
7. Before removing the cord, the cord should be soaked in water to allow it to be easily removed from the sulcus. Removal of the cord when dry is traumatic and tears the inner epithelial lining and initiates hemorrhage [50].
8. The tooth preparation(s) should be gently dried and the impression made.

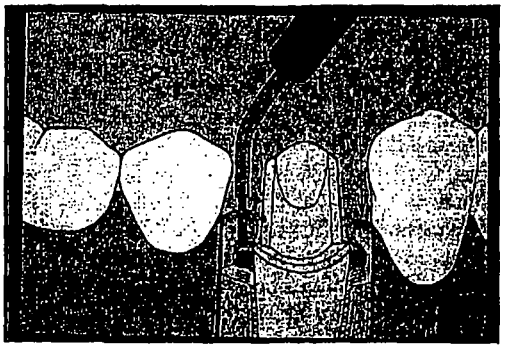

Fig. 6. If excess soft tissue obscures the prepared cervical margin, it should be removed using electro-surgery or a soft tissue laser.

The double cord technique

The double cord technique is routinely used when making impressions of multiple prepared teeth and when making impressions when tissue health is compromised and it is impossible to delay the procedure [20]. Some clinicians use this technique routinely for all impressions (Fig. 7).

1. A small-diameter cord (Deknatal 2/0 Surgical Silk Suture Material; J. Deknatal, Queens Village, New York) is placed in the sulcus. The ends of this cord should be cut so that they exactly abut against one another in the sulcus. This cord is left in the sulcus during impression making, and if the cord is too short (creating a space between the ends) or too long (creating overlapping ends), it may become impregnated into the

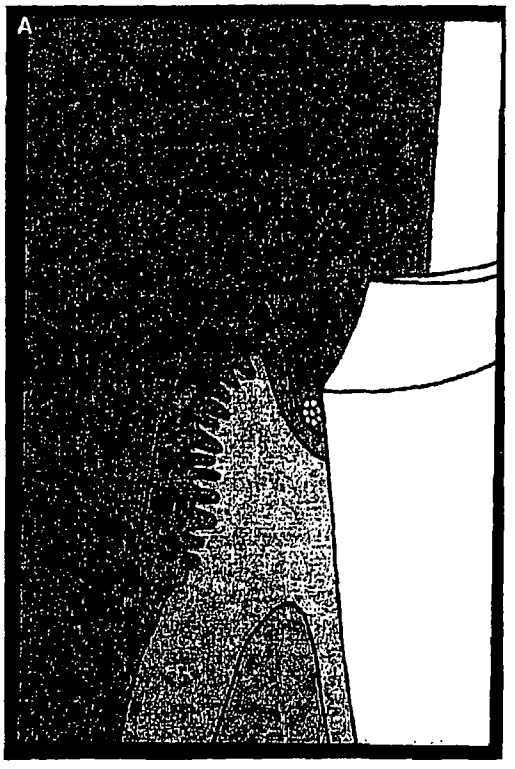

Fig. 7. With the double cord technique: (*A*) A small-diameter cord with no medicament is first placed in the depth of the sulcus. (*B*) A larger-diameter cord with the medicament is placed above the small-diameter cord. After waiting 8 to 10 minutes, the large-diameter cord is soaked in water and removed. The small-diameter cord is left in the sulcus during impression making.

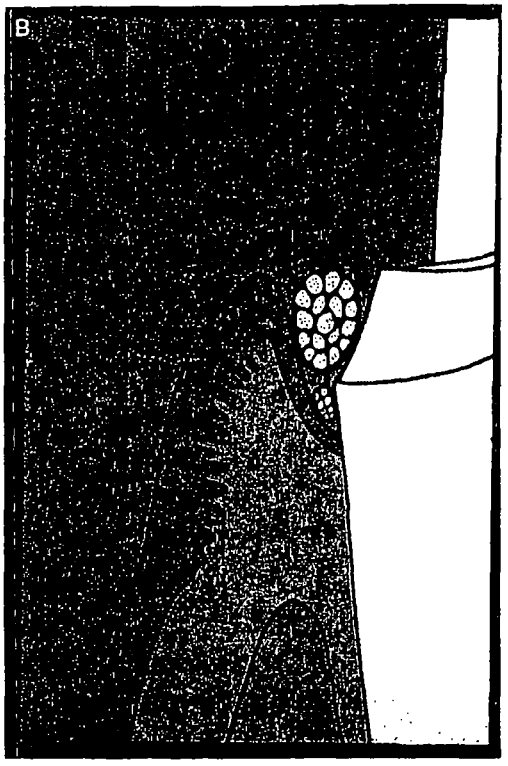

Fig. 7 (*continued*)

impression. This can create difficulties later in pouring the impression and trimming the dies.

2. A second cord, soaked in the hemostatic agent of choice, is placed in the sulcus above the small-diameter cord. The diameter of the second cord should be the largest diameter that can readily be placed in the sulcus.
3. After waiting 8 to 10 minutes after placement of the large cord, the second cord is soaked in water and removed. The preparation(s) are dried, and the impression is made with the primary cord in place.
4. After successfully making the impression, the small-diameter cord is soaked in water and removed from the sulcus.

This technique can be used with single or multiple preparations. It is especially useful with multiple preparations where gingival fluid exudate can seep over the prepared cervical margins of the last teeth to be impressed after cord removal.

The infusion technique of gingival displacement

The infusion technique for gingival displacement uses a significantly different approach from the single or double cord techniques [21].

1. After careful preparation of the cervical margins in an intra-crevicular position, hemorrhage is controlled using a specifically designed dento-infusor with a ferric sulfate medicament. Two concentrations of ferric sulfate, 15% (Astringedent; Ultradent Dental Products, Salt Lake City, Utah) and 20% (Viscostat; Ultradent Dental Products, Salt Lake City, Utah), are available. The 20% material is preferred because it is less acidic than the 15% solution and does not remove the smeared layer of dentin from the prepared tooth.
2. The infusor is used with a burnishing motion in the sulcus and is carried circumferentially 360° around the sulcus. The medicament is extruded from the syringe/infusor as the instrument is manipulated around the gingival sulcus.
3. When hemostasis is verified, a knitted retraction cord (Ultrapack Retraction Cords; Ultradent Dental Products) is soaked in the ferric sulfate solution and packed into the sulcus.
4. Advocates of this technique recommend leaving the cord in place 1 to 3 minutes.
5. The cord is removed, the sulcus is rinsed with water, and the impression is made.

In the opinion of the authors, this technique is effective in achieving hemostasis, but, because the cord is left in place for only 1 to 3 minutes, it may not provide adequate lateral displacement to permit an adequate bulk of impression material into the sulcus. It is not recommended that the cord be left in the sulcus for longer times because histologic data are not available to demonstrate that it is safe to do so.

The dento-infusor and the 20% ferric sulfate have proven to be an effective ancillary technique for control of hemorrhage when using the single cord technique. Occasionally, even with careful technique, isolated areas of bleeding may occur when the cord is removed from the sulcus. In such situations, the infusor and medicament can be used in the sulcus with firm burnishing pressure for approximately 15 seconds. This predictably controls hemorrhage.

When using ferric sulfate materials, patients should be forewarned that the tissues may be temporarily darkened. The tissues take on a blue-black appearance that usually disappears in a few days.

The "every other tooth" technique

When making impressions of anterior tooth preparations, it is critical that no damage is done to the gingival tissues that may result in recession. With teeth with root proximity, placing retraction cord simultaneously

around all prepared teeth may result in strangulation of the gingival papillae and eventual loss of the papilla. This creates unesthetic black triangles in the gingival embrasures.

This undesirable outcome can be prevented with the "every other tooth" technique. This can be used with the single or double cord technique. Retraction cord is placed around the most distal prepared tooth. No cord is placed around the prepared tooth mesial to this tooth. Retraction procedures are completed on alternate teeth. If, for example, teeth #5 through #12 are prepared, cords would be placed around teeth #5, #7, #9, and #11. The impression is made; gingival displacement is accomplished on teeth #6, #8, #10, and #12; and a second impression made. A subsequent pick-up impression allows fabrication of a master cast with dies for all eight prepared teeth.

New materials

As with other procedures in restorative dentistry, a few relatively new products and techniques have been introduced. These include strips of a sponge-like synthetic polymer that expands after insertion into the sulcus. This material can theoretically be placed in the sulcus with no local anesthetic and thus results in minimal trauma [51,52]. Another material is supplied in a syringe and is designed be injected into the unretracted sulcus (Expasyl; Kerr Dental Products, Romulus, Michigan). Once in the sulcus it theoretically expands and provides displacement and hemostasis. The predictability and efficacy of these materials has yet to be established.

Summary

Gingival displacement is an important procedure with fabricating indirect restorations. Gingival displacement is relatively simple and effective when dealing with healthy gingival tissues and when margins are properly placed a short distance into the sulcus.

The most common technique used with gingival displacement is use of gingival retraction cords with a hemostatic medicament. Retraction cords of sufficient diameter should be used to provide adequate lateral displacement to create a mean sulcular width of 0.2 mm. Epinephrine containing retraction cords should be avoided.

Several techniques have proven to be relatively predictable, safe, and efficacious. No scientific evidence has established the superiority of one technique over the others, so the choice of technique depends on the presenting clinical situation and operator preference.

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Effective Hemostasis and Tissue Management

Written by Dean Elledge, DDS, MS Wednesday, 06 October 2010 18:01

INTRODUCTION

A common clinical challenge dentists face with restorative procedures is blood contamination. There are a variety of reasons that the gingiva can bleed, including from plaque, trauma, and/or an encroached biologic width. Plaque causes gingivitis, caries, and periodontitis. Trauma that happens during the restorative procedure can cause bleeding. Wedges can press laterally and aggressively against the gingival papilla, and metal or plastic matrix bands' sharp edges can cut healthy/inflamed tissue during the isolation of the cavity. Burs are used to excise the caries, excise inflammatory tissue, and widen the gingival sulcus. Cords are packed to deflect or retract the gingiva in attempt to expose the cavity margin. Any of these events can result in blood contaminating the restorative field, thus negatively affecting impressions, cavity preparation, restorative materials, and cementation.

There is an association between restorative care and periodontal health. An encroachment of the biologic width happens when the restorative margins are placed too deep within the sulcus. Inadequate restorations can have ledges or areas that are not cleansable, which can contribute to plaque accumulation. Adolescents and geriatrics alike can have poor oral hygiene. New restorations are often needed because plaque control has been compromised. In addition, a high-carbohydrate (sugary, carbonated beverages) and nutrient-poor (refined foods) diet is a primary contributing factor in the patient examples presented in this article.

To eliminate gingivitis and a periodontal condition, there must be an accurate marginal fit of the restoration. A good example is a fixed prosthodontic restoration. The fit of the restoration is related to the completeness of the impression. An inadequate impression from blood contamination creates a problem with the restoration if the impression is forwarded to the dental laboratory. The impression will produce an inaccurate die due to negative voids or positive bubbles (Figure 1).

If the dental laboratory technician team fabricates a restoration to an inaccurate die, the dentist receives an unacceptable restoration that will be rejected. The doctor must reappoint the patient and send a new impression back to the lab. The revenue stream is broken for all involved. The patient may have to take time off from work, the dentist has to provide additional chair time, and the dental technicians involved in the case will be expected to accommodate the process.

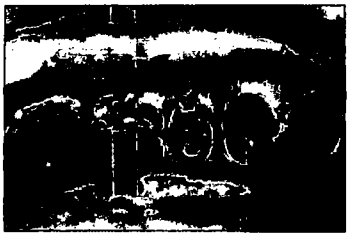

Figure 1. (Case 1) Blood has contaminated first impression to create voids.

When there's a problem, we tend to blame someone else. To the dentist, it feels like a personal failure, but it is often actually a systems failure. If the system is not corrected, profits for both the dentist and laboratory are negatively impacted. The challenge is to look at the system of controlling blood and fluids in the restorative treatment site to see how the technical steps and/or materials being used can be improved.

With case examples, this article will demonstrate how one can improve the quality of one's indirect restorative work by changing his or her technique protocol (system) to effectively control bleeding and manage the soft tissues.

HEMOSTASIS: A CHALLENGE IN THE PRESENCE OF TISSUE INFLAMMATIOn

Case 1

The system that produced the defective impression seen in Figure 1 was a standard cord soaked in a hemostatic solution and a one-step impression. The cord was placed on inflamed tissues after restorative techniques were accomplished for subgingival caries. Subgingival caries required a subgingival core buildup, which led to a subgingival crown preparation. Inflamed tissue usually bleeds, and it was unlikely that the aforementioned system would have been able to effectively control bleeding during the impression-taking procedure.

For this patient, a new impression was necessary to optimize the accuracy of the indirect technique in the dental laboratory. To correct a faulty system, a new impression-taking protocol needed to be utilized. One change that was incorporated into the impression retake steps included the use of Traxodent (Premier Dental Products). This paste system is used prior to taking impressions for both gingival retraction and hemostasis. Traxodent contains aluminum chloride (Hemodent) that causes contraction and shrinkage of tissues, protein to precipitate, blood vessels to contract, and fluids to be removed from tissues. Aluminum chloride paste also reduces the risk of postoperative inflammation. According to the scientific literature, it is the least irritating of the retraction medicaments.[1] In addition, it produces no detectable recession of the gingiva after placement into the sulcus.

Before retaking the impression, the bleeding tissue was rinsed, and attempts were made to dry the oozing area. A straight cannula was applied to the Traxodent syringe and, in this case, the cannula was formed over a mirror handle to make a 90° bend. The bend helps placement in the posterior regions of the mouth where direct access is not possible. The Traxodent paste was then applied on top of the bleeding tissue and slowly injected above the sulcus and around the periphery of the preparation margin. It should be allowed to remain in the sulcus from 1 to 2 minutes (Figure 2). When using Traxodent paste, one first notices that the gingiva blanches, and then, any oozing blood will become brown and stagnant. These are the 2 signs of hemostasis, ensuring a successful outcome of the impression.

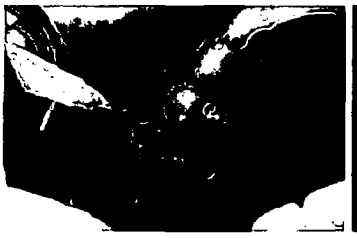

Figure 2. Hemostatic paste (Traxodent [Premier Dental Products) was extruded into bleeding sulcus. (It is left in place for one to 2 minutes.)

Figure 3. The impression was retaken. Note the blood-free retake impression without voids as a result of using a different and improved protocol (system).

The paste was then rinsed thoroughly with an air-water spray and dried. Once these steps were done, hemostasis was achieved and the gingival sulcus was dry. A light and medium-body impression material (Honigum [DMG America]) was used to make a one-step impression (Figure 3).

The techniques employed in this case, Traxodent with Honigum, resulted in an excellent impression without additional cord packing. (Other impression materials/techniques could be used effectively as well.) Note also that a small amount of impression material has flowed beyond the prepared margin (Figure 3), allowing the dental technician to accurately trim the gypsum die. This will permit the fabrication of a precise fitting restoration.

HEMOSTASIS AFTER ROTARY CURETTAGE
Case 2

Figure 4. (Case 2) Blood and fluid were evident in the gingival trough.

Figure 5. Hemostatic paste was placed in direct contact with the bleeding tissues.

Figure 6. A retraction cap (Premier Dental Products) adds pressure for additional gingival deflection.

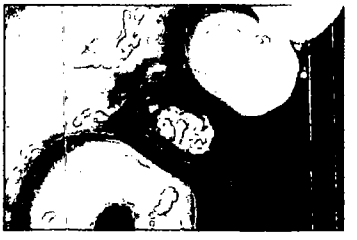

Figure 7. The hemostatic paste was rinsed away and dried, prior to taking the impression.

The tooth in Figure 4 had an amalgam core buildup supported by pins. The tooth needed the support of a full crown. It had a healthy sulcus and sufficient attached gingiva. The full crown here required the incorporation of a ferrule in the preparation design for an improved long-term prognosis. Creating the ferrule in this case required that the tooth be prepared to the bottom of the gingival sulcus. Rotary curettage with a high-speed diamond (Curettage GCP 254.SB [Premier Dental Products]) was used to trough and quickly excise the sulcular lining adjacent to the margin. Research shows that rotary curettage has little effect on the marginal heights of gingiva if adequate keratinized gingiva is present.[2] Rotary curettage was also needed to create a 0.2-mm space in the sulcus to maintain adequate thickness of polyvinyl siloxane impression material. This thickness of impression material is needed to prevent tearing and to prevent distortion upon removal from the mouth.[3] The removal of the sulcular lining resulted in bleeding (Figure 4). Traditional methods would require cord placement for 4 to 10 minutes for sulcular expansion. In this case, the Traxodent paste was placed for 2 minutes to stop the bleeding created by the rotary curettage (Figure 5). Additional deflection was achieved using a retraction cap (Premier Dental Products) (Figure 6). After thoroughly rinsing the paste off with an air-water spray, only amalgam debris remained. The sulcus was dry, and hemostasis had been effectively achieved (Figure 7).

HEMOSTASIS PRIOR TO CEMENTATION

Case 3

Bleeding is sometimes an unexpected event. In this case, when the temporaries were removed, there was bleeding throughout the treatment site (Figure 8).

Figure 8. (Case 3) Bleeding obscures finish lines.

Figure 9. Hemostatic paste was applied to the inflamed and lacerated tissues and left in place for 2 minutes.

Figure 10. Hemostatic paste was rinsed away to expose finish lines.

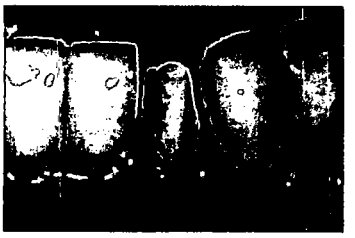

Figure 11. (Case 4) Veneer preparation with a bleeding sulcus.

Many times the operator will encounter blood in a cementation site. If blood were to intermix with cement, it would be detrimental to the physical properties of the cement. If blood were to remain on the tooth prior to cementation of a restoration, it would function like a separating medium with a resultant loss of retention. Additional problems could include pulpal inflammation with sensitivity to a stimulus such as cold, heat, or pressure. Pulpal inflammation would initially be reversible; however, the potential for irreversible pulpitis and loss of the tooth are a possibility. Sometimes, the patient is aware of bleeding near the treatment site when flossing. More often, bleeding comes from not flossing the interproximal tissue regularly to remove plaque. The tissue becomes inflamed and poorly keratinized, and it will bleed with minimal stimulation. The gingival tissue has the signs of erythema owing to the proliferation of capillaries.

In this case, Traxodent paste was applied immediately to the sulcular area (Figure 9). After 2 minutes, it was rinsed away, and the teeth were ready to receive their cemented crowns (Figure 10). Traxodent effectively controlled the bleeding and allowed for visualization/isolation of the treatment site for an intact cementation without contamination.

AESTHETIC ZONE TREATMENT

Case 4

In anterior aesthetics, it may not be desirable to create a trough around the margin with a bur, a cord, or laser since this may be detrimental to the aesthetic outcome. Cosmetic restorations are challenging because the preparation line is in close contact with the gingiva. When the root shade is very dark, it can create a dark line in the cervical area. Patients are aware of this problem as an aesthetic concern. Cord placement could lead to ulceration or inflammation of the junctional epithelium. The problem is that it is hard to accurately control the forces used in the placement of cord. If the facial gingiva is a thin biotype, there is a chance of gingival line migration. Other trauma, such as mechanical pressure or surgical trauma, can cause an undesirable migration of the gingival line away from the margin. Like Magic FoamCord (Coltène/Whaledent), using a hemostatic paste is a less traumatic method to dry the field and to achieve mild retraction of the tissue.[4]

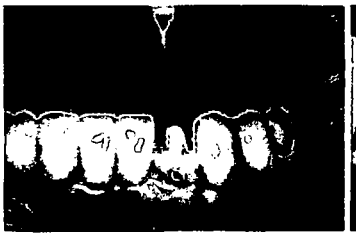

Figure 12. The hemostatic paste was extruded with the cannula aligned parallel to tooth.

Figure 13. Hemostatic paste was then rinsed away.

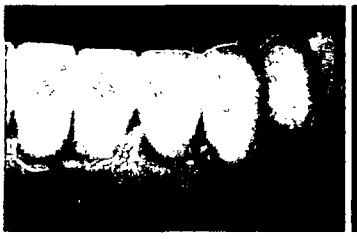

Figure 14. Full gingival rebound at a 3-month recall. Ceramic veneer (Root Dental Lab) fabricated of Empress (Ivoclar Vivadent).

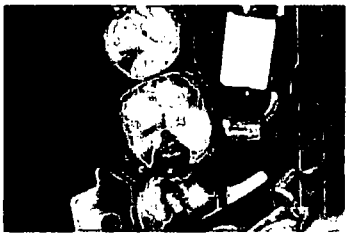

Figure 15. (Case 5) The gingiva was inadvertently lacerated during caries excavation.

The patient in Figure 11 has high aesthetic concerns and dislikes the dark and contrasting colors along the gum line. She presented with a fractured porcelain veneer that required replacement. The tooth had already been prepared at the crest of the gingival sulcus. The veneer was removed with a high-speed diamond bur, with the location of the margin left in the same location. Inadvertent bur contact to sulcular tissue resulted in lacerated areas that bled. To prepare the tooth for the impression-taking procedure, Traxodent was placed into the sulcus and allowed to remain (Figure 12). After 1 to 2 minutes, the tooth was rinsed with air-water spray and dried (Figure 13). A one-step impression (light body on the tooth and a medium-body tray material) produced an accurate impression without bubbles or voids. The replacement veneer was cemented with a subgingival margin. At the 3-month recall, the margin level remained stable and within the aesthetic zone (Figure 14).

HEMOSTASIS WITH DIRECT RESTORATIONS

Case 5

Blood contamination during a Class II filling has the same risk as a crown and bridge procedure. It can mean lengthening of the procedure for the patient and disruption of the patient schedule for the doctor.

In this case, the problem began with interproximal caries (Figure 15). Interproximal hemorrhage can often be associated with caries. Caries seen on the radiograph is an approximation of the depth of the caries. In the mouth, the caries is often more extensive, and its removal requires an expansion in cavity size. Other times, the subgingival preparation is used to obtain an adequate resistance and retention form for clinical crown length. With these patients, bleeding is common and upregulated if the patient is on a blood thinner such as Warfarin, aspirin, or Plavix. Bleeding begins from the inflamed interproximal gingiva if it is touched with a bur during caries excavation.

Figure 16. Hemostatic paste was applied directly to the bleeding tissue.

Figure 17. The hemostatic paste was rinsed away, revealing effective hemostasis.

Bleeding can also occur during isolation procedures when the band, wedge, or rubber dam is placed in contact with inflamed tissue (Figure 16). In this case, Traxodent was applied to the bleeding area located in the deepest part of the interproximal box and allowed to remain for the recommended time (Figure 17). Then, it was rinsed away with air-water spray, dried, and hemostasis was confirmed. Visualization of the entire cavosurface was evident. The direct filling was then placed in a routine manner.

DISCUSSION

These case reports demonstrate a hemostatic system (Traxodent paste) that effectively addressed the common problem of bleeding in the restorative treatment sites. The paste has a thixotropic property that allows entrance into restrictive sulcular spaces and then remains in position. This property is important when treating the maxillary arch or the mandibular arch because the medicament remains in the sulcus, not in the vestibule or throat. Once applied, the product remains in position, even if contact is made by the tongue or cheek. This is important to the patient because it allows a less offensive procedure.

In general, hemostatic agents are strong astringents that create a dry, puckering feel in the mouth with a sandpapery sensation. This delivery system is important to the dentist because it allows the medicament to remain with intimate contact and at full strength in the gingival sulcus, thus preventing the need for reapplication due to dilution by saliva or gravity runoff. The paste differs from liquid hemostasis agents because it has the ability to absorb fluids in a manner similar to Expasyl (Kerr) paste.

Treatment sites adjacent to alveolar mucosa may communicate to deeper spaces. The operator should be aware of the problems of a poor treatment site that lacks attached, keratinized tissue. One precaution would be the risk of washing hemostatics into deep spaces between tissues where the product is not intended to be applied. Traxodent paste is intended to be injected on top of tissue, not submucosally. It is also not intended to be used for the treatment of gingivitis, periodontitis, or other conditions. The operator needs to supervise its application in the dental treatment site.

CONCLUSION

Hemorrhage is a common problem that is encountered during restorative procedures. Common causes are a plaque-induced erythema from gingivitis next to the treatment site or inadvertent instrumentation that lacerates gingival tissues in the restorative procedure. Any trauma to inflamed tissue or healthy tissue results in bleeding into the restorative field. Bleeding results in distorted impressions, unbonded fillings, and contaminated cements.

It is vital to control gingival bleeding and to manage the soft tissue without additional tissue damage to produce successful restorations for the dentist and patient.

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J Indian Soc Periodontol. 2010 Jan-Mar; 14(1): 35–39.
doi: 10.4103/0972-124X.65436
PMCID: PMC2933527

Effect of retraction materials on gingival health: A histopathological study

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Abstract

Go to:

Background:

Gingival retraction methods are used in dentistry for impressions of subgingival crown margins, such as, mechanical, chemical, chemicomechanical, and surgical. These methods may injure the gingival sulcular epithelium. Hence, the present study is carried out to evaluate the effect of different retraction materials, such as, Expasyl, Magic Foam Cord, and impregnated retraction cord on the gingival sulcular epithelium.

Materials and Methods:

This study included 30 cases of bilateral premolar extraction patients with Loe and Silness gingival index zero. Retraction materials were kept in the dry, isolated labial gingival sulcus for the required time. The retraction materials were removed by rinsing with water. Retracted gingiva of 2 – 3 mm from the gingival margin along with the tooth was extracted and the decalcified sections were microscopically studied. Data analysis: Data were analyzed by applying the chi-square test.

Results:

This study showed better results with retraction paste as compared to the retraction cord, and there was a significant association between retraction materials and the relative degree of injury to the sulcular epithelium.

Conclusion:

There is a significant association between retraction materials and gingival sulcular epithelium. It can be stated that impregnated retraction cord, may be used commonly but it needs proper tissue manipulation and is technique sensitive. Newly advanced material in the form of retraction paste like Expasyl or Magic Foam Cord was found to be better than cord as assessed histologically, it respects periodontium.

Keywords: Expasyl, magic foam cord, junctional epithelium, retraction cord

INTRODUCTION

Go to:

Impressions for subgingival crown margins require gingival tissue retraction. Conservative retraction methods involving tissue displacement include the placement of copper bands or cords with or without caustics and astringents. In other methods, the gingival tissue is excised, as in resection by electrosurgery. Copper-band impression was indicated as the major factor producing gingival recession. Also sulcus damage with electrosurgery was reported to vary depending on the type of unit used.[1]

The relationship between periodontal health and restoration of teeth is intimate and inseparable. For restoration to survive long term, the periodontium must remain healthy so the teeth are maintained. For the periodontium to remain healthy, restoration must be critically managed in several areas so that they are in harmony with the surrounding periodontal tissue. Restorations play an important role in the ecological balance of plaque and maintenance of the periodontium.[2] If a margin of restoration has to be placed supragingivally or equigingivally then there is no need for gingival retraction. However, in unavoidable conditions, like in anterior restorations, for esthetic purposes, margins must be placed subgingivally; hence, it needs gingival retraction procedures, which may cause a violation of biological width. The dimension of the space that the healthy gingival tissue occupies above the alveolar bone is called the 'biologic width'. This comprises of 1.07 mm of connective tissue attachment and 0.97 mm of junctional epithelium. The biologic width should not be violated in any restorative procedure. The average biological width is 2.04 mm.[3]

Various gingival retraction methods are mechanical, mechanochemical, electrosurgery, rotary gingival curettage, etc. The most commonly used method is the mechanochemical one. Use of the mechanochemical method leads to violation of biological width, causing bone loss and recession. Studies on the chemicomechanical and purely mechanical cord retraction techniques have shown various degrees of necrosis and/or stripping of the gingival sulcus.[4] Gingival electrosurgery for crevicular troughing involves a considerable risk of producing permanent periodontal damage.[5]

Very few histological studies have been reported on the effects of using retraction materials on the gingival sulcular tissue, although disruption of the sulcular epithelium could be expected. Hence, this study has been carried out to identify whether chemicomechanical and mechanical retraction materials injure the gingival sulcus epithelium. If so, which retraction material is better and causes less injury.

Aims and objectives

Dental surgeons generally believe that retraction materials do not cause injury to the gingival sulcus epithelium. As injury to sulcular epithelium cannot be detected clinically, except after the most severe damage, this study is based on histological findings.

1. To determine the effect of the most commonly used retraction materials: Expasyl, Magic Foam Cord, and impregnated retraction cord on gingival sulcular epithelium.
2. To find out the association between Expasyl, Magic Foam Cord, and the impregnated retraction cord and gingival sulcular epithelium.

MATERIALS AND METHODS

Go to:

Thirty patients of age 11–17 years, with bilateral first premolar extraction cases in both maxillary and mandibular arches, were selected, irrespective of sex, who referred to the Orthodontia Department Rural Dental College, Loni, with Loe and Silness gingival index zero. Patients with improper oral hygiene, crowding, bleeding on probing, periodontal pocket, gingival recession or enlargement and any systemic diseases or conditions were excluded from the study. The protocol was clearly explained to all the patients and informed consent was obtained from all the recruits.

Material

A) Retraction paste

i. Expasyl – Aluminum chloride (15%), Kaolin, Water (Satelec ACTEON group)
ii. Magic Foam Cord – Polyvinylsiloxane, addition type silicone elastomer

vailable in form of Base – White; Catalyst – Blue (Coltene / Whaledent AG, Switzerland)

B) Retraction cord

Impregnated retraction cord with 5% Aluminum Chloride (Ultrapak, Ultradent products, Inc., Germany)

Retraction procedure for Expasyl

Expasyl is a paste for temporary gingival retraction that ensures separation of the marginal gingiva and drying of the sulcus. The material is supplied in capsules (cartridges), and comes with a preformed gun-type of device into which the capsule has to be placed and then the material is expressed. Labial gingival sulcus of the maxillary right first premolar was rinsed with water, dried with air stream and isolated with cotton rolls. The retraction paste was slowly injected into the sulcus (2 mm/s) with the tip parallel to the long axis of the teeth, as shown in Figure 1a. The point of the cannula must create a closed space between the tooth and the marginal edge of the gingiva. Clinically, the complete filling of the sulcus can be discerned by a slight blanching of the gingival marginal area.[6] Depending on the tonicity of the gingiva it is kept in place for one minute in the thin and two minutes in the thick marginal gingiva. It is easily visible because of its color. Subsequently, it is removed by air and water spray.

Figure 1a

Expasyl paste in gingival sulcus of maxillary right 1st premolar

Retraction procedure for Magic Foam Cord

As shown in Figure 1b, the labial gingival sulcus of the mandibular left first premolar was rinsed with water and dried with an air stream. A Magic Foam Cord cartridge was placed in the dispenser and the cartridge cap removed. The handle was compressed to express some material onto a paper until the base and catalyst flowed out of the opening in equal amounts, which ensured an optimum mixture. The oral tip was placed onto the mixing tip. The Magic Foam Cord was slowly injected into the sulcus and then the Comprecap Anatomic was placed. Due to the counter pressure of the Comprecap Anatomic, there was an expansion of the Magic Foam Cord in the sulcus. It was kept in place for five minutes. Subsequently, after proper setting, both the Magic Foam Cord and Comprecap were removed in one piece. Next the Magic Foam Cord was completely removed by air and water spray.

Figure 1b

Magic Foam Cord in gingival sulcus of mandibular left 1st premolar

Retraction procedure for retraction cord

The use of gingival retraction cords with 5% aluminum chloride has been shown to be safe and effective.[7] The labial gingival sulcus of the maxillary left-sided first premolar is rinsed, dried, and isolated with cotton rolls [Figure 1c]. An Ultrapak, 00 #, 5% aluminum chloride impregnated retraction cord is cut for the required length and placed in the sulcus with a cord packer and placed for ten minutes. It is suggested that the placement starts at the interproximal gingival crevice, where there is usually more tissue, and continues circumferentially. After the required period, the time cord was removed, and the gingival sulcus washed and dried.[8]

Figure 1c

Retraction cord in gingival sulcus of maxillary left 1st premolar

In this case the retraction procedure was performed by the same expert prosthodontist to minimize interexaminer error.

Extraction and laboratory procedure

As microscopically the features of acute inflammation can be seen as early as within 48 hours, the patients were considered for extractions after 48 hours of retraction. The patient was anesthetized using 2 ml of 2% lidocaine with 1: 50,000 epinephrine. An incision using a No. 15 surgical blade was made facially 2 – 3 mm away from the marginal gingiva. The extraction was performed mainly with an elevator to reduce tissue trauma. The tooth was extracted with the adjacent marginal gingiva, decalcified with 10% formic acid, processed with a series of 70, 80, and 90% absolute alcohol, xylene2, and xylene1. Microscopic sections were obtained by cutting the labiolingual block sections at eight microns, with microtome and staining done with hematoxylin and and eosin stain.[9]

Histological examination

As the cellular response to the retraction materials was the main interest, the following criteria were used to determine the changes depending upon the relative injury caused by the retraction materials.[9]

Normal – Normal gingival epithelium
Mild – Stripping and desquamation of the epithelium

Moderate – Hydropic degeneration, hyperemia, inflammatory cells
Severe – Epithelial proliferation and necrosis

RESULT

Go to.

The histological specimen of the retraction cord revealed that the cord was pressed past the cementoenamel junction with facial displacement of the entire gingival unit. The sulcular epithelium was present, but disrupted. The junctional epithelium was sometimes missing from the outermost border. The residual junctional epithelium displayed intracellular hydropic degeneration, stripping, and desquamation of the epithelium [Figure 2a].

Figure 2a

Histologic view with Expasyl

However, the histological specimen of the retraction paste shows only eight cases of disrupted junctional epithelium and sulcular epithelium, as compared to the retraction cord. The remaining specimens show an intact junctional epithelium [Figure 2a and b].

Figure 2b

Histologic view with Magic FoamCord

Thus, mechanical and mechanochemical methods do cause injury to the gingival sulcus epithelium, but the injury varies from slight with retraction paste to severe with retraction cord [Figure 2c].

Figure 2c

Histologic view with retraction cord

From the observations shown in Table 1, it was perceived that out of the 30 cases studied, mild injury was noticed with the use of Expasyl, Magic Foam Cord, and impregnated retraction cord, of 6.67, 20, and 36.67%, respectively. Moderate injury was observed with the use of impregnated retraction cord in 20% of the cases. No severe injury was observed with the use of different retraction materials.

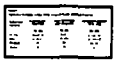

Table 1

Distribution of relative degree of injury caused by the retraction materials

By applying the chi-square test, it has been proved that there is a significant association between different retraction materials and the relative degree of injury to the gingival sulcular epithelium, that is, $P<0.05$.

DISCUSSION

Go to:

Although, from periodontal point of view, it is preferable to place the margins of restorations supragingivally, for esthetic or other reasons, the dentist may be forced to place them subgingivally.[10] Other studies using clinical and histopathological evaluation of gingival retraction in humans show that gingival retraction with the cord caused destruction of the junctional epithelium, which took about eight days to heal. The average postoperative gingival recession seen with cord retraction was 0.2±0.1 mm.

The most widely used and popular method is the use of retraction cords. A study by Van der Velden and De Vries has shown that the epithelial attachment sustains injuries at a force of 1 N/mm², while it ruptures at 2.5 N/mm². The cord technique requires almost 2.5 N/mm². The retraction cord achieves the desired retraction, but placing a retraction cord is not an easy method.[6] It needs physical manipulation of the tissue, leading to gingival bleeding. Thus, use of a retraction cord has the risk of epithelial attachment injury, pain during cord placement, sometimes requiring local anesthesia. Also, more time is required, and it may initiate gingival bleeding and oozing.

A complete paradigm shift has been made with the introduction of a very novel idea to achieve retraction and hemostasis at the same time. In our study we compared the two retraction materials: Expasyl and Magic Foam Cord with the conventional retraction cord. We used the maxillary right first premolar for gingival retraction with Expasyl and the mandibular left first premolar with Magic Foam Cord. The fundamental principle of the Expasyl was to insert a stiff, hemostatic, plastic, non-setting material into the gingival sulcus under mild pressure and allow the material to stay in place for 1 – 2 min6. In our study, the histological specimen of the retraction cord revealed that the disrupted sulcular epithelium and junctional epithelium were sometimes missing. Also, the junctional epithelium displayed intracellular hydropic degeneration, stripping, and desquamation of epithelium. These findings are similar to Jon Ruel *et al.*[8] and R. Azzi *et al.*[10] The histological specimens of the retraction paste showed only six cases of disrupted junctional epithelium and sulcular epithelium as compared to the retraction cord. The remaining specimens showed an intact junctional epithelium. According to Patrick Lesage and Mona Kakar, the material under pressure caused sufficient displacement of the gingival tissue and this displacement stayed in place long enough for either recording of the impression or to carry out the restorative or bonding procedures. [6] It was noninvasive, simple to use, painless, reliable, a hemostatic agent, effective, safe, increased patient comfort, and saved time.

Magic Foam Cord is a product for an easy, nontraumatic, and less time consuming retraction of the sulcus. It is biologically very compatible, with no adverse side effects or interactions. Polyvinylsiloxane has a high tear resistance. The technique is faster and easier than the use of retraction cords or scalpel / rotary instruments.

CONCLUSION

Go to

To conclude, the results of the present study clearly reveal that there is a significant association between retraction materials and the gingival sulcular epithelium. It can be stated that the impregnated retraction cord, may be used frequently, but it needs proper tissue manipulation and is technique sensitive.

A definite alternative for gingival retraction now exists in the form of retraction paste (Expasyl / Magic Foam Cord). In regard to hemostasis, there is no doubt about the efficacy of these materials and their ability to be extremely effective clinically. The retraction procedure also appears very safe and easy to use. Thus, the newly advanced material in the form of retraction pastes like Expasyl or Magic Foam Cord have been found to be better than the cord, as assessed histologically, with respect to the periodontium. The patient tolerance was observed to be very good. No anesthesia was required and the material exhibited total biocompatibility.

Future research

The long-range effects of the marginal fit are probably the most important factors for enhancing periodontal health. This study has involved only healthy periodontal subjects. Different effects on the junctional epithelium may be observed in tissues, characterized by gingivitis or periodontitis. A broader study involving a greater range of procedures and conditions is recommended, to evaluate each retraction technique. This study has involved teeth that have an adequate zone of attached gingiva. More complicated and perhaps altered sequences may be observed if the procedures are performed on gingival margins of alveolar mucosa, thin gingival walls or areas of root prominence and thin cortical bone.

Acknowledgments

Go to

Contributions that need acknowledging, but do not justify authorship, here I acknowledge Mr. Hemant Pawar (Asso. Prof.), Department of Medical Bioinformatics, Rural Medical College, Loni, for his valuable guidance regarding the statistical analysis of the data. I would also like to thank the technicians in the Department of Oral Pathology Mr. Sunil and Mrs. Manisha for their help in the laboratory.

Footnotes

Go to

Source of Support: Nil

Conflict of Interest: None declared.

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Bond Strengths of Resin Cements to Astringent-contaminated Dentin

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Clinical Relevance

The contamination of the dentin surface with an astringent-containing aluminum chloride does not reduce the bond strength of either the resin cement used in conjunction with an etch-and-rinse or the resin cement with a self-etching adhesive. However, the contamination probably interferes with the etching ability of the self-etching primer and the adaptation of the resin cement to the dentin surface.

SUMMARY

The current study evaluated the micro-shear bond strength of two resin cements to astringent-contaminated dentin. Twelve occlusal dentin discs were prepared from extracted caries-free human molars and divided into two groups subjected to two types of resin cements, Panavia F (PF) and Variolink II (VL). Each disc was ground with 600 grit SiC paper and sectioned into two semi-disks, one for the normal dentin surface and the other for the contaminated dentin surface. For contaminated dentin, an astringent containing aluminum chloride was applied for two minutes and rinsed before the bonding procedures. A micro tygon tube was placed on the dentin surface following the bonding application and then filled with a resin cement. After the resin was polymerized, the specimen was kept in water for 24 hours before the micro-shear bond strengths evaluation. The micro morphology of the treated surfaces and resin-dentin interfaces were observed under a scanning electron microscope (SEM). Aluminum content under different dentin conditions was also examined. No significant differences were found between the dentin bond strengths to normal dentin and contaminated dentin surfaces in both the PF and VL groups ($p>0.05$). PF showed similar bond strengths to VL on normal and contaminated dentin ($p>0.05$). SEM observations of the VL groups revealed no

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DOI: 10.2341/08-107

differences in the treated dentin surfaces and the resin-dentin interfaces between normal and contaminated dentin. However, for the PF group, an inconsistent etching pattern of the self-etching primer and gap formation at the interface of resin cement to contaminated dentin were observed.

INTRODUCTION

The use of adhesive resin cements for bonding indirect tooth-colored and casting restorations, such as inlays, onlays and crowns, is increasing. These cements bond to both the fitting surface of the restoration and the tooth structure. At the tooth surface, an adhesive system is used to bond the resin cement to both enamel and dentin surfaces. Currently, adhesive resin cements can be categorized according to the adhesive system used as either etch-and-rinse or self-etching system.[1]

During the cementation procedures of indirect restorations at the cervical area, gingival fluid and blood sometimes appear as a result of trauma from tooth preparation. In this clinical situation, hemostatic agents are frequently used to control bleeding and gingival fluid. The pH of these hemostatic agents has been reported to vary from 0.7-3.0.[2,3] The tooth structure, especially dentin, which is a major part of the preparation, may be contaminated with these highly acidic astringents. Of these hemostatic agents, aluminum chloride, with a concentration between 20%-25%, is frequently used.[3] Land and others[4] reported that dentin surfaces treated with 21.3% aluminum chloride for five minutes exhibited complete smear layer removal with some degree of demineralization.[3,4] Since some effects of the smear layer on the adhesion of self-etching adhesives have been reported,[5,6] smear layer removal by hemostatic agents could affect the bonding mechanism of the self-etching adhesive used with a resin luting cement.

In a previous study by the current authors, a light-cured, two-step self-etching adhesive used in conjunction with a direct resin composite exhibited lower bond strength to dentin contaminated with 25% aluminum chloride solution compared to normal dentin, but an etch-and-rinse adhesive exhibited similar bond strength to both contaminated and normal dentin.[7] However, there is no report regarding the bonding efficiency of adhesives used with resin cements to dentin contaminated with a hemostatic agent. Therefore, the purpose of the current study was to evaluate the microshear bond strengths of two resin cements to astringent-contaminated dentin, one used with an etch-and-rinse adhesive and the other with a self-etching adhesive. The null hypothesis is that the bond strengths to astringent-contaminated human dentin of resin cements used with these adhesives are not different from the bond strengths to normal dentin. To observe the micro morphological differences among the test groups, non-stress, resin-dentin interfaces and dentin surfaces with and without contamination were observed under SEM. The aluminum content under different dentin conditions was also determined.

METHODS AND MATERIALS

Preparation of Dentin Surface (Figure 1)

Twelve 2-mm thick dentin discs were prepared by perpendicular section to the long axis of the extracted caries-free human molars using a slow-speed diamond saw (Isomet, Buehler Ltd, Lake Bluff, IL, USA) under water lubrication. The surfaces of the dentin discs were hand ground with 600 grit silicon carbide papers (Struers, Ballerup, Denmark) under running water to standardize the resulting smear layers. The ground dentin discs were then hemi-sectioned into 12 pairs of dentin semi-discs. All semi-discs were equally divided into two groups, the control and contaminated groups. In the control group, the dentin surface of each semi-disc was rinsed and dried. In the contaminated group, the dentin surface of each semi-disc was treated with 25% aluminum chloride (Racestyptine, Septodont, Cedex, France) for two minutes, rinsed with water spray for 30 seconds and dried with oil-free air. Semi-

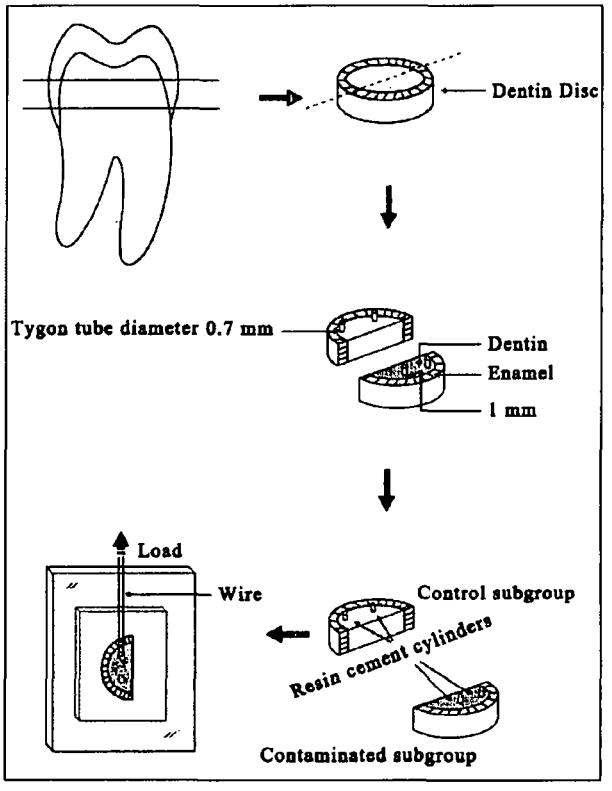

Figure 1. *Schematic illustration of the experimental design.*

Table 1: *Resin Cements and Their Adhesives Used*

Resin Cements	Composition	Manufacturer	Batch #
Panavia F ED II Primer	Primer A: HEMA, MDP, 5-NMSA, water, accelerator	Kuraray Medical Inc Okayama, Japan	00225A
	Primer B: 5-NMSA, accelerator, Water, sodium benzene sulfinate		00104A
Luting Resin	Base paste: hydrophobic aromatic (and aliphatic) dimethacrylate, hydrophilic dimethacrylate, sodium aromatic sulfinate (TPBSS), N,N-diethanol-p-toluidine, functionalized sodium fluoride, silanized barium glass		00197A
	Catalyst paste: MDP, hydrophobic aromatic (and aliphatic) dimethacrylate, hydrophilic dimethacrylate, silanized silica, photoinitiator, dibenzoyl peroxide		00108A
Variolink Excite DSC	Etchant Total Etch: 37% phosphoric acid	Ivoclar Vivadent, Schaan, Liechtenstein	F40503
	Primer-adhesive: HEMA, DMA phosphoric acid acrylate, silica (0.5 wt%), ethanol, initiators		
Luting Resin	Base paste: Bis-GMA, UDMA, TGDMA, fillers (72.3 wt%), pigments and stabilizers		G26397
	Catalyst paste/low viscosity: Bis-GMA, UDMA, TGDMA, fillers (71.2 wt%), pigments, stabilizers and catalysts		H17779

discs of both the control and contaminated groups were further divided into two subgroups of six pairs of semi-discs each according to the resin cement systems used (Table 1).

Bonding Procedures

The composition and batch number of the adhesive resin cements used are presented in Table 1.

Subgroup 1 (PF) ED primer A and B were mixed and applied to the dentin surfaces of both the control and contaminated groups, left for 30 seconds and gently air dried. Irises that had been cut from micro bore tygon tubing (TYG-030, Small Parts Inc, Miami Lakes, FL, USA), with an internal diameter and a height of approximately 0.75 and 0.50 mm, respectively, were placed at two positions on the primed dentin surface 1 mm from the dentino-enamel junction. Freshly mixed dual-cured resin cement of Panavia F (Kuraray Medical Inc, Okayama, Japan) was used to fill the tubing and then light cured for 20 seconds using a halogen light-curing unit (Curing Light XL 3000, 3M ESPE, St Paul, MN, USA) with an output of 700 mW/cm². The bonding interface was covered entirely with liquid glycerin gel (Oxyguard II, Kuraray Medical Inc) for three minutes to enable optimal anaerobic polymerization and the gel was then rinsed out. The bonded specimens were left at room temperature (25°C) for one hour before removal of the tygon tubing by longitudinally cutting with a razor blade. This resulted in 12 resin cement cylinders bonded to the dentin surface of the control and contaminated groups.

Subgroup 2 (VL) The dentin surfaces of the semi-discs of both the control and contaminated groups were etched with 37% phosphoric acid for 15 seconds, then thoroughly rinsed with water spray. Excess water on the dentin surface was blot-dried with lint-free absorbent tissue prior to the application of primer-adhesive (Excite DSC) and agitated gently for 30 seconds. The treated dentin surface was gently air dried for three seconds and light cured for 20 seconds before placing the tygon tubing in the same manner as in Subgroup 1. Variolink II low viscosity base and catalyst paste (1:1 ratio) were mixed, filled the tygon tubing and were light cured for 20 seconds. The specimens were left at room temperature for one hour before removing the tygon tubing as in Subgroup 1. All the specimens were stored in distilled water at 37°C for 24 hours before the micro-shear bond test.

Micro-shear Bond Test

After 24 hours, the resin cement cylinders were checked under an optical microscope (30x) for bonding defects. The cylinders, which showed interfacial gap formation and/or bubble inclusion, were excluded and replaced. Twelve specimens were tested for each test group. The micro-shear bond test was performed with

the bond test apparatus (Bencor-Multi-T, Danville Engineering Co, San Ramon, CA, USA) attached to a universal testing machine (EZ-test 500N, Shimadzu Co, Kyoto, Japan).[8] The dentin semi-disc with the resin cement cylinder was fixed to the apparatus with a cyanoacrylate adhesive (Zapit, DVA, Corona, CA, USA). A thin wire (0.2 mm in diameter) was looped around the resin cement cylinder, making contact through the lower half of its circumference and gently held flat against the resin/dentin interface. The resin cement cylinder and the center of the load cell were aligned as straight as possible to ensure the desired orientation of the shear test force. A shear force was applied to each specimen at a crosshead speed of 1 mm/minute until fracturing occurred.

After debonding, bond strengths were recorded and the fracture modes of all the specimens were observed under a SEM (JSM-5310V, JEOL Ltd, Tokyo, Japan). The fracture mode was classified as follows: adhesive failure at the resin-dentin interface, cohesive failure in dentin or cohesive failure in resin cement. The percentage of each type of failure in the specimens was recorded.

The data were statistically analyzed by two-way ANOVA (type of dentin, adhesive resin cement system) followed by *post hoc* multiple comparisons with the Student's *t*-test. For the fracture modes, the Kruskal-Wallis test was used to compare differences among each experimental group. All analyses were performed using the SPSS program. Statistical significance was considered to be $p<0.05$.

EDS Microanalysis of the Dentin Surfaces

The surfaces of normal dentin after grinding as a control, the surfaces of astringent contaminated dentin and both dentin conditions after etching with phosphoric acid and self-etching primer (ED primer) were all measured for aluminum (Al) content on the surface using an energy dispersive spectrometer (Oxford ISIS Pentafet link model 6647, Highwy Combe, England) operated at 20 KV. The relative amounts of Al to Ca were measured at 500x magnification.

SEM Observation of the Treated Dentin Surfaces and the Bonding Interface

The surfaces of ground dentin and astringent-contaminated dentin and both dentin conditions after etching with phosphoric acid and self-etching primer were observed. For the PF group, ED primer A and B were mixed and applied to the dentin surface for 30 seconds before being thoroughly rinsed with acetone and water to remove residual resin. They were then air-dried. The morphological changes induced on the dentin surfaces were observed using SEM.

The interfacial morphology between both normal and contaminated dentin and the resin cements were also observed after the acid-base challenge. Another 12 pairs of semi-discs were divided into four groups of three semi-discs each and received the same treatment as for the micro-shear bond test. Twenty-four hours after bonding, the specimens were sectioned perpendicular to the bonded surface using the slow-speed diamond saw (Isomet, Buehler Ltd) under water spray. The cut specimens were fixed in 10% buffered formalin before being embedded in a self-cured epoxy resin (Epon 812, Nisshin M Co, Ltd, Tokyo, Japan), then ground and polished using wet silicon carbide papers and diamond pastes of decreasing abrasiveness down to 0.25 µm. The surfaces of the polished specimens were subjected to 10% phosphoric acid for five seconds and 5.25 % NaOCl for five minutes. After rinsing thoroughly, the specimens were dried overnight, sputter coated with gold and observed under high vacuum in SEM.

pH Measurement

The pH determination of the astringent was preformed using a pH meter (Twin pH, Horiba, Tokyo, Japan). The pH reference solutions at pH 7 and pH 4 were used to standardize the electrode. The measurements were done in triplicate.

RESULTS

The pH of the 25% aluminum chloride Racestyptine was 0.8. The micro-shear bond strength of both resin cements to normal and contaminated dentin and the mode of fracture are presented in Tables 2 and 3, respectively.

The bond strengths of both resin cements to contaminated dentin were not significantly different from those of normal dentin. The bond strengths of PF and VL to normal and contaminated dentin were also not signifi-

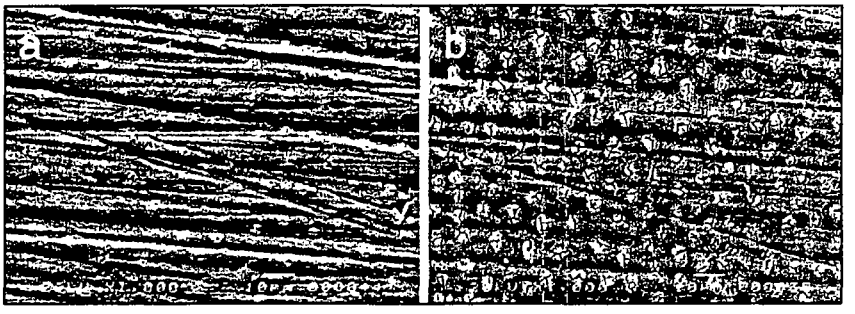

Figure 2. *(a) SEM photomicrograph of a normal dentin surface after grinding with 600 grit SiC paper. A thick smear layer covered the entire surface. (b) Dentin surface after two-minute contamination with 25% aluminum chloride and washed out. Part of the smear layer was removed. Opening of the dentinal tubules were occluded with smear plug (original magnification 1000x).*

Table 2: *Micro-shear Bond Strengths (MPa) of Panavia F and Variolink II to Normal Dentin and Contaminated Dentin (n=12)*

Groups	Normal Dentin	Contaminated Dentin
Panavia F (PF)	22.23 (9.94)[a]	24.72 (5.72)[a]
Variolink II (VL)	22.29 (5.86)[a]	23.89 (3.19)[a]

Groups with the same superscript are not statistically different (p<0.05).

Table 3: *Mean Percentage of Failure Mode After Micro-shear Bond Test*

		Cohesive Failure[b]	
	Adhesive Failure[a]	In Dentin	In Composite
Variolink			
Normal Dentin	96.67	3.33	0
Contaminated Dentin	97.72	0	2.08
Panavia F			
Normal Dentin	83.33	9.58	7.09
Contaminated Dentin	72.08	0	27.92

There is no significant difference among each group (p<0.05).
[a]Adhesive failure = failure between resin and dentin.
[b]Cohesive failure = failure that occurred within the dentin or in the resin composite.

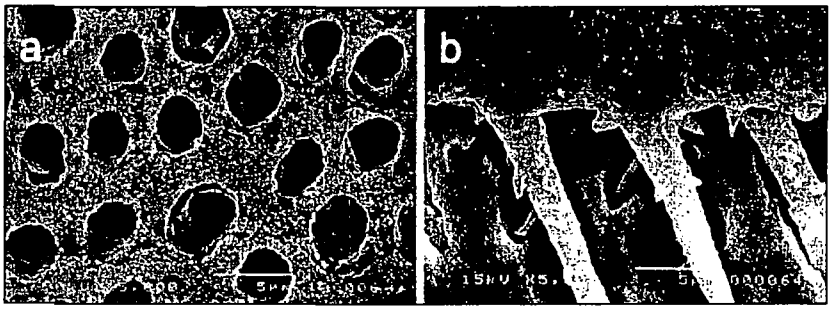

Figure 3. *(a) SEM photomicrograph of the normal dentin surface after etching with 37% phosphoric acid. The smear layer was completely removed. Widening of the dentinal tubules was observed. (b) The interface between Variolink resin cement and normal dentin with a 2 µm thick hybrid layer and funnel-shape resin tags with lateral branches (original magnification 5000x).*

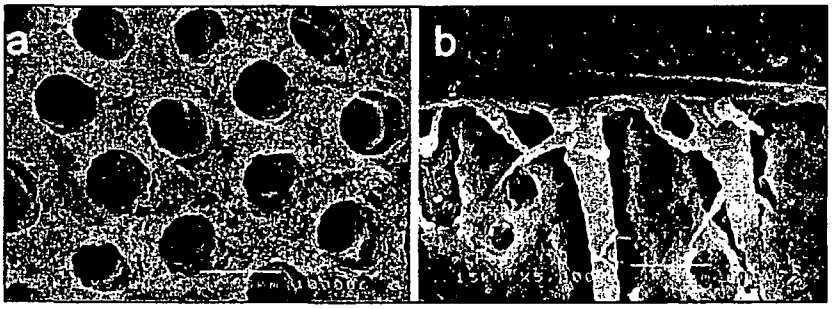

Figure 4. *(a) SEM photomicrograph of the contaminated dentin surface after etching with 37% phosphoric acid and (b) the interface between Variolink resin cement and contaminated dentin, which was not different from that of normal dentin (original magnification 5000x).*

cantly different from each other. Most failures were adhesive (Table 3). For the VL groups, analysis of the mode of failure did not show significant differences between that of normal and contaminated dentin. Most failures were adhesive. Variation in failure mode was found in the PF groups, which demonstrated a slight increase in cohesive failure in resin, especially in the contaminated group.

Surface morphological study showed that, in the control group, a thick smear layer was left on the dentin surfaces (Figure 2a). In the contaminated group, noticeable etching effects were observed. The smear layer was partially removed and the dentinal tubules can be located with smear plugs still occluding the tubule orifices (Figure 2b). The surfaces of normal and contaminated dentin after phosphoric acid etching were similar, with the absence of the smear layer and peritubular dentin, as well as clearly visible patent dentinal tubules (Figures 3a and 4a). The normal dentin after treatment with ED primer revealed consistent etching patterns of a clear surface without the smear layer and with opened dentinal tubules with the remaining peritubular dentin (Figure 5a). However, the contaminated surfaces treated with ED primer showed inconsistencies in etching patterns. The surfaces were clear without the smear layer and also with open dentinal tubules with and without peritubular dentin. In a few tubules, the remaining smear plugs still occluded the tubule openings (Figure 6a).

No difference was found between the SEM's appearance of the bonded interfaces of VL II to normal dentin and contaminated dentin (Figures 3b and 4b). Approximately 2 µm thick hybrid layers with funnel-shaped resin tags were observed. Many resin tags showed lateral extension of the microtags branching off from the main tags in the dentinal

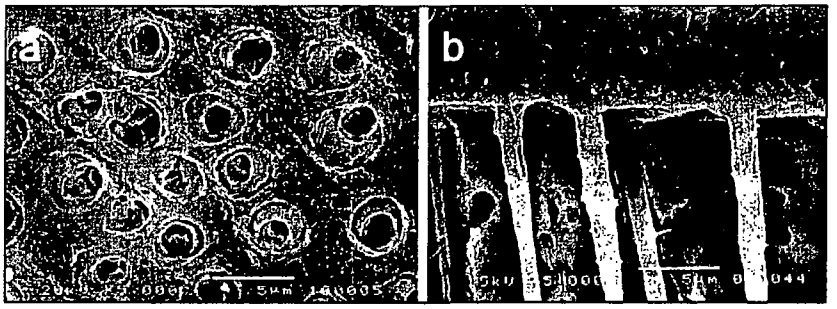

Figure 5. *(a) SEM photomicrograph of a normal dentin surface after application of the ED primer. The smear layer was removed and most dentinal tubules were opened with the remaining peritubular dentin. (b) The interface between Panavia resin cement and normal dentin with approximately a 0.5 µm thick hybrid layer and long cylindrical resin tags (original magnification 5000x).*

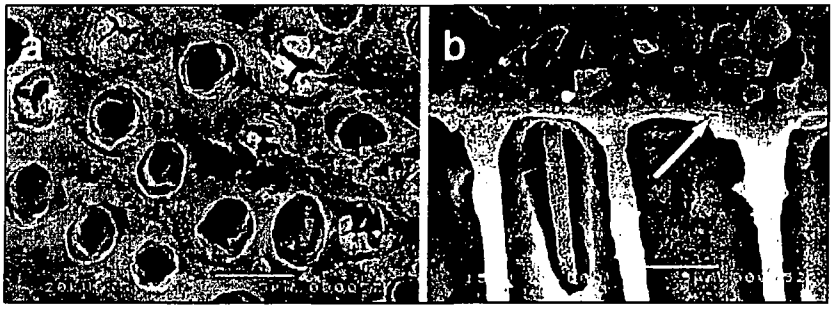

Figure 6. *(a) SEM photomicrograph of the contaminated dentin surface after the application of ED primer. The smear layer was removed. Dentinal tubules are clearly visible with different degrees of tubular opening. (b) The interface between Panavia resin cement and contaminated dentin. A thin hybrid layer with small gaps between resin cement and the top of the hybrid layer (arrow). Funnel-shape and cylindrical resin tags are observed in the same area (original magnification 5000x).*

tubules. The interface between PF to normal and contaminated dentin was similar, with a 0.5 µm thick hybrid layer and cylindrical resin tags with lateral protrusion of micro tags from the side of the main tags (Figures 5b and 6b). However, at the interface of the PF and contaminated dentin, small gaps were found at the junction between the top of the hybrid layer and the bottom of the resin cement layer, which were not found in normal dentin. In addition, regular cylindrical tags extending into the dentin were found in the normal dentin. In the contaminated dentin, irregular shapes of resin tags were observed, especially at the upper part of the tags. Cylindrical resin tags were frequently revealed, but funnel-shaped resin tags were also observed in some areas due to more aggressive etching patterns that removed the peritubular dentin. Fewer resin tags exhibited a constriction at the upper end next to the hybrid layer.

EDS analysis showed slightly higher aluminum content in the groups of contaminated dentin treated with ED primer (2.46%Al) compared with normal dentin treated with ED primer (0.75%Al) and contaminated dentin treated with phosphoric acid (0.46%Al).

DISCUSSION

Many studies have reported that the results of the bond strength test will vary due to different dentin substrate conditions, such as the age of the tooth and storage conditions.[9-10] However, these factors could be omitted in the current study, since all specimens in the control and contaminated groups were prepared from the same dentin disks. In addition, the location of the bonding area was controlled by placing the resin cement cylinders at the same distance from the dentino-enamel junction.

In the current study, the bonding ability of two resin cements, one utilizing an etch-and-rinse, single bottle adhesive, and the other utilizing a self-cured, all-in-one self-etching adhesive to astringent-contaminated dentin were comparable to those in normal dentin. The results of the current study thus lead to acceptance of the null hypothesis that the bond strengths to a hemostatic agent-contaminated human dentin of both resin cements are similar to that of normal dentin.

The self-etching ED primer of PF with pH 2.4 has less etching effect on the dentin surface than phosphoric acid. On the normal dentin surface, this weak acid removed the smear layer and the smear plug as well as slightly demineralizing the intertubular dentin, but it was not strong enough to demineralize the peritubular dentin. This resulted in a 0.5 µm thick hybrid layer and uniform cylindrical resin tags of PF compared to a 2 µm thick hybrid layer and funnel-shaped resin tags of the etch-and-rinse adhesive in the VL group.

The hemostatic agent containing 25% $AlCl_3$ Racetyptine and the two-minute application time used in the current study were in accordance with the methods used in the previous study conducted by the current authors.[7] The results showed that the two-minute application of this agent removed the smear layer on the surface and, to a small extent, it removed the smear plug from most dentinal tubules. The demineralization effect of $AlCl_3$ also seems to have enhanced the etching effect of the self-etching ED primer on the contaminated dentin in some areas, since few open dentinal tubules without peritubular dentin were observed (Figure 6a). Even though the results of the EDS analy-

sis showed that, after application of the ED primer, a higher Al content (2.46%) remained on the contaminated dentin surface than on the normal non-contaminated dentin surface (0.75%), the remaining Al seemed to have no obvious effect on the etching ability of the ED primer. This result is in contrast to the previous study in which a self-etching primer of a light-cured, two-step self-etching adhesive, Clearfil SE Bond, was applied for 20 seconds on the contaminated dentin and showed a subsequently less etching effect than to normal dentin. The authors of the current study ascribe this to the displacement of Ca in the hydroxyl apatite by Al, which resulted in the formation of the insoluble $Al(OH)_2H_2PO_4$ compound. The compound might have increased resistance to acid of the dentin surface.[11] However, this explanation could only be partially applied to the contaminated dentin of the PF group, since the results of SEM observation revealed inconsistencies in etching patterns on the contaminated dentin. More or less localized etching effects were found on the same surfaces of contaminated dentin after the ED primer was rinsed off. This varied etching effect corresponded to the SEM pictures of the resin-contaminated dentin interface of PF, which showed greater variation in resin tag formation.

The finding that the contamination of dentin with the $AlCl_3$ solution did not adversely affect the bond strength of this self-cure, self-etch primer used with Panavia was different from the results of previous studies.[7,12] In previous studies, the light-cured, self-etch adhesives used with direct resin composite restoration showed lower bond strengths to astringent-contaminated dentin. The main reason is probably the greater etching ability of the self-cured ED primer compared to that of the light-cured self-etching SE primer. The greater etching effects of the ED primer may not be explained by the acidity of the primer, since the pH of the ED primer (pH 2.4) is higher than that of the SE primer (pH 2).[13,14] This is probably due to the longer etching time (30 seconds) of the ED primer compared to the 20 second-etching time of the SE primer as per the manufacturer's instructions. This may support the previous study, in which the etching effect of self-etching primer was greater when priming time was extended from 20 seconds to 40 seconds.[7] The other reasons may be the different composition of the self-etching primer/adhesives utilized and the different mode of curing that may have enabled a good infiltration of the ED primer into the dentin. These reasons may have resulted in substantially similar bond strengths to that of normal dentin.

Although the bond strength of Panavia to contaminated dentin was not different from that of normal dentin, this result should be cautiously interpreted, since the ultramorphology of the bonding interfaces of Panavia to contaminated dentin revealed small gaps between the top of the hybrid layer and the resin cement (Figure 6b). Previous studies have reported that no correlation was found between the bond strength values and degree of microleakage.[15,16] These gaps may be the result of either incompatibility between the dual-cured resin cements and the acidic monomers in the ED primer or the semi-permeable property of the cured one-step self-etch primer/adhesive as reported in a previous study.[17] This may result in the susceptibility of this adhesive system to microleakage or lower durability of the bonding. However, in the current study, this adverse effect was noticeable only with bonding to astringent-contaminated dentin, since no such gaps were found at the interface between this cement and normal dentin. The remaining aluminum content on the surface of hemostatic-contaminated dentin may increase the adverse effect of ED primer on the adaptation and strength of resin cement. This may be the reason why a higher cohesive failure of resin was found in the contaminated subgroup of PF when compared to that of the normal dentin subgroup.

In many studies regarding the bond of adhesives to dentin contaminated by other agents, such as zinc oxide eugenol, hydrogen peroxide or astringents, the etch-and-rinse adhesive generally provided similar bond strengths to contaminated dentin compared with normal dentin.[7,18-21] It was assumed that the phosphoric acid used in etch-and-rinse adhesives would remove most of the contaminants from the dentin surface before the adhesive resin application.[20] This may explain the similar bond strengths to normal and astringent-contaminated dentin of the etch-and-rinse system of VL in the current study. The aggressive etching effect of phosphoric acid with pH 0.5 might have demineralized and removed all contaminant-induced effects on the dentin surface. This was supported by the result of the EDS analysis, which showed similar remaining aluminum content on the surfaces of normal and contaminated dentin after etching with phosphoric acid. The acid etching patterns of the dentin surfaces of the normal and contaminated groups of VL were also similar.

The astringent used in the current study contained 25% aluminum chloride. Its acidity had a demineralizing effect on dentin surfaces. However, this did not affect the dentin bond strengths of both resin cements. From the SEM pictures, the ED primer has less of an etching effect when compared with the phosphoric acid used in the adhesive of Variolink II. It seems that, in terms of bond strength, this self-etching effect is sufficient to remove any contaminants from the astringents and provides similar bond strength. However, further study regarding the sealing ability and long-term durability is needed.

CONCLUSIONS

Dentin contaminated with astringent containing 25% aluminum chloride, Racestyptine, had comparable bond strengths to normal dentin of both resin luting cements. These results are limited to the materials used in the current study. Other materials might exhibit differently from the current report.

Acknowledgment

This research was supported by the NRCT-JSPS Core University Program in Dentistry and the Faculty of Dentistry, Mahidol University.

(Received 11 August 2008)

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Bond Strengths of Two Adhesive Systems to Dentin Contaminated with a Hemostatic Agent

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P Senawongse • J Tagami

Clinical Relevance

A self-etching adhesive exhibited significantly lower bond strength to dentin contaminated with 25% aluminum chloride solution compared to normal dentin, but a total-etching adhesive exhibited no difference in bond strength to either contaminated or normal dentin. Longer primer application of the self-etching adhesive significantly increased the dentin bond strength of the contaminated group.

SUMMARY

This study evaluated the bond strength of a total-etch and a self-etch adhesive to dentin contaminated with a hemostatic agent containing aluminum chloride ($AlCl_3$). Eighteen occlusal dentin discs were prepared from human molars. Each disc was ground and sectioned into two halves, one for normal dentin and the other for contaminated dentin. The specimens of both normal and contaminated dentin were randomly divided into three groups and treated with the following materials: 1) Excite (EX); 2) Clearfil SE Bond with 20-second primer application time (CB 20) and 3) Clearfil SE Bond with 40-second primer application time (CB 40). The microshear bond strength specimens were prepared using the resin composite Clearfil APX. The bond strengths were evaluated on a universal testing machine. Statistical analysis was performed at α=0.05. The surface micromorphology and aluminum content of the different dentin conditions were also examined. In EX, no significant difference was found between the bond strengths of normal dentin and contaminated dentin. The bond strength of CB20 to contaminated dentin was significantly lower than that to normal dentin. The

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DOI: 10.2341/06-121

extension of primer application time from 20 to 40 seconds significantly increased the bond strength of CB to contaminated dentin.

INTRODUCTION

Moisture and blood contamination have a detrimental effect on bond strength between adhesives and tooth structures.[1-3] As a result, the use of a rubber dam is mandatory for all adhesive restorations.[4] In general practice, however, operators do not routinely work with a rubber dam, instead, other moisture control techniques are used. In some clinical situations, such as the gingival area, blood and sulcular fluid frequently appear as a result of gingival trauma from tooth preparation or gingival inflammation. Currently, in that condition, dry operative fields can be obtained after the application of hemostatic agents to control bleeding and decrease gingival fluid. Examples of these materials are aluminum chloride, aluminum sulfate and ferric sulfate. Previous studies have demonstrated that these hemostatic agents are highly acidic and their pH varies from 0.7-3.0.[5-6] Aluminum chloride ($AlCl_3$), with a concentration between 20%-25%, is a commonly used hemostatic agent.[7] It has been shown that dentin surfaces treated with 21.3% $AlCl_3$ exhibit various degrees of demineralization. Complete smear layer removal with some dentin demineralization can be observed after applying this agent for five minutes.[6]

Currently, adhesive systems can be classified into two groups, total-etching and self-etching systems. Since some effects of the smear layer to the adhesion of self-etching adhesive have been reported,[8] smear layer removal by hemostatic agents could affect the bonding mechanism of this adhesive system. It has been shown that the bond strength of a self-etching adhesive to dentin contaminated with ferric sulfate or $AlCl_3$ dramatically decreased, compared to the normal dentin group.[9]

One of the problems that occurs in bond testing is fracture of the specimens within the materials, not at the interface. Micro-tests, including a microtensile and a microshear bond test, have been developed to improve their efficiency.[10-12] This has resulted in an increase in specimens fracturing at the interface. Therefore, the bond strengths obtained from these tests should be more reliable and represent the true bond strength between materials. Also, the microshear bond test has some advantages, such as ease of specimen preparation and reliable results with a narrow standard deviation.[11-12]

This study evaluated the microshear bond strengths of a total-etch and a self-etch adhesive to human dentin contaminated with a hemostatic agent containing $AlCl_3$.

METHODS AND MATERIALS

Eighteen 2 mm-thick dentin discs were prepared by perpendicular sectioning to the long axis of extracted caries-free human molars using a low-speed saw, under copious water spray (Isomet, Buehler, IL, USA). The dentin surfaces were then hand ground with 600-grit SiC paper under running water and hemi-sectioned, resulting in 18 pairs of dentin semi-discs. Next, the pairs of semi-discs were randomly assigned to three groups of six pairs each. For each group, the six pairs of semi-discs were separated and subdivided into control and contaminated subgroups. The diagram of specimen preparation is shown in Figure 1 and the composition of the materials used in this study is shown in Table 1.

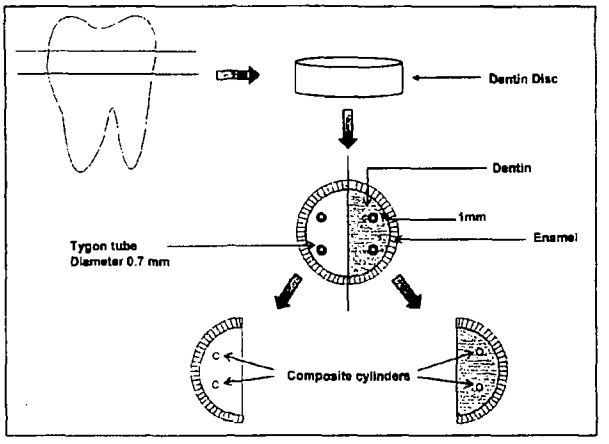

Figure 1. *Diagram illustrating bonding procedures for microshear bond strength test.*

The treatment protocol for each group was as follows: for Group 1 Excite (EX), the dentin surface of each semi-disc in the control subgroup was dried with oil-free air to remove excess water. In the contaminated subgroup, further dentin surface treatment was performed. The hemostatic agent Racestyptine (Septodont, Cedex, France) was applied to the dentin surfaces for two minutes, then the dentin was rinsed with water spray for 30 seconds and dried with oil-free air. Consequently, the dentin surfaces of both the control and the contaminated groups were etched with 37% phosphoric acid for 15 seconds and thoroughly rinsed using water spray. Excess water was blot-dried from the surface with lint-free paper (Kimwipes, Kimberly Clark Corp, Roswell, GA, USA) to achieve moist dentin. The adhesive Excite was used according to the manufacturer's instructions by applying the adhesive resin onto the dentin surface for 15 seconds, then drying with oil-free air for five seconds. The irises that were cut from micro bore tygon tubing (TYG-030, Small Parts Inc, Miami Lakes, FL, USA) with an internal diameter and height of approximately 0.75 and 0.50 mm, respectively, were then positioned at two locations on each dentin semi-disc, 1 mm from the dentino-enamel junction. Light polymerization was performed for 10 seconds with a light-curing unit

Table 1: *Materials Used in This Study*

Material	Composition	Batch #	Manufacturer
Racestyptine	25% m/V hexahydrate aluminum chloride, oxyquinol, hydroalcoholic excipient	M1 115	Septodont, Cedex, France
Clearfil SE Bond	*Primer*: HEMA, MDP, Hydrophilic dimethacrylate, water, ethanol, dl-camphorquinone, N,N-Diethanol-p-toluidine	00443 A	Kuraray, Osaka, Japan
	Adhesive: HEMA, MDP, Bis-GMA, Hydrophilic dimethacrylate, dl-camphorquinone, N,N-Diethanol-p-toluidine, silanated colloidal silica	00609 A	
Excite	*Etchant*: 37% phosphoric acid *Adhesive*: Dimethacrylate, alcohol, phisphonic acid acrylate, HEMA, SiO_2, initiators, stabilizers	F 40503 F 63821	Ivoclar Vivadent, Schaan, Liechtenstein
Clearfil APX	BisGMA, TEGDMA, barium glass, colloidal silica	01028 A	Kuraray, Osaka, Japan

(Curing Light XL 3000, 3M ESPE, St Paul, MN, USA). A hybrid resin composite, Clearfil APX shade A2, was used to fill in the tubing and was light-cured for 40 seconds. The tubing was then removed from the composite cylinder by longitudinal cutting with a razor blade. This resulted in 12 composite cylinders for this adhesive, each in the control and contaminated groups. For Group 2 Clearfil SE Bond, 20 second primer application (CB 20), after the dentin surfaces were prepared for the control and contaminated subgroups in the same manner as in Group 1, Clearfil SE Bond was used according to the manufacturer's instructions. The primer was applied to the dentin surfaces with agitation, left for 20 seconds, then dried with oil-free air for five seconds. The adhesive resin was then applied to the primed surfaces. Next, the composite cylinders were prepared in the same manner as in Group 1. For Group 3 Clearfil SE Bond, 40-second primer application (CB 40), only the contaminated subgroup was performed. The specimen preparation and preparation for the microshear bond test were performed as in Group 2, except that the primer application time was extended from 20 to 40 seconds. Therefore, only 12 composite cylinders in the contaminated group were prepared. After storage in distilled water at 37°C for 24 hours, all specimens were inspected under an optical microscope (30x). The specimens with defects, such as interfacial gap defect and bubble inclusion, were excluded and replaced.

The microshear bond test was performed on the microshear bond test apparatus (Bencor-Multi-T, Danville Engineering Co, San Ramon, CA, USA) attached to a universal testing machine (EZ-test 500 N, Shimazu Co, Kyoto, Japan) as described by Shimada and others.[11] The dentin disc was placed on the apparatus with a cyanoacrylate adhesive (Zapit, Dental Venture of America, Corona, CA, USA). A thin wire, 0.2 mm in diameter, was looped around the small resin composite cylinder. This procedure makes the lower half of the cylinder contact the wire, which is gently held flush against the resin-dentin interface. The resin cylinder and the center of the load cell were aligned as straight as possible (Figure 2). A shear force was applied to each specimen at a crosshead speed of 1 mm/minute until fracture. Two-way ANOVA and multiple comparisons at $p<.05$ were used to analyze the data.

Morphological changes of the normal dentin surface after grinding, dentin contamination with a hemostatic agent and both dentin conditions after etching with phosphoric acid and self-etching primer application for 20 and 40 seconds were observed using a scanning electron microscope (JSM-5310V, JEOL Ltd, Tokyo, Japan). The specimens were observed and analyzed for aluminum content using an energy dispersive spectrometer (EDS, Oxford ISIS Pentafet Link Model 6647, High WyCombe, England) operated at 20 KV.

A pH meter (Twin pH, Horiba, Tokyo, Japan) was used to determine the pH of the hemostatic agent.

RESULTS

The pH of the hemostatic agent, Racestyptine, consisting of 25% $AlCl_3$, was 0.8. Table 2 shows the microshear bond strengths of the adhesives used in this study to normal and contaminated dentin. The microshear bond strength of Excite adhesive to normal dentin and contaminated dentin were 18.42 ± 2.28 and 22.49 ± 5.89 MPa, respectively. No statistically significant difference between these two groups was exhibited ($p>.05$). The microshear bond strength of the self-etching adhesive Clearfil SE Bond to normal dentin was 36.59 ± 5.94 MPa, which was significantly higher than the microshear bond strength of this adhesive to contaminated dentin (CB20), 19.35 ± 6.05 MPa ($p<.05$). The microshear bond strength of Clearfil SE Bond to contaminated dentin, when the primer application time was extended to 40 seconds, 29.09 ± 6.93 MPa, was significantly higher than that of the contaminated group with a 20 second primer application ($p<.05$). Nevertheless, the bond strength of the 40 second primer application group was still significantly lower than that of the control group ($p<.05$), which was the highest bond strength obtained in this experiment.

Scanning electron micrographs of the dentin surface in the control group revealed that the thick smear layer was left intact on the surfaces and the dentinal tubules could not be seen (Figure 3). In the contaminated group, noticeable etching effects were observed. The smear layer was partially removed and the dentinal tubule opening was located. However, the smear plug still occluded the tubule orifices (Figure 4). The surfaces of normal and contaminated dentin after phosphoric acid etching were similar, with the absence of the smear layer and peritubular dentin, and the clearly visible patent opening of the dentinal tubules were exhibited (Figures 5 and 6). After treatment with SE primer for 20 seconds, normal dentin revealed clear surfaces without smear layers and open tubules with the remaining peritubular dentin (Figure 7), while the contaminated surface treated with SE primer for 20 seconds showed surfaces without smear layers, with some tubules still occluded (Figure 8). With the 40 second SE primer application, the contaminated dentin surface exhibited a more pronounced etching effect, with the surface of the smear layer depleted and more widely open dentinal tubules without peritubular dentin. Well-defined peritubular collagen fibers could be observed inside the tubules (Figure 9).

EDS analysis showed more aluminum content in the groups of contaminated dentin and contaminated dentin treated with SE primers at both 20 and 40 seconds (3.22%-4.76%Al) compared with normal dentin (0.49%Al) and contaminated dentin treated with phosphoric acid (0.46%Al).

Table 2: *Microshear Bond Strengths (MPa) of a Total-etching Adhesive, Excite and a Self-etching Adhesive, Clearfil SE Bond, to Normal Dentin and Contaminated-dentin*

Groups	Normal Dentin	Contaminated Dentin
Excite (EX)	18.42 ± 2.28[c]	22.49 ± 5.89[c]
Clearfil SE Bond: 20 seconds primer (CB20)	36.59 ± 5.94[a]	19.35 ± 6.05[c]
Clearfil SE Bond: 40 seconds primer (CB40)	--	29.09 ± 6.93[b]

Groups with the same superscript are not statistically different (p>0.05).

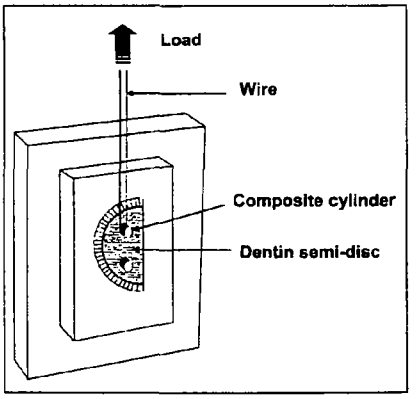

Figure 2. *Schematic of the microshear bond test.*

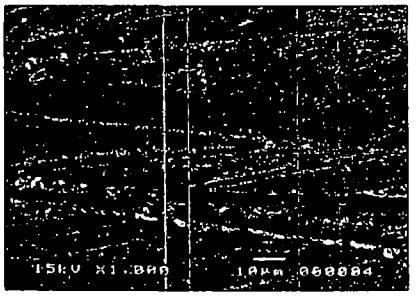

Figure 3. *Scanning electron micrograph of normal dentin after grinding with 600 grit SiC paper. Thick smear layer covered the dentin surface. No dentinal tubule opening was visible (1000x).*

DISCUSSION

In this study, specimens in the contaminated group and control group were prepared on the same dentin disks. Therefore, variables from different dentin substrates, such as age of the tooth and storage condition, could be excluded. Since dentin depth is one factor affecting the dentin bond strength of adhesives,[13,14] the dentin level was controlled in this study by fabricating resin composite cylinders at the same distance, 2 mm from the dentino-enamel junction.

Bond strength of the total-etch system in this study was significantly lower than that of the self-etching system. Results appear to be similar to the 2006 study by De Munck and others.[15] The low bond strength of a total-etching adhesive (Scotchbond 1), 11.9 MPa, compared with that of a self-etching system (Clearfil SE Bond), 41.3 MPa was also demonstrated. The explanation may be that the total-etching system is very technique sensitive. The dentin should be properly moist. Moreover, the dentin etched by an acid may be too deep to be penetrated by the adhesive. This results in nanoleakage, which possibly occurs with the total-etching system. Dentin bond strength in the microtest, microtensile or microshear bond strength test of Clearfil SE Bond was frequently found to be a high value, 32.9 MPa[16] and 39.81 MPa.[17] In contrast, studies showed the wide range of microtensile bond strength of Excite to be 6.03 MPa[18] and 40.8 MPa.[19]

The hemostatic agent containing 25% $AlCl_3$, Racestyptine, was selected as a representative agent, because it is effective in controlling bleeding and is frequently used in clinical practice. The two-minute con-

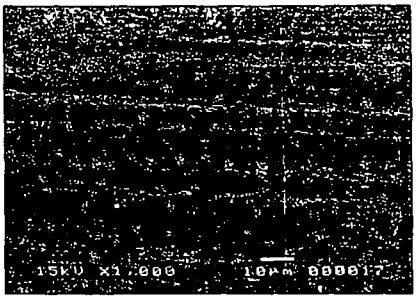

Figure 4. *Scanning electron micrograph of dentin contaminated with 25% aluminum chloride for two minutes. The smear layer was partially removed and the dentinal tubule orifices can be localized (1000x).*

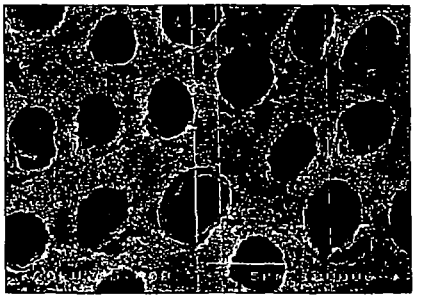

Figure 5. *SEM observations demonstrating the absence of the smear layer, peritubular dentin and patent tubule openings of normal dentin after etching with 37% H_3PO_4 (5000x).*

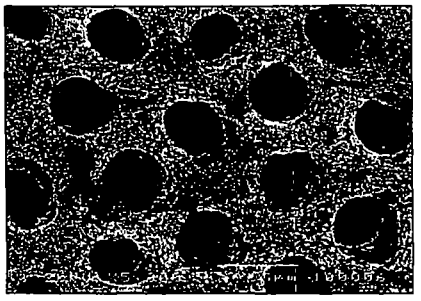

Figure 6. *Contaminated dentin appears similar to normal dentin after etching with 37% H_3PO_4, as shown in Figure 5 (5000x).*

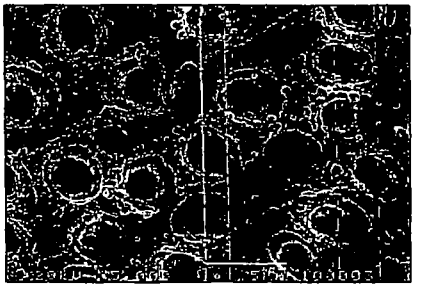

Figure 7. *Normal dentin after Clearfil SE Bond primer application for 20 seconds. The smear layer is completely removed; dentinal tubules with peritubular dentin are observed (5000x).*

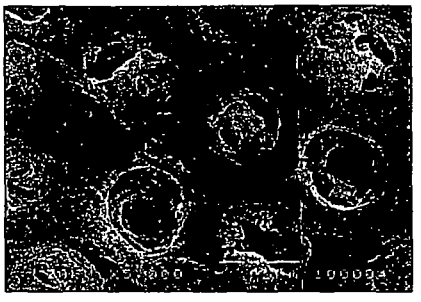

Figure 8. *Contaminated dentin after Clearfil SE Bond primer application for 20 seconds reveals no smear layer, but some tubules are occluded with smear plug (5000x).*

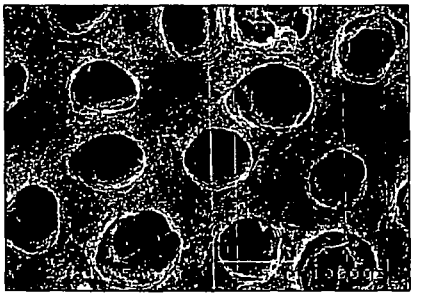

Figure 9. *Contaminated dentin after Clearfil SE Bond primer application for 40 seconds. More aggressive etching pattern is detected, compared with Figure 8. Complete smear layer removed; wide open dentinal tubules without peritubular dentin are exhibited (5000x).*

tamination time was chosen, as it is the average application time when this solution is applied onto soft tissues to control bleeding before restoration is initiated. The results indicated that the $AlCl_3$ solution had some demineralizing effect on the dentin surface. However, the degree of demineralization was less than the previous study,[7] which showed an aggressive etching pattern with complete smear layer removal. An explanation might be the shorter contamination time in this study, two minutes, instead of five minutes, as in the previous study. The degree of dentin surface changes after exposure to 21.3% $AlCl_3$ solution, Hemodent, has been shown to depend on contamination time. Dentin exposed to 21.3% $AlCl_3$ solution for two minutes exhibited smear layer removal and partially occluded dentinal tubules, while dentin exposed to this solution for

five minutes revealed a totally removed smear layer, including demineralized peritubular dentin. Nevertheless, at the 30-second and 2-minute exposure times, the affected dentin surfaces were similar.[7]

Although some demineralization of dentin contaminated with the $AlCl_3$ solution was exhibited in the current study, application of the self-etching primer on contaminated dentin did not enhance its demineralization effect. In contrast, after priming with the self-etching adhesive, the contaminated dentin showed a less etching effect compared to the control group, where the dentin was normal. In addition, the dentin bond strength of CB 20 on the contaminated group was dramatically decreased, compared to that of the control group. The same result was also reported in a previous investigation.[9]

It has been shown that enamel treated with $AlCl_3$ solution for 20 minutes could uptake aluminum (Al) from the solution, especially within the first 20 μm of enamel.[20] Moreover, this $AlCl_3$ treated enamel revealed inhibition of the demineralization process of hydroxyapatite (HAP), which was exposed to a demineralizing solution,[21,22] even though the Al concentration was as low as 0.1 μmol/l.[23] This mechanism has been explained by displacement of calcium in the HAP by Al, which results in the very insoluble Al $(OH)_2$ H_2PO_4 compound.[24] Because HAP is also the major part of dentin-like enamel, the influence of $AlCl_3$ solution on dentin could be similar to enamel.

Since the Clearfil SE primer has weak acidity, with the pH being approximately 2,[25] the demineralizing effect on dentin contaminated with $AlCl_3$ solution might be similarly inhibited. For self-etching adhesives, the dentin bonding mechanism is due to the exposed collagen network and smear layer modification by self-etching primer incorporated into resin adhesives. As a result, less dentin etching effect of the primer could result in bond strength decreases, as shown in this study. The results of EDS analysis confirmed that a higher aluminum content remained on the contaminated dentin surface following application of SE primer for either 20 or 40 seconds. Nevertheless, the 40-second primer application might be a proper method to use for Clearfil SE Bond when the dentin surface is contaminated with this hemostatic agent, since the bond strength in this group was significantly higher than that in the CB 20 group. The surface morphology of the CB 40 group showed more aggressiveness of the etching pattern. Extending the primer application time of the self-etching adhesive might enhance the etching effect of the primer and can result in higher dentin bond strength of this adhesive system.

However, for the total-etching adhesive used in this study (EX), the contamination of dentin with $AlCl_3$ solution did not have a detrimental effect on bond strength. The microshear bond strengths of the control and contaminated group were comparable. This might be due to the aggressive etching effect of phosphoric acid, with pH 0.5,[26] which simultaneously demineralized and removed all contaminants on the affected dentin surfaces. This was suggested by the fact that contaminated dentin and normal dentin, after phosphoric acid etching, revealed similar remaining aluminum content that was less than that of contaminated dentin and contaminated dentin treated with SE primer for both 20 and 40 seconds. Moreover, the dentin etching patterns of the control and contaminated group of EX after acid etching were similar.

From the SEM of this study, the total-etching adhesive showed the complete smear layer and peritubular dentin removal after phosphoric acid etching; therefore, it could enhance fluid movement across the resin-dentin interface. In contrast, the self-etching system could result in less fluid movement due to a less aggressive etching pattern, resulting in superior dentin sealing compared with the total-etching system.[27] This might be the reason why the self-etching adhesives exhibited less incidence of post-op sensitivity.[28]

Currently, few studies have reported the effect of hemostatic agent on the bond strength of adhesives to tooth structures. The different composition of the hemostatic agents might affect tooth structure differently. Thus, future studies reporting on this aspect are needed. Given the results of this study, care should be taken when the hemostatic agent is used before application of self-etching adhesives. Extending the primer application time of the self-etching adhesive or using the total-etching systems might be appropriate in this situation.

CONCLUSIONS

When self-etching adhesive was used, dentin contaminated with the hemostatic agent Racestyptine, containing 25% aluminum chloride, had significantly lower bond strength compared to normal dentin. The hemostatic agent did not have any effect on dentin bond strength of the total-etching adhesive. These results are limited to the materials used in this study. Other materials might perform differently from these findings.

Acknowledgement

This research was supported by the NRCT-JSPS core university program in dentistry and the Faculty of Dentistry, Mahidol University. The authors are grateful to assistant professor Dr Thomas Hoy and the Language Center, Faculty of Graduate Studies, Mahidol University for kindly reviewing the article.

(Received 18 September 2006)

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Dental Research

Effect of 3 medicaments on the dimensional accuracy and surface detail reproduction of polyvinyl siloxane impressions

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Karen Williams, RDH, MS[3]/James Corcoran[4]

Objective: The purpose of this study was to determine the effect of retraction cord medicaments (aluminum chloride, ferric sulfate, and ferric subsulfate/ferric sulfate) on the dimensional accuracy and surface detail reproduction of polyvinyl siloxane impressions. **Method and materials:** Polyvinyl siloxane impressions were made of standardized metal dies (American Dental Association [ADA] specification No. 19) treated with 1 of the 3 retraction cord medicaments. Dimensional accuracy was evaluated by comparing the average length of a line in the impressions to the standard die. Surface detail reproduction was evaluated by viewing the impressions under low-angle illumination at ×10 magnification. Reproduction was considered satisfactory if 2 of 3 horizontal lines were reproduced continuously. The dies were also evaluated under the microscope before the impression was made. **Results:** The medicaments did not significantly effect the dimensional accuracy; mean shrinkage was within ADA guidelines in the treatment groups. All of the medicaments had an adverse effect on surface detail reproduction. These effects were statistically significant compared to the untreated control. **Conclusion:** Although the changes in dimensional accuracy were within ADA guidelines, the surface detail reproduction was modified such that the impression would be considered clinically unacceptable. For optimal results, care must taken to remove all traces of these retraction cord medicaments prior to recording of a polyvinyl siloxane impression. (Quintessence Int 2000;31:201–206)

Key words: dimensional accuracy, polyvinyl siloxane impression material, retraction cord medicament, surface detail reproduction

CLINICAL RELEVANCE: The 3 retraction cord medicaments used in this study adversely affected surface detail reproduction in polyvinyl siloxane impressions. All traces of these medicaments must be removed from the preparation prior to making a polyvinyl siloxane impression.

The popularity of polyvinyl siloxane (PVS) impressions has been attributed to several characteristics, including the dimensional accuracy and stability of this material.[1] Dimensional accuracy is a critical property, because imperfections in the impression can result in an inaccurate die and restoration. Dimensional stability means that, in general, impressions made with these materials will not distort even when stored for periods up to 1 week.[2] These properties of PVS materials, in addition to their ease of manipulation and excellent elastic recovery, contribute to their wide acceptance.

Polyvinyl siloxane impression materials do, however, suffer from 1 severe limitation: they are hydrophobic. The hydrophobic nature of these materials compromises their application in areas where moisture control is difficult. Some manufacturers have addressed this problem by incorporating surfactants into the material, but this only makes the PVS less hydrophobic, not hydrophilic.[1] The hydrophobic nature of these materials demands that the clinician pay particular attention to those techniques and/or reagents that control moisture in problematic areas such as the gingival sulcus.

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Presented at the American Association for Dental Research, Annual Meeting, Vancouver, British Columbia, Canada, March 1999.

TABLE 1 Chemical medicaments used in the study

Material	Brand name	Manufacturer	Batch No.
Aluminum chloride	*Buffered Hemodent*	*Premier*	*18964*
Ferric sulfate	Hemodent FS	Premier	18952
Ferric subsulfate/ ferric sulfate	Astringedent X	Ultradent	2RRQ

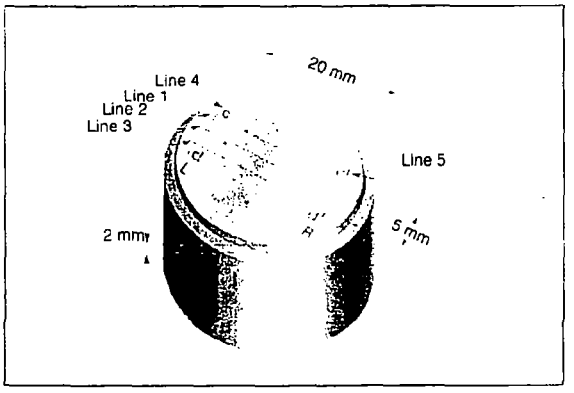

Fig 1 Standardized stainless steel metal die with 3 horizontal lines (1, 2, and 3) and two vertical lines (4 and 5). The intersections of the cross lines are labeled c, c', d, and d'. (L) Left; (R) right.

Clinically, many fixed prosthesis preparations finish at or below the gingival margin; blood, gingival fluid, and saliva can severely compromise the ability to register margins in these areas. Retraction cords, with or without chemical medicaments, are commonly used to improve access to the margins of the preparation.[3,4] The retraction cords displace the gingiva laterally while the medicaments prevent or control hemorrhage in the gingival sulcus.

Commonly used medicaments include racemic epinephrine, 25% buffered aluminum chloride, aluminum sulfate, aluminum potassium sulfate, ferric sulfate, and ferric subsulfate. It has been reported anecdotally that these chemical medicaments, especially those medicaments containing sulfur, may retard or inhibit the set of PVS impression materials, particularly "hydrophilic" PVS.[5] These conclusions were based largely on earlier studies that indicated that the platinum catalyst in PVS materials was contaminated by the sulfur compounds from latex gloves and rubber dam, resulting in an inhibited or retarded set.[6,7]

Other investigators have questioned the effect of retraction cord medicaments on the set of PVS impression materials.[2,8-10] These investigators suggested that the inhibited polymerization, described in earlier reports, is attributable to inadvertent contamination by latex rubber gloves rather than to exposure to gingival retraction cord medicaments.[8-10]

The effect of retraction cord medicaments, particularly those containing sulfur, on the set of PVS impression materials remains controversial. The purpose of this study was to determine the effect of 3 medicaments–aluminum chloride, ferric sulfate, and ferric subsulfate/ferric sulfate–on the dimensional accuracy and surface detail reproduction of polyvinyl siloxane impression materials. If either of these properties is adversely affected by the retraction cord medicaments, the accuracy of the die and, ultimately, the restoration will be compromised.

METHOD AND MATERIALS

Preparation of specimens

Twenty-one sample impressions were made of metal dies treated with each of the 3 retraction cord medicaments (Table 1) for a total of 63 treated specimens. Twenty-one additional impressions of the untreated dies served as the controls. Five standardized stainless steel dies (similar to those described in American Dental Association [ADA] specification No. 19)[11] with 3 horizontal and 2 vertical lines were used (Fig 1). The width of all 3 lines was 160 µm. The dies were individually numbered and marked with an arrow to facilitate orientation. The horizontal lines were numbered 1, 2, and 3, and the vertical lines were numbered 4 and 5. Four intersections (cross lines) were labeled c, c', d, and d' (see Fig 1). The horizontal lines (1, 2, and 3) measured 20 mm between the cross lines, and the vertical lines (4 and 5) measured 5 mm between the cross lines.

All 3 of the commercially available retraction cord medicaments used in this study are astringents. A medium-bodied type I polyvinyl siloxane impression material (Reprosil, batch No. 980307, LD Caulk) was used to make the impressions.

Gauze squares were soaked in the medicaments; excess fluid was removed by blotting, and the gauze was placed on the master die for 30 seconds. The gauze was removed and the die was blown dry with

compressed air for 1 minute. Care was taken to ensure that the medicament was dried on the die before the impression was made. For the control specimens, no medicament was placed on the die. Between each impression, the dies were sonicated for 2 minutes in alcohol and air dried to ensure dies were free of any surface contaminants.

Prior to the actual study, a pilot study showed that water, used in the same manner as the medicaments with gauze, did not affect the surface detail reproduction or dimensional accuracy of the impression material. Therefore, no change could be attributed to the gauze or water.

An impression gun was used to automix prepackaged cartridges of the impression material. The material was loaded into an impression syringe with a fine tip. Care was taken to push the impression material ahead of the syringe tip. Based on the results of the pilot study, this technique yielded the most accurate impressions.

The PVS was dispensed onto the dies with the impression syringe, and then 5-mm-high molds were placed on top of the dies to support the impression material (Fig 2). This resulted in a consistent impression thickness of 3 mm. First polyethylene strips and then flat metal pieces were placed on top of the molds, to keep the polyvinyl siloxane in the mold. The dies were transferred into a water bath; to ensure that the dies did not move, 500-g weights were placed on top of the flat metal plates. A water bath maintained at 32°C ± 1°C was used in accordance with ADA specification No. 19.[11]

The entire assembly, that is, dies, weights, flat metal sheets, and polyethylene, was removed from the water bath after 10 minutes. As recommended by ADA specification No. 19, this was 3 minutes longer than the manufacturer's published time for complete set.[11] The impression material was marked with an arrow pointing to the corresponding arrow on the die. These marks were used as a reference for orienting the specimen prior to measurement. The mold and die were then removed from the impression, and the impression was numbered on the back. The specimens were coded to ensure blind evaluation by the examiner.

Evaluation of dimensional accuracy and surface detail reproduction

Dimensional accuracy was evaluated by measuring the length of horizontal lines c–c' on each impression. Readings were made in triplicate to the nearest 0.001 mm by 2 calibrated examiners using an Unitron Bi5-3174 measuring microscope at ×10 magnification. These readings were then averaged to minimize measurement error. The percentage of change was then calculated by subtracting the known standard line length on the die from the averaged impression value and dividing by the standard line value.

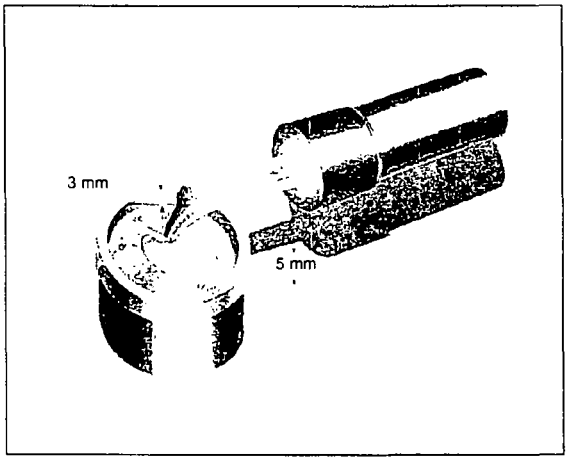

Fig 2 Polyvinyl siloxane impression material injected onto a standardized stainless steel die with a 5-mm high plastic mold in place. This mold supports and provides a consistent 3-mm thickness of impression material.

Surface detail reproduction was evaluated 1 hour after removal of the impression from the water bath. Each of the horizontal lines (numbered 1, 2, and 3) was viewed under a Unitron Bi5-3174 at ×10 magnification using low-angle illumination.[11] The reproduction was considered acceptable if 2 of 3 of the horizontal lines were reproduced continuously and well defined for the full 20 mm between the cross lines. The reproduction of a line was considered unacceptable if any part of the line was indistinct, eg, appeared melted or flattened, or the borders of the line were fuzzy or blurred. In addition, if the medicament pooled on the impression material and obscured the line or was incorporated into the material and destroyed the line's integrity, the line was considered unacceptable. If any impression had 2 indistinct lines, the surface detail reproduction was considered unacceptable. An impression was considered successful if at least 2 of the 3 lines were considered acceptable; anything less than this was considered unacceptable.

The standard and treated dies were also evaluated under the Unitron Bi5-3174, at ×10 magnification, before the impression was made, to determine whether the retraction cord medicaments had any affect on the dies before the impression was made. The dies were closely evaluated for pooling of medicament on the dies, the formation of a surface coating, and any effects of the medicament on the surface detail of the dies.

TABLE 2 Surface detail reproduction

Result	Control	Aluminum chloride	Ferric sulfate	Ferric subsulfate/ ferric sulfate	Total
Acceptable	21	0	0	0	21
Unacceptable	0	20	21	21	62
Total	21	20	21	21	83

TABLE 3 Dimensional accuracy

Group	Horizontal change (mean ± SD)
Control	0.086% ± 0.083%
Ferric sulfate	0.029% ± 0.076%
Ferric subsulfate/ ferric sulfate	0.049% ± 0.114%
Aluminum chloride	0.011% ± 0.093%

Collection of data

Twenty-one specimens were made for each of the 3 medicaments and the controls, for a total of 84 specimens. One specimen in the aluminum chloride group was eliminated from the study because of unrelated methodologic problems.

Prior to initiation of the study, sample size was statistically determined based on an α of 0.05 and power of 0.80 to detect a 0.10% change in acceptable detail reproduction. Based on calculations, it was determined that a sample of 30 impressions of each medicament would be needed. However, the presence of overwhelming trends in the data led the researchers to conduct a preliminary analysis to determine if any further specimens were needed. Based on this analysis, it was decided that no further specimens were necessary.

All data were then entered into SPSS statistical software (version 7.0 for Windows), along with the impression number, the stainless steel die number, and the group designation number. The surface detail reproduction was entered as a nominally scored variable, acceptable or unacceptable.

Statistical analysis

Fisher's exact test was used to examine the effect of medicament exposure on surface detail reproduction. The dimensional accuracy data were evaluated statistically using a 1-factor analysis of variance with Tukey's mean comparison post hoc analysis. Consistency of measurement (reliability) of the dimensional accuracy for observers was taken against the standard die. Average measurement error was found to be 0.01%, with a 95% confidence interval of ± 0.05.

RESULTS

Surface detail reproduction

The results of this study are presented in Tables 2 and 3. Medicaments had a statistically significant adverse affect ($P < 0.05$) on surface detail reproduction. All of the impressions on dies treated with the medicaments were determined to have unacceptable surface detail. In contrast, all of the control impressions (untreated dies) were acceptable with respect to surface detail; ie, the lines were clearly reproduced with distinct edges along their entire length.

When the standard dies were evaluated under the microscope prior to impression making, the dies were clean, without a surface film, and the horizontal and vertical lines were clearly visible and well defined between the cross lines. When the dies that were treated with the aluminum chloride retraction cord medicament were viewed under the microscope, there was obvious contamination of the dies. No pooling of the liquid was observed, but the medicament caused uneven changes in the color of the die. The horizontal and vertical lines remained distinct and were not obliterated.

In comparison, dies that were treated with ferric sulfate did not appear to have a surface coating, and the horizontal and vertical cross lines were distinct. Under ×10 magnification, very small pools of medicaments were, however, noted in some areas along the vertical and horizontal lines. These dies appeared dry to the naked eye. The ferric subsulfate/ferric sulfate had a similar effect on the dies.

Although all 3 medicaments adversely affected the surface detail reproduction according to the defined criteria, the manner in which aluminum chloride affected the surface detail of the PVS was quite different from the way in which the ferric sulfate and ferric subsulfate/ferric sulfate affected the specimens. The aluminum chloride medicament produced a very rough, almost "melted" appearance; whole sections of lines were destroyed on many of the specimens. This may have resulted from contamination and/or a film effect of the aluminum chloride on the die. The ferric sulfate and ferric subsulfate/ferric sulfate retraction cord medicaments had much less of an effect on surface

detail reproduction. However, the surface detail was determined to be unacceptable, because pooling of liquid did occur in some small areas around the edges of the lines, destroying their integrity according to the defined criteria.

Dimensional accuracy

There was no statistically significant difference ($P > 0.05$) in dimensional accuracy between the control and the various medicament groups or between any of the medicament groups. Shrinkage values ranged from 0.110% to 0.029% for the medicament-treated impressions compared to 0.086% for the control samples. All values fell within the ADA standards of less than 0.500% for type 1 nonaqueous elastomeric dental impression materials.

DISCUSSION

The dimensional accuracy did not appear to be affected by any of the retraction cord medicaments used in this study. Shrinkage occurred in all impressions, including the control, but these dimensional changes were within the ADA specifications for PVS material.[11]

The medicaments, however, clearly affected the quality of the impression, and this observation should be noted by all clinicians. Surface detail reproduction was adversely affected by all of the retraction cord medicaments. Aluminum chloride had an effect that was distinctly different from that of ferric sulfate and ferric subsulfate/ferric sulfate. The aluminum chloride produced an extremely rough, melted appearance; whole sections of the lines were completely obliterated. When the aluminum chloride–treated dies were viewed under the microscope, the surface of the dies was obviously contaminated. The medicament caused uneven changes in the color of the dies, but the horizontal and vertical lines were visually distinct.

In the polyvinyl siloxane impressions of the aluminum chloride–treated dies, the horizontal lines were visually indistinct in many areas. It is unclear whether the medicament had an additional affect on the PVS impression material or whether the PVS impression material accurately recorded a contaminated die. Either way, it is critical that the clinician remove all traces of aluminum chloride medicament from the preparation prior to making a PVS impression.

In comparison, the adverse effects of ferric sulfate and ferric subsulfate/ferric sulfate were associated primarily with pooling of residual medicament around the edges of the lines. Often this pooled medicament was incorporated into the edges of the line, destroying its integrity. When the dies that were treated with these medicaments were viewed under the microscope, they did not appear to have a surface coating, but very small traces of medicaments were noted along the vertical and horizontal lines. These dies appeared dry to the naked eye.

Although the impressions of these treated dies were considered unacceptable, the ferric sulfate and ferric subsulfate/ferric sulfate medicaments had a less severe adverse effect on the impressions and the dies than did aluminum chloride. The horizontal lines were distinct in most areas of the impressions, except in very small areas where remnants of the liquid were incorporated into the lines or edges of the lines. With the ferric sulfate and ferric subsulfate/ferric sulfate medicaments, it appeared as if a contaminated die was reproduced in the impression.

The results of this study do not support the conclusions presented by previous authors.[2,8-10] For example, De Camargo et al[8] concluded that the chemical medicaments aluminum chloride, epinephrine, aluminum sulfate, aluminum potassium sulfate, and ferric sulfate do not have any inhibitory affect on the polymerization of PVS impression materials. Several criteria were used to define *inhibition* in their study, including an obvious lack of detail reproduction on the surface of the impression material.[8] Others have used anecdotal clinical reports to discount the possibility of interaction between aluminum chloride and various PVS impression materials and did not investigate further.[9,10] Although it cannot be stated that these medicaments inhibit the set of PVS impression material, the manner in which they were used in the present study suggests that these materials adversely affect surface detail reproduction.

One explanation for these contradictory results is that the methodology used in this study is different. The earlier study, by De Camargo et al,[8] evaluated impression materials injected over 1-inch segments of retraction cord and 1-cm² squares of cotton. The retraction cord and cotton were impregnated with the medicament and blotted dry, and the impression was recorded and evaluated under ×10 magnification.

In contrast, the current study used impressions of standardized metal dies similar to those described in ADA specification No. 19.[11] The quantity of impression material injected was carefully controlled. Surface detail reproduction was evaluated by examination of the depth, width, and character of 160-μm lines that were recorded in the impression. Close inspection of these lines at ×10 magnification facilitated the detection of any effect the retraction cord medicament had on the polyvinyl siloxane impressions of the treated dies.

In this investigation, the medicament was not washed off the die before the impressions were made. This protocol was used to simulate the most severe clinical situation, ie, where the clinician fails to rinse the medicament off the tooth or retraction cord prior to recording the impression. In studies where gloves were found to inhibit the set of the material, the only effective method for completely removing the inhibiting particles from the tooth or die was mechanical removal of any trace of the material with a toothbrush or prophylaxis head and pumice.[12] Simple rinsing with mouthwash, hydrogen peroxide, or an air-water syringe was ineffective at removing the inhibitor particles.[9,12] A similar study on the most effective method for completely removing retraction cord medicaments from the die is required.

It is critical that impressions, particularly for fixed prosthodontics, accurately reproduce the preparation; an imperfection in the impression will result in an inaccurate die and, ultimately, an unsatisfactory restoration. The results of this study suggest that the clinician must be diligent in his or her efforts to remove retraction cord medicaments prior to recording a polyvinyl siloxane impression. Further investigations are needed to determine if rinsing with air and water is sufficient to remove retraction cord medicaments. Additional studies are required to determine the effects of other medicaments as well as the interaction of the medicaments used in this study on the wide variety of commercially available polyvinyl siloxane impression materials.

CONCLUSION

Within the limits of this study, the following conclusions were derived from the results:

1. There was a statistically significant difference in surface detail reproduction between all of the retraction cord medicament groups and the control group investigated in this study.
2. Surface detail reproduction in the polyvinyl siloxane impressions was adversely affected by all of the retraction cord medicaments.
3. There was no statistically significant difference in dimensional accuracy among any of the groups. All of the impressions exhibited shrinkage that was within the ADA's acceptable limits for type I nonaqueous elastomeric dental impression materials, ie, less than 0.5% shrinkage.

ACKNOWLEDGMENTS

This project was supported in part by the Rhinehart Foundation, University of Missouri–Kansas City, School of Dentistry.

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Smear layer instability caused by hemostatic agents

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The effect of hemostatic agents, other than a 15.5% $Fe_2(SO_4)_3$ solution, on prepared tooth structure is unknown. The purpose of this study was to (1) compare the effect of six commonly used hemostatic solutions and two nondental astringents on the dentinal smear layer and (2) determine whether different responses caused by product and/or time could be established. Standardized dentinal smear layers were exposed to eight astringent solutions for 30, 120, and 300 seconds (n = 6). A total of 144 SEM photographs at ×2400 magnification were ranked according to predetermined criteria for five categories of smear layer removal and etching of underlying tooth structure. There were significant differences ($p < 0.001$) caused by the solution, exposure time, and their interaction. Greatest smear layer removal was observed with 21.3% $AlCl_3$-6 hydrate, 8% racemic epinephrine HCl, and 15.5% $Fe_2(SO_4)_3$ solutions at longer exposures. These caused significantly more removal than did almost pH neutral tetrahydrozoline or oxymetazoline ($p < 0.05$). (J Prosthet Dent 1996;76:477-82.)

In a previous pilot study, a 15.5% $Fe_2(SO_4)_3$ solution was shown to remove the dentinal smear layer and etch the underlying dentin with partial loss of peritubular dentin.[1] The effect of other hemostatic agents on prepared tooth structure is unknown. The purpose of this study was to compare the effect of six commonly used hemostatic solutions and two nondental astringents on the dentinal smear layer and to determine whether different responses caused by product and/or time could be established. Two nondental astringents, Visine and OcuClear (Table I), used as eye drops, were included in this study because they are almost pH neutral. The possible dental application of such solutions has been suggested, and the hemostatic efficacy of tetrahydrozoline hydrochloride, the active ingredient in Visine astringent, has been tested.[2]

The use of retraction cord that has been soaked in an astringent or vasoconstrictor is a common procedure in dentistry. Its primary objective is to assist in hemostasis and tissue displacement to facilitate impression making.[3] Nemetz and Seibly[4] have reported on commonly used chemical agents in gingival retraction. Commonly used dental astringents include aluminum chloride, aluminum potassium sulfate, aluminum sulfate, and ferric sulfate, which are typically dispensed in buffered aqueous or aqueous/glycol solutions. Recently, a gel-based ferric sulfate astringent was introduced. Vasoconstrictors such as racemic epinephrine hydrochloride by itself or in combination with zinc chloride or zinc phenolsulfonate are also available as either impregnated cords or pellets to assist with hemostasis before impression making. Astringents exert weak vasoconstrictive and protein denaturing properties. They are relatively safe and almost devoid of systemic effects although they may produce local tissue irritation and transient staining.[5] A vasoconstrictor, such as epinephrine, has potent sympathomimetic and vasoconstrictive properties, and systemic absorption of the topically administered form cannot be controlled or quantified.[5] Accordingly, the advantages of its use need to be carefully weighed against the potential risks, especially in patients with significant cardiovascular histories.

The hypothesis of this study was that as the pH of routinely available astringent solutions is typically highly acidic,[1,5] smear layer removal and etching of underlying dentin would result, whereas when prepared dentin was exposed to pH-neutral astringents neither the smear layer nor underlying dentin would be affected.

MATERIAL AND METHODS

A total of 144 tooth preparation specimens were used. Recently extracted molar teeth were obtained from the Oral Surgery Department at Southern Illinois University School of Dental Medicine. Tooth selection was based on predefined criteria: intact clinical crown, no existing restorations, no excessive decalcifications, and an intact

Presented before the 24th annual meeting of the American Association for Dental Research, San Antonio, Tex., March, 1995.
This study was funded in part by Southern Illinois University Research Grant DSRA 94-2.
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Table I. Hemostatic agents tested

Hemostatic agent	Active ingredient	pH
Astringedent (AS) (Ultradent Products, Inc., Salt Lake City, Utah)	15.5% $Fe_2(SO_4)_3$	0.8
Hemogin-L (HG) (Van R. Dental Products, Inc., Oxnard, California)	25% $AlCl_3$ aqueous	0.9
Hemodent (HD) (Premier Dental Products Co.)	21.3% $AlCl_3$ aqueous/glycol	1.3
Cranberry Styptin (ST) (Van R. Dental Products, Inc.)	20% $AlCl_3$ buffered glycol	1.3
Gingi-Aid 25% (GI) (Gingi-Pak Laboratories, Camarillo, Calif.)	25% $AlCl_3$ NF	1.9
Orostat 8% (OR) (Gingi-Pak Laboratories)	8% racemic Epinephrine	2.0
Visine (VI) (Leeming Div., Pfizer, Inc., New York, N. Y.)	Tetrahydrozoline hydrochloride	6.8
Ocu Clear (OX) (Health Care Products, Inc., Memphis, Tennessee)	Oxymetazoline HCl	6.5

cementoenamel junction (CEJ). The teeth were initially stored in a glutaraldehyde solution and handled in accordance with applicable CDC guidelines. The teeth were prepared for complete ceramic crowns with heavy shoulder preparations with coarse diamonds by use of conventional high speed instrumentation and water spray. The teeth were prepared in this manner to ensure removal of all axial tooth enamel. All teeth were then instrumented for 30 seconds, each with a new 557D medium-grit diamond (Brasseler USA, Savannah, Ga.) under water spray to standardize the resulting smear layers. The teeth were sectioned with a diamond disk (model 7941M, Brasseler USA). The root portions were sectioned several millimeters below the CEJ in a direction perpendicular to the long axis of the teeth, and then all pulpal tissues were removed. Each tooth was sectioned buccolingually and mesiodistally into four individual specimens, which were stored in vials with an isotonic sodium 0.2 % azide solution.

Surface treatment

Exposure time to the various hemostatic solutions was consistent with those used in a previous pilot study.[1] The solutions, their manufacturers, and their respective pH measurements are listed in Table I. A total of 24 experimental groups (n = 6) were treated within 24 hours of tooth preparation. The teeth were dried by three short blasts of air from a dental multifunction syringe that simulates clinical drying of tooth preparations. Subsequently, each specimen was submerged in the hemostatic agent for the applicable time. Immediately after the timed exposure the specimens were removed and subjected to a three-phase irrigation cycle in water followed by a 10-second spray with the multifunction syringe. The irrigant was changed for each experimental group.

For ensuring blind conditions to prevent examiner bias, the specimens were transferred to 144 numbered individual vials before their return as numbered specimens for SEM examination and photography.

Table II. Scoring criteria for the residual dentinal smear layer

Rank	Category	Description
1	Smear layer intact	Outline of tubular pattern not visible; Amorphous mass of debris; Possible rotary instrument tracks; Possible artifact, deposit, coagulum
2	Smear layer partially removed, tubules occluded	Smear layer barely removed, some with apparent residual debris Recognizable tubular pattern with cracks across tubular opening All occluded
3	Smear layer (partially) removed, tubules largely occluded	Some smear layer residue Identifiable tubular pattern Some cracking Substantial number remain occluded
4	Smear layer removed tubules largely open	Clearly identifiable tubular pattern Substantial number of open tubules Odontoblastic processes typically not discernible
5	Smear layer removed tubules open dentin visibly etched	Tubules wide open Intertubular dentin with etch pattern Odontoblastic processes visible, may or may not protrude

Mounting

The specimens were dried for 24 hours and mounted on aluminum stubs with silver colloidal paste (Electron Microscopy Sciences, Ft. Washington, Pa.). The perimeter of each stub was notched to permit standard orientation of the tooth specimen on the stub and in the SEM chamber. The specimens were positioned so that the treated surface was located approximately 3 mm above and parallel to the top of the stub. The corresponding specimen number was engraved in the base of the stub. The specimens were then stored in plastic specimen holders and the colloidal paste was allowed to dry for 24 hours.

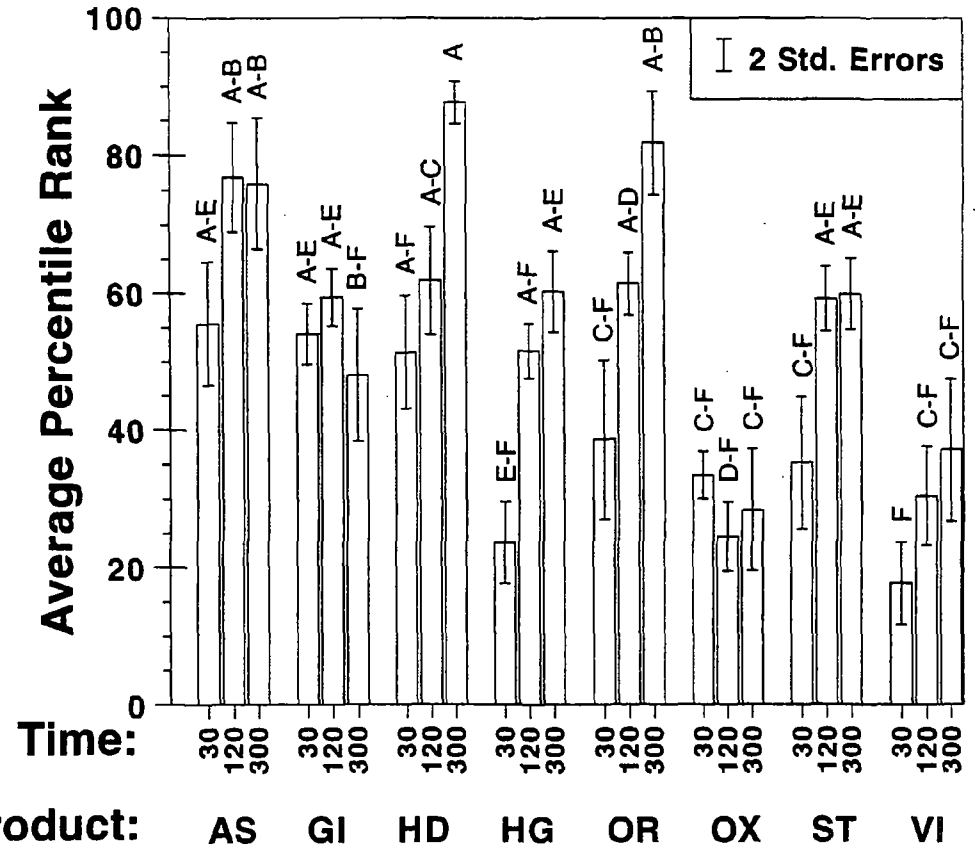

Fig. 1. Average percentile ranks by product and exposure time. Average percentile ranks that have common identifying letter over base were not statistically significant. Product abbreviations are listed in Table I.

Table III. Means and standard deviations of the average ranks for the subgroups

Product	Duration of exposure					
	30 Seconds		120 Seconds		300 Seconds	
	Mean	SD	Mean	SD	Mean	SD
Astringedent	55.60	20.10	76.86	19.19	75.95	23.07
Gingi-Aid	54.16	10.91	59.48	10.23	48.04	23.80
Hemodent	51.39	20.26	61.84	19.23	87.62	7.72
Hemogin-L	23.58	14.76	51.62	9.83	60.23	14.43
Orostat 8%	38.60	28.43	61.41	11.11	81.81	18.22
Oxymetazolone	33.39	8.42	24.44	12.40	28.28	21.74
Styptin 120	35.17	23.58	59.20	11.60	59.89	12.66
Visine 120	17.59	14.68	30.32	17.59	37.07	25.52

Sputter coating

After drying, the specimens were coated with a thin film of AuPd in an Anatec LTD Hummer VI (Anatec Ltd., Springfield, Va.) sputter system. Based on results obtained in a pilot study, a 4-minute coating cycle was used for each specimen.

SEM observation

Specimens were examined with a scanning electron microscope (model JSM 35 LF, Jeol U.S.A. Inc., Peabody, Mass.) at 25 kV, tilt 0, condenser lens 4.3, and contrast 4.6. The orientation mark on the stub was used to standardize specimen position in the chamber. The specimens

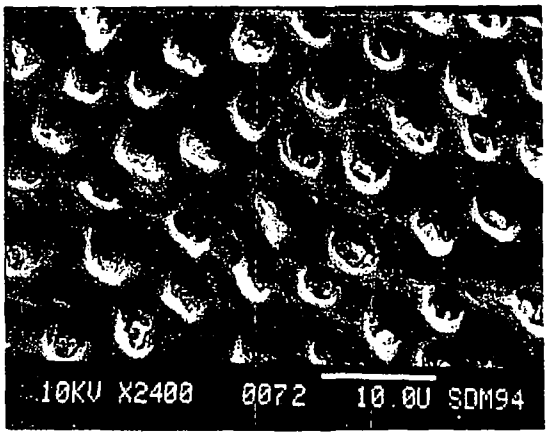

Fig. 2. After 5-minute exposure to 15.5% $Fe_2(SO_4)_3$, complete smear layer removal and severe etching results.

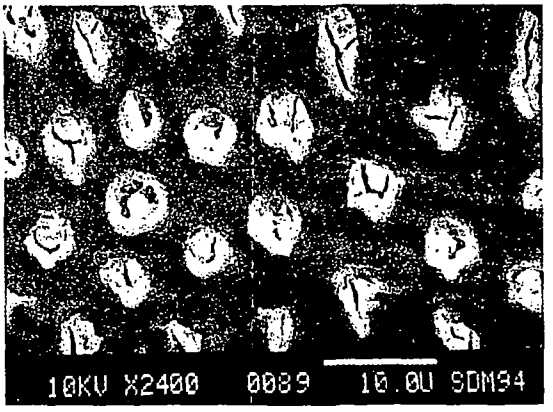

Fig. 3. Five-minute exposure to 21.3% $AlCl_3$ 6 hydrate results in complete smear layer removal and noticeable dentin etching, although some tubules remain partly occluded.

were rotated so the prepared cavosurface line angle was parallel to the bottom of the video screen. All specimens were initially examined at ×240 magnification and focus was done for all specimens at ×18000. Scanning electron micrographs (SEMs) were then made at ×2400 magnification with Polaroid 55N film. Photography location was standardized from specimen to specimen; all micrographs were taken in the center of the horizontal surface of the specimens, one video screen height (at ×2400) occlusal from the prepared cavosurface margin.

Evaluation

After all 144 micrographs were obtained, four evaluators rated each micrograph according to predetermined criteria for five ranked categories; smear layer: (1) intact; (2) partially removed, tubules occluded; (3) partially removed, tubules largely occluded; (4) removed, tubules largely open; and (5) removed, tubules open, dentin visibly etched. Table II lists the criteria for these categories in detail. SEM observation, interpretation, and ranking were completed under blind conditions.

Statistical significance was determined by first converting the ranked categories to percent ranks for each evaluator.[7] Where the repeated measure for each sample was the ranking of the four evaluators, and the between-subject factors were product and exposure time, a full repeated measures analysis of variance of these ranks was performed. Because the evaluator factor and every interaction that involved evaluator showed no statistical significance, the ranks of the four evaluators were averaged, and these average percentile ranks were subjected to the Ryan-Einot-Gabriel-Welsch multiple range (REGWQ) test.[8]

RESULTS

Before the study began, it was anticipated that the acidic hemostatic solutions would result in smear layer removal and etching of the underlying dentin, whereas the pH-neutral solutions would affect the smear layer to a lesser degree. The analysis of variance (ANOVA) of the average ranks indicated that there were statistically significant differences caused by the solution ($p < 0.001$), exposure time ($p < 0.001$), and their interaction ($p < 0.02$). Figure 1 illustrates the average percentile rank for each tested solution by exposure time.

Greatest smear layer removal was observed with 21.3% $AlCl_3$ 6 hydrate, 8% epinephrine HCl, and 15.5% $Fe_2(SO_4)_3$ solutions at longer exposures. These caused significantly more removal than tetrahydrozoline or oxymetazoline ($p < 0.05$).

Representative results are presented in Figures 2 through 5. These SEMs illustrate respectively a typical response to 15.5% $Fe_2(SO_4)_3$ and 21.3% $AlCl_3$ 6 hydrate both after a 5-minute exposure time (Figs. 2 and 3). Figure 4 represents a 5-minute exposure to tetrahydrozoline HCl, which is comparable to the responses seen with oxymetazoline. Figure 5 shows appearances after 30 seconds, 2 minutes, and 5 minutes of exposure with 8% racemic epinephrine HCl exposure.

DISCUSSION

This investigation serves as an initial step to determine and quantify the extent of surface change as a result of exposure to hemostatic agents. When prepared tooth structure is exposed to acidic solutions, the smear layer will be removed to various degrees and the underlying dentin etched. Exposure to hemostatic agents is a regular occurrence in general dentistry. Informal inquiries among general practitioners suggest that a 10-minute exposure to a hemostatic solution may be considered routine with longer exposure times not unusual as the complexity of the restorative procedures (for example, the number of tooth preparations) increases.

Although the intraoral use of tetrahydrozoline and

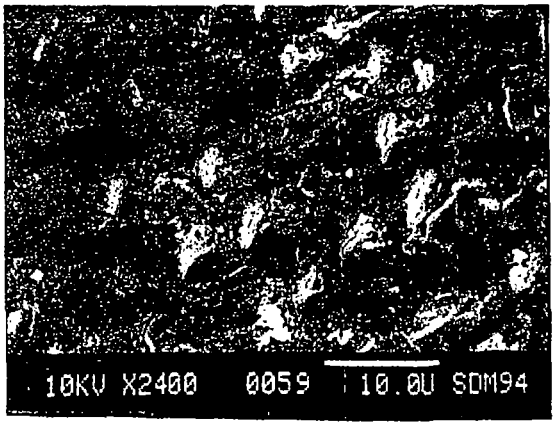

Fig. 4. After 5-minute exposure to tetrahydrozoline HCl, smear layer remains intact. This is also seen after prolonged exposure to oxymetazoline.

oxymetazoline is not commonplace, it is reasonable to assume that the vast majority of dental hemostatic agents used are highly acidic. Therefore, in clinical practice, the smear layer in proximity to the cavosurface line angle will be removed and the underlying tooth structure will be etched. Exposed tooth enamel also will be etched. The "keyhole" etching pattern typical of etched enamel was seen on many specimens during the SEM observations.

With the exception of the Gingi-Aid hemostatic agent, all acidic solutions exhibited an increased surface effect as a function of time. The active ingredient in the Hemogin-L, Hemodent, Cranberry Styptin, and Gingi-Aid agents is $AlCl_3$ in concentrations that range from 20% to 25%. At the time intervals 30 seconds and 2 minutes, the response to these materials seemed to be comparable. The difference in surface change after longer exposure (namely 5 minutes) is not readily explained on the basis of chemical composition alone.

A 2-minute exposure to 15.3% ferric sulfate results in severe etching comparable to a 5-minute exposure to Hemodent and Orostat hemostatic agents. A longer exposure (5 minutes) to ferric sulfate did not appear to increase the resulting surface effect. For Hemodent and Orostat agents, the degree of surface change appeared to be a function of time, and longer exposure had a definite effect on the residual smear layer and underlying tooth structure.

Significance of smear layer retention

The desirability of smear layer retention versus smear layer removal has been the subject of controversy.[9,10] Correlations have been suggested between postoperative pain and fluid movement through the dentinal tubules.[11] It has also been argued that maintaining the smear layer effectively diminishes fluid flow through the dentinal tubules by as much as 8%.[12] In

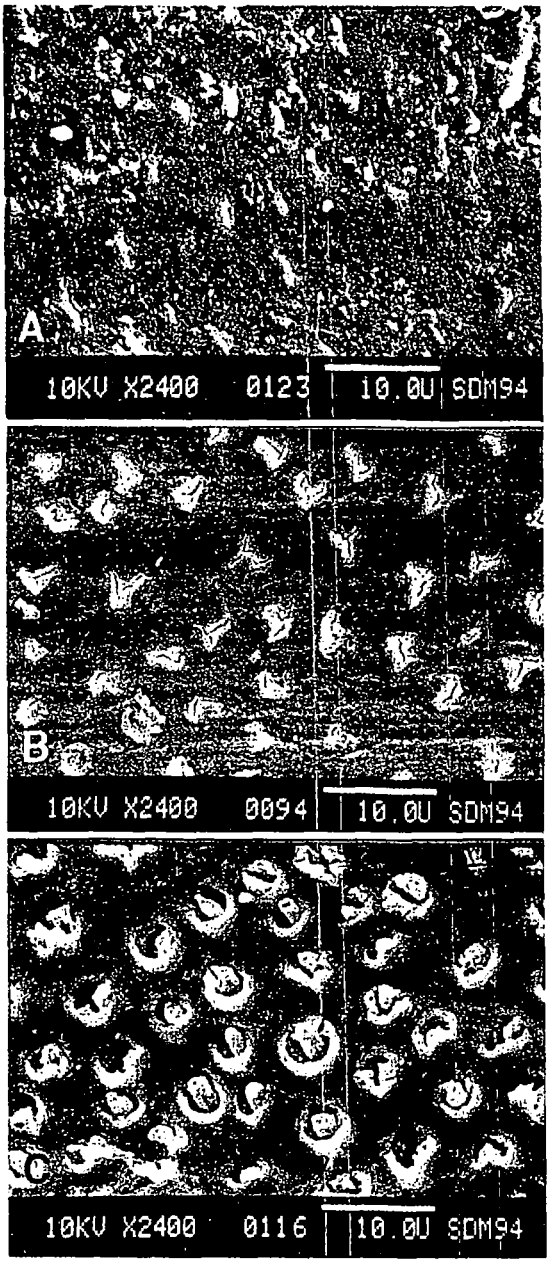

Fig. 5. Representative appearances after respectively 30 seconds (**A**), 2 minutes (**B**), and 5 minutes (**C**) of exposure to 8% racemic epinephrine HCl. Progressively increased smear layer removal and etching is noticeable as exposure time increases.

addition, increased bacterial infiltration has been demonstrated after smear layer removal.[13] These findings suggest that it may be beneficial from a biologic perspective to maintain the smear layer completely or in part because postoperative discomfort may be dimin-

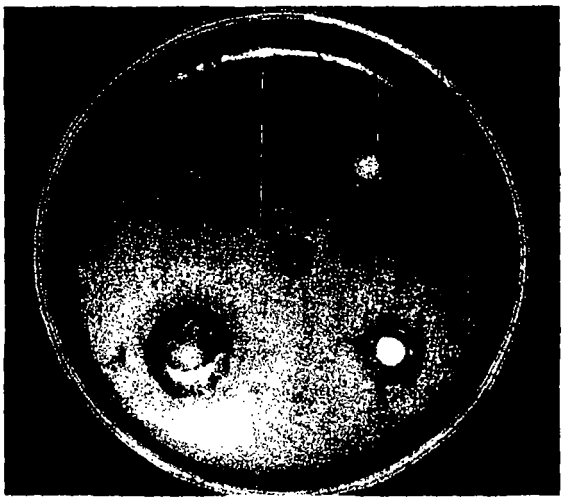

Fig. 1. Representative agar plate inoculated with *S. salivarius* contained wells of tested materials. Zones of growth inhibition after 2 days of incubation. *Top left,* Syntac; *top right,* Optibond; *center,* Heliobond; *bottom left,* Vitremer; *bottom right,* Variglass VLC.

The aim of this laboratory study was to evaluate the inhibitory effect of two dentin bonding systems on bacterial growth, one with fluoride and the other with glutaraldehyde, and two light-cured glass ionomer cements that are frequently used as liners.

MATERIAL AND METHODS

The materials used and manufacturer information are presented in Table I. All materials were prepared in accordance with manufacturers' recommendations. The glass ionomer cements, Vitremer and Variglass VLC, were prepared in the consistency of liner. Because Syntac adhesive contains no polymerization initiators, it was mixed with Heliobond bonding agent in a ratio of 1:1. In a pilot project, it was found that Heliobond bonding agent had negligible antibacterial activity; thus it was used as negative control.

Antibacterial activities of the materials were evaluated against the following bacteria: *S. mutans* (ATCC 25175), *S. sobrinus* (ATCC 27609), *Streptococcus sanguis* (ATCC 10556), *Streptococcus salivarius* (clinically isolated), *Lactobacillus casei* (ATCC 4646), *Enterococcus faecalis* (ATCC 29212), *Fusobacterium nucleatum* (ATCC 10953), and *Actinomyces viscosus* (ATCC 15987). Vitremer glass ionomer cement was not tested against *S. sanguis, F. nucleatum,* and *A. viscosus* because it was included after the study had started.

Cultures of the bacteria species used herein were reconstituted from lyophilization, grown and maintained in a brain-heart infusion broth, prereduced, and anaerobically sterilized (BHI-PRAS). All procedures were carried out under aseptic conditions in a laminar air flow cabinet. The turbidity of inoculum, prepared in BHI-PRAS, was adjusted to the optical density of a 0.5 McFarland standard (1.5×10^8 bacteria/ml).

Table I. Materials used

Name	Manufacturer
Optibond light-cured adhesive	Kerr, Romulus, Mich.
Syntac adhesive	Vivadent, Schaan, Liechtenstien
Vitremer	3M, St. Paul, Minn.
Variglass VLC	Dentsply, Petrópolis, Brazil
Heliobond (control group)	Vivadent

The agar diffusion test was used. Petri plates that contained BHI agar were inoculated with the bacteria tested by use of sterile cotton-tipped applicators that were brushed across the medium. Wells 5 mm in depth and 6 mm in diameter were punched in agar plates and filled with the materials tested. After placement, the materials were light cured according to manufacturers' recommendations. Each assay was made in duplicate for each material and bacterial strain. Positive control plates were streaked with bacteria but no material was used.

The bacteria agar plates were placed into anaerobic jars. Anaerobic conditions were produced by the evacuation-replacement procedure, in which the air in the jar is removed by use of a vacuum pump and replaced with a mixture containing 10% hydrogen and 10% carbon dioxide in nitrogen. The jars were incubated at 37° C for 2 days. Afterward, the diameters of the zones of growth inhibition were measured (Figs. 1 and 2), with the 6 mm diameter as the cutoff value.

Statistical analysis was not performed because of the different diffusibility coefficients of the tested materials in agar. Hence a semiqualitative comparison as carried out by Al-Khatib et al.[24] was made.

RESULTS

The means of the zones of bacterial inhibition for each material are presented in Table II. Vitremer glass ionomer cement exhibited the largest zones of inhibition against the bacterial strains tested. Syntac adhesive was inhibitory against all strains, but it was not more effective than Vitremer glass ionomer cement. Variglass VLC, the other light-cured glass ionomer used, exhibited antibacterial activity against most of the bacterial strains and was ineffective only against *L. casei* and *S. sobrinus*. There were no zones of growth inhibition for Optibond or Heliobond bonding agents.

DISCUSSION

The agar diffusion test has been widely used to evaluate the antibacterial activity of dental materials.[25-27] For this method the zones of growth inhibition provided by the materials depend on the toxicity of the material against the bacteria tested, and the diffusibility of the material across the culture medium used. A material that

Table II. Zones of inhibition (in millimeters)

	OPT	S/H	HEL	VIT	VAR
S. mutans	0	12	0	14	10
S. sobrinus	0	6	0	21	0
S. sanguis	0	5	0	*	14
S. salivarius	0	6	0	11	10
L. casei	0	3	0	12	0
F. nucleatum	0	6	0	*	10
E. faecalis	0	3	0	8	3
A. viscosus	0	7	0	*	32

OPT, Optibond light-cured; *S/H*, Syntac adhesive/Heliobond; *HEL*, Heliobond; *VIT*, Vitremer; *VAR*, Variglass VLC.
*Not tested.

diffuses more easily will probably provide larger zones of inhibition. Thus, in addition to direct cytotoxicity, the different diffusion rates of the different materials used in this experiment may have influenced the results. This factor may be less important when bacterial suspensions, which permit direct contact between materials and bacterial cells in an aqueous medium, are used. Thus we believe that further studies with another method such as the microdilution broth technique are necessary to compare and contrast the antibacterial activities of the materials. On the other hand, to our understanding, the great advantage of the agar diffusion test is the elimination of some variables, such as different inoculum size and medium manipulation, so long as the materials are placed in the same agar plate, and hence the allowance of an effective comparison among materials. Moreover, the method used in this study allowed measurement of the inhibitory activity against bacteria colonizing a surface, which imparts clinical relevance if in vitro data are being extrapolated to oral bacteria colonizing around or on restorative materials.

Most of the bacterial strains used in this study were ATCC isolates. The use of standard bacterial strains was preferred for the results to be reproducible. However, different bacterial susceptibilities may be observed in strains other than fresh clinical isolates.

The results of this study demonstrated adverse conditions for most of the bacterial species when glass ionomer cement was used during setting, especially for Vitremer glass ionomer, which showed the largest zones of inhibition. It has been assumed that the antibacterial effects of glass ionomer cements are the result of the release of fluoride and zinc ions from the materials.[22] In addition, dual setting, which is a characteristic of some glass ionomer cements such as Vitremer, causes a slow acid-base reaction with consequently prolonged low surface pH. Therefore these materials may promote an acidification of the medium, thereby creating a condition unsuitable to bacterial growth.

It was concluded by Woolford and Chadwick[28] that glass polyalkenoates maintain a low surface pH for the first 60 minutes of setting. Therefore a significant initial inhibitory effect on bacterial growth is observed when this material is used. On the basis of the in vivo study conducted by van Dijken et al.,[29] it is believed that a low fluoride release only is not sufficient for a significant antibacterial effect. These authors concluded that the fluoride levels in plaque adjacent to glass ionomer cement would not become high enough to inhibit the accumulation of *S. mutans*, total streptococci, and lactobacilli on sound enamel surfaces and 1-year-old glass ionomer cement.

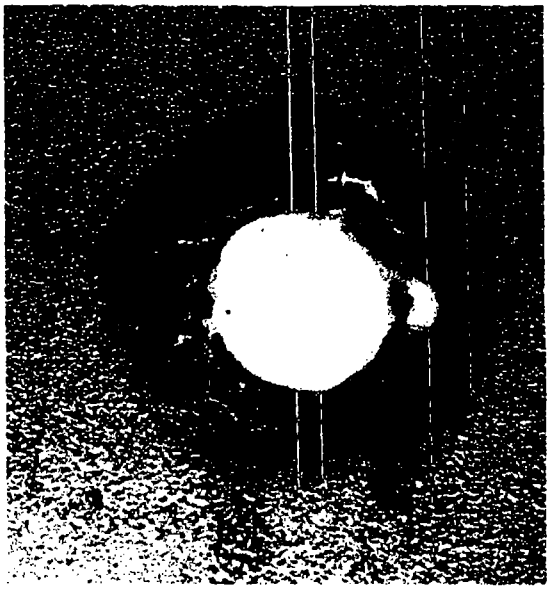

Fig. 2. Higher magnification of inhibitory effect of Veriglass VLC on *Streptococcus salivarius*.

No effect was shown by a dentin bonding agent with fluoride in its composition; however, a significant inhibition occurred when the dentin bonding agent that contained glutaraldehyde was tested. It is known that these materials are similar in composition, which suggests that the dissolution mechanism and release of their agents may also be similar. The most important difference between Optibond and Syntac/Heliobond is the incorporation of fluoride and fillers in the former and glutaraldehyde in the latter. The higher disinfectant effect of glutaraldehyde was probably the reason for the better results it provided. The substances may be released by the dissolution of materials or by some other means of matrix erosion.[30] It is possible that Optibond bonding agent does not release fluoride ions during setting. It is also possible that this release provides only a low fluoride concentration around the material, which may have been insufficient to inhibit bacterial growth.

On the basis of data from this study, it would appear that Vitremer glass ionomer cement was superior in inhibiting bacterial activity compared with the other materials tested. However, the obvious limitations of in vitro

studies indicate that direct extrapolation to a clinical situation must be done with caution.

CLINICAL IMPLICATIONS

Some studies have demonstrated inhibitory effects of dental materials on bacterial growth. The presence of bacteria in prepared cavities may cause pulpal pathosis. We believe that remaining microorganisms in dentinal tubules can be eliminated by the low surface pH of the glass ionomer liner or by glutaraldehyde released by Syntac adhesive during setting. It is possible that the inhibitory effect caused by setting materials has clinical significance. Furthermore, a low release of antibacterial compounds from liners or adhesives can occur for a long time after setting and may inhibit secondary caries.

SUMMARY

1. Vitremer, a dual-cured glass ionomer, demonstrated the largest zones of inhibition against the bacterial strains tested.

2. Variglass VLC glass ionomer cement showed antibacterial effect on six bacterial species but did not show any action on *L. casei* and *S. sobrinus*.

3. The dentin bonding with glutaraldehyde Syntac adhesive exhibited inhibitory activity on growth of the eight bacteria species used in this study.

4. Optibond light-cured or Heliobond bonding agents did not demonstrate any antibacterial effect.

We thank Mr. Fernando A.C. Magalhães for technical assistance.

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Efficacy review

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British Journal of Pharmaceutical Research
1(3): 66-87, 2011

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Pharmacological Agents in Dentistry: A Review

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Review Article

Received 3rd May 2011
Accepted 2nd June 2011
Online Ready 5th June 2011

ABSTRACT

All clinicians should be fully aware of the recent trends in their speciality to enable them to provide effective and successful treatment to their patients. One vital aspect of the treatment is that the clinician should constantly update his knowledge on the drugs being administered during the course of treatment and their interactions. The purpose of this article is to review the current pharmacological agents being used in Prosthodontics along with their interactions and indications. The paper mainly focuses on Therapeutic drugs and drugs that aid in prosthodontics treatment. Therapeutic drugs include local anesthetics, antiseptics, steroids, analgesics, antimicrobials, antifungals, antianxity drugs, centrally acting muscle relaxants. Drugs that aid in prosthodontics treatment include astringents, vasoconstrictors, hemostatic agents, sialogogues, anti-sialogogues, denture cleansers, gum paints, denture cleansers, denture adhesives, ORAL protective agents and demulcents. An odontologist should have sound knowledge of the benefits and drawbacks of all these agents. This will enable the clinician to provide a safe and predictable treatment to the patients.

Keywords: Pharmacotherapeutics; Drugs; Dentistry;

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British Journal of Pharmaceutical Research, 1(3): 66-87, 2011

1. INTRODUCTION

Rapid progress in dental pharmacotherapeutics requires that clinicians constantly update their knowledge of new drugs, drug interactions and useful therapeutic trends. The pharmacological agents aid in rapid healing and repair of the damaged tissues, relieve patients of pain and bring back the tissues to the healthy state. These drugs play a useful role in prosthodontics in the treatment of ulcerations, inflammations, xerostomia and bleeding during gingival retraction. They also help in reducing dentinal hypersensitivity during vital tooth preparation and increasing the gingival resistance against infections.

These pharmacological agents can be classified as:-

I. Therapeutic drugs.
II. Drugs that aid in prosthodontics treatment.

2. THERAPEUTIC DRUGS

2.1 Local Anesthetics

Local Anesthetics (LA) are the drugs which upon topical application or local injection cause reversible loss of sensory perception, especially of pain, in a restricted area of the body. These drugs act by excessive stimulation followed by depression (Bennett, 1984a). To work efficiently, the dental local anesthetics should have some requirements (Haas, 2002) such as:

- High intrinsic activity, which ensures complete anesthesia for all dental treatment
- Rapid onset
- Adequate duration of anesthesia (30 to 60 min for standard dental treatment)
- Low systemic toxicity
- High efficacy-toxicity ratio
- Low overall incidence of serious adverse effects

Chemically local anesthetics are classified as either Esters or Amide types. The ester based agents Procaine and Cocaine are no longer widely used as dental anesthetics due to their unwanted side effects. The commonly used injectable dental local anesthetics are explained in table 1. Anesthetic preparations for dental use differ from those for nondental use. The concentration of local anesthetics for dental use is higher, because the volume which can be injected into the oral mucosa is limited. Local anesthetics cause some degree of vasodilation, therefore, vasoconstrictor agents can be added to local anesthetic solutions to antagonize LA action, reduce bleeding at surgical site, diminish toxicity and prolong the duration of anesthesia (Table 1.1). An acidic carrier solution is added to the LA cartridge to maintain the pH of the solution. Apart from this the dental cartridge also contains a reducing agent Metabisulfite that prevents oxidation of the vasoconstrictor and Thymol that acts as a fungicide (Bahl, 2004).

Local anesthetics containing vasoconstrictor agents are to be used with caution in patients with pheochromocytoma, uncontrolled or unstable angina, cardiac arrhythmias, congestive heart failure, hyperthyroidism, or diabetes. Recommended maximum dosage of epinephrine for a healthy individual is 0.2 mg, while 0.04 mg for a patient with clinically significant cardiovascular disease. If 1:100,000 concentration of epinephrine is considered then the

amount of Lignocaine administered is 20 ml in healthy individual (Bennett, 1984b) and 4 ml in patients with cardiovascular diseases (Bennett, 1984c).

For short dental procedures a short or medium acting local anesthetic likes 2% Lidocaine+1:100,000 Epinephrine is used, whereas for long dental procedures such as implants one can use 0.5% Bupivacaine+1:200,000 Epinephrine (Bennett, 1984d). Along with these anesthetic agents, Articaine has also been widely used and it has been seen that, soft tissue anesthesia and pain experience after 4% Articaine with 1:100,000 Adrenaline, and 2% Lignocaine with 1:100,000 Adrenaline are similar (Oliveira et al., 2001). Occasionally, these local anesthetic agents may lead to local and systemic side effects, if not used carefully. The local adverse effects can be in the form of hematoma, spread of infection, temporary/permanent nerve damage (Chen, 1998), while systemic reactions fall into four categories: toxic (drug overdose, rapid absorption, intravascular injection), psychogenic, idiosyncratic, or allergic (Malamed, 1990). Theamide classes of local anesthetics are significantly less allergenic than the ester type. If allergic reactions occur, the immediate treatment is intravenous injection of 0.01 ml per kilogram body weight adrenaline, supplemented by antihistamine agents such as 10 to 20 mg chorpheniramine, or 50 mg hydroxyzine or promethazine hydrochloride (Ball, 1999). Although, allergy to lignocaine is known to be extremely rare, it continues to be suggested as a cause when adverse reactions to dental injections occur. In fact, the overwhelming majority of adverse reactions to local anesthetics is psychogenic in nature and related to fear. A smaller proportion of adverse responses can beattributed to intravascular injections that are avoidable if injections are administered carefullyand with previous suction (Rood, 2000). Apart from these injectable agents, certain topical anesthetics (Table 2) are used in the oral cavity to provide pain relief at needle insertion site and over ulcerations. Topical anesthetic agents can also provide some form of relief in patients exhibiting gagging during the impression procedure. Glycerine, lanolin, petrolatum, mineral oil, sodium carboxymethylcellulose, propylene glycol and polyethylene glycol are used as vehicles for topical anesthetics (Adriani and Zepernick, 1964).

2.2 Antiseptics

Antiseptics are drugs that are applied on the body surfaces to prevent infection by killing or inhibiting the growth of pathogenic bacteria either by oxidation of bacterial protoplasm or denaturation of bacterial proteins including enzymes (Tripathi, 2008a). Amongst the various types of antiseptics available, chlorhexidine a biguanide, is one of the most commonly used. It is found to be more effective against Gram positive micro-organisms, while less effective against Gram-negative micro-organisms, fungi, and ineffective against spores and viruses. Therefore, mouth rinses containing chlorhexidine are widely prescribed in patients with persistent areas of oral inflammation (Newman et al., 2006). Daily oral irrigation with 0.06 to 0.12% chlorhexidine has been shown to be an effective method for the treatment of chronic gingivitis and apthous ulcers (Brownstein et al., 1990). Chlorhexidinedigluconate, at concentrations of 0.12%, binds to hard tissue, soft tissue and salivary protein of oral cavity and then releases slowly, thereby reducing the formation of plaque and inflammation (Yankell et al., 1982). The patient suffering from traumatic ulcer and inflammation after denture insertion is asked to swish 10 ml of chlorhexidine mouthwash for 1 minute that will facilitate healing. Commonly available chlorhexidine containing mouthwashes include Peridex, Periochip, Perichlor, Corsodyl and Periogard oral rinse. Recently, alcohol free dentyl pH mouthwash has been introduced which has a distinctive working action.

British Journal of Pharmaceutical Research, 1(3): 66-87, 2011

Table 1. Injectable Local Anaesthetic agents used in Dentistry

Parameters	Anaesthetic agents				
	Lignocaine	Articaine	Bupivacaine	Prilocaine	Mepivacaine
Concentration	2-3%	4%	0.25-0.5%	3-4%	2-3%
Vasoconstrictor	Epinephrine 1:50,000-1:100,000	Epinephrine 1:100,000-1:200,000 or without	Without epinephrine	Felypressin 1:1,850,000	Epinephrine 1:66,000 -1:100,000 or without
Chemical class	Amide	Amide with Ester side chain	Amide	Amide	Amide
Onset	Rapid	Rapid	Slow	Slow	Rapid
Duration (with Epinephrine)	120-240 minutes	140-270 minutes	4-8 hours	90-360 minutes	120-180 minutes
Maximum dose	4.5-7 mg/kg	4-7 mg/kg	2.5-3 mg/kg	5-7.5mg/kg	5-7mg/kg
Brand name	Xylocitin/Xylestesin	Ubistesin/Ultracain /Septocaine	Carbostesin/ Marcaine	Xylonest/ Citanest	Scandonest/Mepivastesin /Carbocaine

Table 1.1. Recommended dosage of L.A.

	With vasoconstrictor	Without vasoconstrictor
Recommended dosage of L.A. (Bernett, 1984)	500mg (6.6 mg/kg body weight)	300 mg (4.4 mg/kg body weight)
Maximum syringes* administered in healthy patients	12.5 syringes	7.5 syringes

** One Syringe contains 2 ml of solution.*
(Each 2 ml contains 40 mg of Lignocaine and 0.02 mg of epinephrine)

This advanced formula consists of two phases, a water-based phase incorporating the antibacterial agent Cetylpyridinium Chloride (CPC), and an oil-based with natural essential oils that removes an adherent bacterial layer from a solid surface and exhibits a continuing inhibitory effect on bacterial activity (New addition to alcohol free mouthwash range, 2009).

Table 2. Topical local anesthetic agents

Parameters	Anaesthetic agents			
	Benzocaine	**Dyclonine**	**Lidocaine**	**Tetracaine**
Concentration	6-20%	0.5-1%	2-5%	0.2-2%
Available as	Liquid, Spray, Ointment, gel,	Solution	Gel, ointment Liquid, Solution, 10% spray	Liquid, Spray, Ointment
Chemical class	Ester	Ketone	Amide	Ester
Duration	30-60 minutes	<60 minutes	30-60 minutes	30-60 minutes
Max dose	5000mg	300 mg	200mg	20mg
Brand name	Anbesol Benzodent Gingicaine Topicale	Dyclone	Xylocaine Alphacaine Octocaine Dologel	Pontocaine Supracaine Cetacaine

2.3 Steroids

Steroids play a role in the modulation of the inflammatory reaction by inhibitory activity affecting the production of mRNA and thus protein synthesis. Application of topical steroid preparations provides temporary relief of symptoms associated with inflammation and ulcerated lesions in the oral cavity such as recurrent apthous stomatitis. These topical ointments include Triamcinolone acetonide 0.1%, Kenalog in Orabase; hydrocortisone acetate 1% and Betamethasone dipropionate 0.05%.Topical use of steroids is usually well tolerated but some patients may develop a secondary erythematous candidosis or pseudomembranous candidosis (thrush) if predisposing conditions like xerostomia, systemic and/or topical use of antibiotics, corticosteroid asthma inhalants, prostheses and cigarette smoking are present in them. Even though clinical experience and laboratory studies have shown systemic absorption of steroids to be insignificant through the oral mucosa but caution should be exercised when used in patients with diabetes, hypertension, tuberculosis and those with extensive area of coverage and unmonitored usage (Savage and McCullough, 2005).

2.4 Analgesics

Analgesic agents are used for the management of pain and can be divided into the Nonopioid (non-narcotic), Acetaminophen (Paracetamol) and the Opioid (narcotic). An important difference between the opioids and the nonopioid analgesic agents is their mechanism of action. The action of the nonopioid analgesic agents is related to their ability to inhibit prostaglandin synthesis at the peripheral nerve endings whereas the opioids affect the amount of pain by depressing the central nervous system.

British Journal of Pharmaceutical Research, 1(3): 66-87, 2011

2.4.1 Non steroidal anti-inflammatory Drugs (NSAIDs')

The NSAIDs constitute a heterogeneous group of drugs with clinically important analgesic, antipyretic and anti-inflammatory properties that rank intermediately between corticoids with anti-inflammatory properties on one hand, and major analgesics – opioids on the other (Poveda-Roda et al., 2007).These agents differ from opioid analgesics in the following ways: (1) there is a ceiling effect to the analgesia; (2) they do not product tolerance or physical dependence; (3) they are antipyretic; and (4) they possess both anti-inflammatory as well as analgesic properties (Yagiela et al., 2004a). Nonopioids are most effective in treating postprocedural pain when given before the procedure (or immediately following a short procedure), thus preventing the synthesis of prostaglandins that quickly follow the surgical insult. Table 3 lists the currently available NSAIDs.

Mechanism of action of NSAIDs

Physical, chemical or mechanical stimuli in the form of tissue damage, hypoxia, immune processes, etc. induce arachidonic acid release and metabolization. NSAIDs inhibit cyclooxygenase (COX) – the enzyme responsible for the transformation of arachidonic acid into prostaglandins and thromboxanes, which are substances generically referred to as eicosanoids. These resulting metabolites (prostaglandins and thromboxanes) exert potent vasodilating action, resulting in increased vascular permeability, with the extravasation of fluids and white blood cells therby contributing to inflammation. Consequently, the inhibition of cyclooxygenase synthesis exerts a clear anti-inflammatory effect (Poveda-Roda et al., 2007).Out of the two forms (isoenzymes) of cyclooxygenase namely cyclooxygenase-1 (COX-1) and cyclooxygenase-2 (COX-2) the latter COX-2 appears to be more involved with synthesis of prostaglandins at sites of inflammation, whereas COX-1 is more involved at sites where adverse effects of NSAIDs are expressed, such as the gastrointestinal tract. Therefore NSAIDs that have more selective inhibitory activity on COX-2 as opposed to COX-1 would be expected to have a more favorable therapeutic index (Waldman et al., 1982). Celecoxib, Rofecoxib and Parecoxib are drugs showing selective COX-2 inhibitory action but these should be avoided in patients with moderate to severe hepatic damage. Potential adverse effects of NSAIDs include peptic ulcer disease, gastrointestinal (GI) bleeding, GI perforation, impaired renal function and inhibition of platelet function. These side effects are more pronounced in drugs showing COX-1 inhibitory activity. Salicylates should be avoided in patients suffering from Ulcers, Asthma, Diabetes, Gout, Influenza and hypercoagulation states. Asprin and related salicylates are contraindicated for treatment in children and teenagers with viral infections, as it has been associated with hepatotoxicity and encephalopathy (Reye's syndrome) (Waldman et al., 1982). Ibuprofen, naproxen sodium, ketoprofen and asprin are currently approved by the food and drug administration for over the counter (OTC) use. These OTC drugs should not be used consecutively for over 10 days for pain and 3 days for fever (Yagiela et al., 2004b). A 200 to 800 mg dose of ibuprofen should be considered as the first choice for management of acute inflammatory pain (Hargreaves and Abbott, 2005).

British Journal of Pharmaceutical Research, 1(3): 66-87, 2011

Table 3. Nonsteroidal anti-inflammatory drugs

Group	Generic name	Trade name	Maximum adult dose (mg)	Dosing interval (hours)	Dosing form
Salicylic acid derivatives	Asprin	-	325-650	4	Tablets
Aryl-Acetic acid derivatives	Diclofenac	Voveran/Diclonac/ Movonac	50	8	Tablets/Suppositories/ Injection
	Aceclofenac	Aceclo/Dolokind			
Oxicams	Piroxicam	Dolonex/Pirox Piricam	40 on first day/20 on following days	12-24	Tablets/ Suppositories
	Meloxicam	Meflam Mel-OD	7.5-15		
	Lornoxicam				
Propionic acid derivatives	Ibuprofen/Ketoprofen/Flurbiprofen/ Fenoprofen/Naproxen/Oxaprozin		400/50/50/200/250/ 600-1200	4-6/6/6/4-6/6-8/24	Tablets/ Suppositories
Anthranilicacid (Fenamates)	Mefenamic acid/ Meclofenamate	Medol/Meftal/ Ponstan	250	6	Capsule/ Tablet/ Suspension
Coxibs	Celecoxib	Celact/Revibra	200	12-24	Capsules
	Etoricoxib	Etody/Etoxib	120		Tablets
	Parecoxib	Revaldo/Valto	40		Solution for injection
Pyrazolones	MetamizolPhenylbutazone Oxyphenbutazone	Analgin	500-1500		Capsules/Solution for injection/Suppositorie/ Sachets
Indole	Indomethacin	Indicin/Indoflam/ Indocap/Recticin	200-400	6-8	Capsules/ Suppository
	Etodolac				
Pyrrolo-pyrrole derivative	Ketorolac	Ketorol/Zorovon/ Torolac	10	4-6	Tablets/Solution for injection

British Journal of Pharmaceutical Research, 1(3): 66-87, 2011

2.4.2 Acetaminophen (Paracetamol)

It has analgesic and anti-pyretic effects, and it is a weak inhibitor of the cyclo-oxygenase sub-groups COX-1 and COX-2. At therapeutic doses it does not inhibit prostaglandin in the peripheral tissues so there is very little, if any, anti-inflammatory action. It is therefore not classified as an NSAID (Felpel, 1997).Tolerance and dependence have not been reported, and Paracetamol does not cause the same gastric irritation or the other complications associated with aspirin and other NSAIDs (Seymour et al., 1999).

The usual recommended adult dose of Paracetamol is 500-1000mg every four to six hours (up to a maximum of 4000mg per day) (Therapeutic guidelines, 2002).

2.4.3 Opioid Analgesics

Opioid analgesics used in dentistry for oral administration are Codeine, Hydrocodone, Oxycodone and Pentazocaine whereas Morphine, Meperidine and Fentanyl are used parenterally (Table 4). Opioids are added to nonopioids to manage pain that is moderate to severe or that does not respond to nonopioids alone. Opioids differ from the nonopioids in that they have no ceiling effect. The only dosing limitation is based on side effects (Felpel, 1997).

Mechanism of action of Opioids

Opioid-induced analgesia results from agonist action at one or more of opiate receptors namely mu (μ), kappa (κ), delta (δ), and sigma (σ) at the level of the brain and spinal cord, whereas side effects result from their activation at both central and peripheral sites. Morphine and Codeine, produce analgesia and euphoria by an agonist action at μ_1-receptors and side effects of respiratory depression and constipation by an agonist action at μ_2-receptors. Opioids, which are agonists at some receptors and antagonists at others, are called "mixed" agents or partial agonists. Pentazocine, for example, causes analgesia by an agonist action at κ-receptors and dysphoria by an agonist action at σ receptors. The third class of opioids is antagonists at opioid receptors and is therefore primarily used to treatopioid overdose (Felpel, 1997). Repeated use of opioids for control of pain can lead to analgesic tolerance (loss of analgesic effect), as well as physical and sometimes psychologic dependence. Their undesirable effects, include respiratory depression, urinary retention, sedation, nausea and vomiting, and constipation. Coadministration of Opioids with Tricyclic antidepressants and Phenothiazines is known to produce additive CNS depression and orthostatic hypotension (Yagiela et al., 2004c). Meperidine a synthetic opioid, can cause a life-threatening drug interaction with Monoamine oxidase inhibitors and in contrast to other opioids, its overdose of causes CNS stimulation.

2.4.4 Combination drug therapy

The goal of combining analgesics with different mechanisms of action is to use lower doses of the component drugs, thereby improving analgesia without increasing adverse effects (Mehlisch, 2002). Patients with acute dental pain are best treated with NSAIDs or acetaminophen as the primary analgesic and the addition of a narcotic should be reserved for situations when additional analgesia is required. Opioid and acetaminophen combination studies show that a combination is better than opioids or acetaminophen alone (Moore et al., 1997). Opioids such as codeine, hydrocodone and oxycodone combined with ibuprofen are superior to manage acute dental pain than ibuprofen alone (Po and Zhang, 1998). The

analgesic properties of aspirin, acetaminophen and ibuprofen have been seen to increase when combined with 65 to 100 mg caffeine. Table 5 lists the drugs available as a combination therapy for use in Dentistry.

Table 4. Opioid analgesics

Group	Generic name	Trade name	Therapeutic dose (mg)	Duration of action (hr)	Route of administration
Agonist analgesics	Alfentanil	Alfenta	0.5-2	0.5	Intravenous
	Codeine	-	30-60	4-6	Oral
	Fentanyl	Sublimaze	0.05-0.1	1-1.5	Intramuscular
			0.05-0.1	0.5-1	Intravenous
	Hydrocodone	Dicodid	5-10	4-6	Oral
	Levorphanol	Levodromoron	2-3	4-5	Subcutaneous Oral
	Meperidine	Demerol	50-100	2-4	Intramuscular Oral
	Methadone	Dolophine	2.5-10	3-5	Intramuscular Subcutaneous
			5-15	4-6	Oral
	Morphine	-	10-15	4-5	Intramuscular Subcutaneous
			20-60	3-5	Oral
	Oxycodone	In percodan	5-10	4-5	Oral
	Oxymorphone	Numorphan	1-1.5	4-6	Intramuscular
	Propoxyphene	Darvon	32-65	4-6	Oral
Agonist-Antagonist	Buprenorphine	Buprenex	0.4-0.8	6-8	Intramuscular Sublingual
	Butorphanol	Stadol	1-4/0.5-2	3-4/2-4	Intramuscular
			1-2	3-4	Intravenous Nasal
	Dezocine	Delgan	5-20	3-6	Intramuscular
			2.5-10	2-4	Intravenous
	Nalbuphine	Nubain	10	3-6	Intravenous Intramuscular Subcutaneous
	Pentazocine	Talwin	30	3-4	Intramuscular
		Talwin NX	50	3-4	Oral
Antagonist	Naloxone	Narcan	0.4-2	1-2	Intravenous
	Naltr	Trexan	25	1-4	Oral
Others	Tramadol	Ultram	50	5-6	Oral

2.5 Antimicrobials

Antibiotics are chemicals virtually always derived naturally with the exception of ulfonamides, fluoroquinolones and oxazolidinones. These drugs act on the microorganisms to effect their viability hence they can be either bactericidal (inducing cell death) or bacteriostatic (preventing cell growth or replication) (Yagiela et al., 2004d). Antibiotics with activity against a wide range of disease-causing bacteria are termed as broad-spectrum antibiotics. It also means that it acts against both Gram-positive and Gram-negative bacteria. This is in contrast to a narrow-spectrum antibiotic which is effective against only specific families of bacteria (Figure 1). Table 6 lists the various antimicrobial agents available for use. Of these,

British Journal of Pharmaceutical Research, 1(3): 66-87, 2011

tetracyclines and clindamycin are accepted by the Council on Dental therapeutics, American Dental Association. Other antibiotics appropriate for use in Dentistry include penicillin, erythromycin, cephalosporins and bacitracin (Felpel, 1997). Oral infections are usually caused by aerobic gram-positive cocci (*Staphylococcus aureus*) and anaerobic microorganisms (Peptostreptococcus) and the use of antibiotics in dentistry is to either treat these or as a prophylaxis to prevent bacterial endocarditis that is caused by α hemolytic streptococci.

Most acute oral infections respond well to one of the oral penicillin preparations. However Penicillin can cause few adverse side effects, and allergic reactions. A true allergic reaction usually manifests as an irritating rash. Anaphylactoid reactions though rare, occur in susceptible patients within 30 seconds of an intramuscular injection. Signs and symptoms of anaphylaxis include oral paresthesia, cold hands and feet, bronchospasm and wheezing, circulatory collapse, and unconsciousness.

Table 5. Combination analgesics used in dentistry

Trade name	Contents	Amount (mg)
Anacin	Asprin	400
	Caffeine	32
Empirin	Asprin	325
	Codeine	15/30/60
Tylenol	Acetaminophen	300
	Codeine	15/30/60
Vicodin	Acetaminophen	660/750
	Hydrocodone	10/7.5
Percodan	Asprin	325
	Oxycodone	2.44/4.88
Percocet	Acetaminophen	325/500/650
	Oxycodone	5/7.5/10
Talwin	Asprin	325
	Pentazocaine	12.5
Talacen	Acetaminophen	650
	Pentazocaine	25
Ultracet	Acetaminophen	325
	Tramadol	37.5
Synalgos	Asprin	356.4
	Caffeine	30
	Dihydrocodeine	16
Vicoprofin	Ibuprofen	200
	Hydrocodone	7.5
Combiflam/Renofen Answell	Acetaminophen	325
	Ibuprofen	400

British Journal of Pharmaceutical Research, 1(3): 66-87, 2011

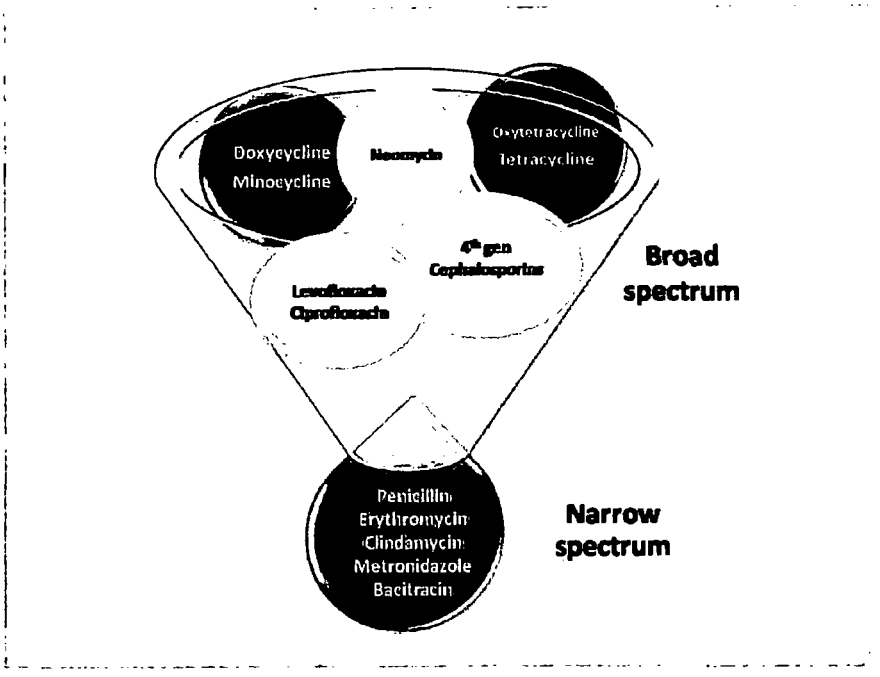

Fig. 1. Spectrum of activity of antibiotics

Alternatives to penicillin include Erythromycin, Cephalosporins, Clindamycin, and Tetracycline but Cephalosporins should not be used in a person with a history of anaphylaxis, angioedema or urticaria with penicillins or ampicillin. Erythromycin estolate and Erythromycin ethylsuccinate are contraindicated in the presence of liver dysfunction as they can cause cholestatic hepatitis. The use of Tetracyclines should be avoided during pregnancy and in children below 8 years because permanent staining of deciduous and permanent teeth and retardation of bone growth may occur. Other adverse effects include gastrointestinal upset, hepatotoxicity, nephrotoxicity, photosensitivity and impaired calcium absorption. Similarly, quinolones should be avoided in children, pregnant or nursing women, and in epileptics (Felpel, 1997). Antibiotic prophylaxis is recommended for dental procedure in patients with prosthetic cardiac valve, previous infective endocarditis, cardiac transplantation recipients who develop cardiac valvulopathyand during the first six months following any procedure to treat congenital heart disease (Prevention of infectiveendocarditis, 2007). Antibiotic coverage for invasive dental procedures is recommended in patients with poorly controlled or uncontrolled diabetes, infective endocarditis, 2007) but not in those having orthopedic prosthesis placed over 2 years prior to the dental procedure. Advisory statement, (2003) lists the dental procedures requiring antibiotic prophylaxiswhile. Figure 2 shows the current regimen of prophylactic antibiotics to be administered (Prevention of infective endocarditis, 2007; Tong and Rothwell, 2000). Prophylactic use of antibiotics in conjunction with dental treatment should be avoided unless there is a clearindication since unwarranted overuse of antibiotics can lead to development of resistant strains of microorganisms (Barker, 1999).

British Journal of Pharmaceutical Research, 1(3): 66-87, 2011

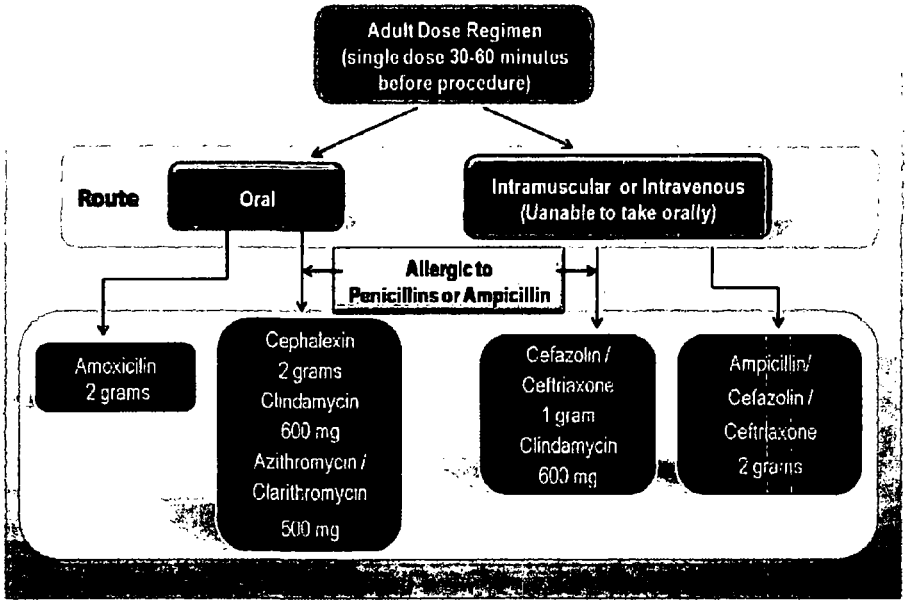

Fig. 2. Antibiotic prophylactic regimen for dental procedures in high risk patients

2.6 Antifungals

Oral moniliasis (thrush) is a fungal infection of the oral cavity caused by Candida albicans. C albicans can also colonize prosthetic devices like dentures. Atleast 2 weeks of therapy are required for treating oral candidiasis. Nystatin (Mycostatin) is the most common drug used in dentistry and it can have a fungistatic or fungicidal effect depending on its dose. A 2-3 ml (100,000 units/ ml) suspension or 1-2 lozenges (200,000 units each) may be used four to five times per day. Colonized dentures can be treated by soaking them in a nystatin solution or applying an ointment (100,000/g) of nystatin to the tissue surface. Clotrimazole (Mycelex), a fungistatic can be used in a dose of 10 mg troches dissolved in the mouth five times a day. Since Nystatin and Clotrimazole are not appreciably absorbed from the gastrointestinal tract, the topical route is preferred for their administration. Oral Fluconazole (Diflucan) in a dose of 50 to 100 mg/day and Itraconazole (Sporanox) 200mg/day are broad-spectrum antifungal agents that are effective in treating oropharyngeal and esophageal candidiasis (Yagiela et al., 2004e).

British Journal of Pharmaceutical Research, 1(3): 66-87, 2011

Table 6. List of Antimicrobial drugs

Mechanism of action	Class	Generic name	Trade name	Dose(mg)/ Interval (hours)	Effect
Inhibition of cell wall synthesis	Penicillin	Ampicillin	Penicillin	250-500/6	Bacteriocidal
		Amoxicillin	Amoxylin	250-500/8	Bacteriocidal
	Beta-lactamase inhibitors	Clavulanic acid	Augmentin	Amoxicillin 250+ Clavulanic acid 125/8	Bacteriocidal
	Cephalo-sporins	Cefadroxil	Duricef	500/12	Bacteriocidal
		Cephelexin	Keflex	250-500/6	Bacteriocidal
		Cephradine	Velosef	250-500/6	Bacteriostatic
		Cefaclor	Keflor	250-1000/8	Bacteriocidal
		Cefixime	Topcef	200/12	Bacteriocidal
Alteration of cell membrane integrity	Polypeptide	Polymyxin B	Aerosporin	Topical	Bacteriostatic
		Neomycin	Mycifradin	Topical	Bacteriostatic
		Bacitracin	Baciguent	Topical	Bacteriostatic
Inhibition of ribosomal protein synthesis	Macrolide	Erythromycin stearate	Erythrocin	250-500/ 6	Bacteriostatic
		Erythromycin estolate	Althrocin	250-500/6	Bacteriostatic
		Erythromycin ethylsuccinate	Erynate	400/6	Bacteriostatic
		Azithromycin	Azithral	500/24	Bacteriostatic
		Roxithromycin	Roxid	150-300/12	Bacteriostatic
	Tetracycline	Oxytetra-cycline	Terramycin	250-500/6-12	Bacteriostatic
		Minocycline	Minocin	100/12	Bacteriocidal
		Doxycycline	Vibramycin	100/12-24	Bacteriocidal
		Tetracycline	Achromycin	250-500/12	Bacteriocidal
	Lincosamide	Clindamycin	Cleocin	150-450/6	Bacteriostatic
Inhibition of nucleic acid synthesis	Nitroimidazole	Metronidazole	Flagyl	400/8	Bacteriocidal
	Fluoro-quinolones	Ciprofloxacin	Ciplox	250-500/12	Bacteriocidal
		Norfloxacin	Norflox	400/12	Bacteriocidal
		Levofloxacin	Tavanic	500/24	Bacteriocidal
Inhibition of folic acid synthesis	Sulphonamides	Sulfadizine	Sulfadizine	500/6	Bacteriostatic
	Cotrimoxazole	Trimethoprim+ sulfa-methoxazole	Septran	80-160+400-800/12	Bacteriocidal

British Journal of Pharmaceutical Research, 1(3): 66-87, 2011

2.7 Antianxiety Drugs

Antianxiety agents are used in clinical dentistry for premedication in an apprehensive patients pending operative procedure like Implant surgery. Antianxiety agents are known to summate with anesthetics, opioid analgesics, antidepressants, sedative-hypnotics and alcohol to cause excessive CNS depression (Yagiela et al, 2004f), hence should be prescribed with caution. Benzodiazepines such as Diazepam (Valium), Lorazepam (Ativan) and Alprazolam (Xanax) and Antihistamines such as Hydroxyzine (Vistaril) and Promethazine (Phenergan) are the preferred anxiolytics for use in dentistry. They should preferably have a rapid onset and a short duration of action. Diazepam (2-10mg), Lorazepam (2-6 mg) and Alprazolam (0.25-1.5mg) have a 12-24 hour duration of action whereas antihistamines in a dose of 25-100mg have a 4-6 hour duration of action. The use of Benzodiazepines is contraindicated in patients with psychosis, acute narrow-angle glaucoma, or liver disease.

2.8 Centrally Acting Muscle Relaxants

These are drugs that reduce skeletal muscle tone without altering consciousness. They are used in chronic spastic conditions and acute muscle spasms of the temporomandibular joint. Table 8 lists the various drugs used alone or in combination with analgesics as muscle relaxants in Dentistry. These drugs usually cause slight sedation hence caution is to be exercised regarding operation of motor vehicles. These drugs have a potential for abuse and dependence hence prolonged administration and abrupt stoppage is to be avoided (Stanko, 1990).

Table 7. Dental procedures requiring antibiotic prophylaxis

Prophylaxis recommended	Prophylaxis not recommended
Dental extractions	Postoperative suture removal
Subgingival placement of antibiotic fibers or strips	Making impressions or Taking radiographs
Intraligamentary local anesthetic injection	Local anesthetic injections
Initial placement of orthodontic bands	Placement and adjustment of removable Prosthesis and Orthodontic appliance
Prophylactic cleaning of teeth or implants with anticipated bleeding	Restorative procedures (with/without retraction cord)
Endodontic instrumentation or surgery beyond the tooth apex	Endodontic procedures, post placement and buildup
Dental Implant placement, reimplantation of teeth	Placement of rubber dams
Periodontal procedures including surgery, scaling, root planing and probing	Bleeding from trauma to lips or mucosa
	Shedding of deciduous teeth

British Journal of Pharmaceutical Research, 1(3): 66-87, 2011

Table 8. Centrally acting muscle relaxants

Generic name	Trade name	Content	Dose (mg)	Dosing interval (hours)
Casiprodol	Carisoma	Casiprodol	350	6-8
	Somaflam	Casiprodol	175	6-8
		Ibuprofen	400	
Chlorzoxazone	Mobizox	Chlorzoxazone	500	
		Diclofenac	50	8
		Paracetamol	500	
	Parafon	Chlorzoxazone	250	8
		Paracetamol	300	
Methocarbamol	Flexinol	Methocarbamol	400	6
		Paracetamol	325	
	Robiflam	Methocarbamol	750	8
		Ibuprofen	200	
Baclofen	Lioresal	Baclofen	10-25	8-12
Dantrolene	Dantrium	Dantrolene	25	4-6
Diazepam	Valium	Diazepam	2-10	12

3. DRUGS THAT AID IN PROSTHODONTIC TREATMENT

3.1 Astringents

Astringents are the substances that precipitate proteins, but do not penetrate cells, thus affecting the superficial layer of mucosa only. They toughen the surface by making it mechanically stronger and decrease exudation. Astringents may be administered by retraction cords already impregnated with the agent or by applying them to cotton pellets. Some of the examples are alum, aluminum chloride, zinc chloride (8-20%) and tannic acid (Table 9). Styptics are the concentrated form of astringents. They cause superficial and local coagulation. Some of the examples are ferric chloride and ferric sulfate. Aluminum chloride and Ferrous sulfate are preferred astringents amongst prosthodontists because they cause minimum tissue damage (Rosenstiel, 2006a).

3.2 Vasoconstrictors

Vasoconstrictors are used in dentistry either as components of the local anesthetic syringe or for application with gingival retraction cords. These agents do not produce coagulation of blood but act by constricting blood vessels. Examples of vasoconstrictors accepted by the Council on Dental Therapeutics include Epinephrine (1:200,000/1:100,000/1:50,000), Levonordefrine (1:20,000) and Norepinephrine (1:30,000). Epinephrine is the vasoconstrictor of choice for use in dentistry (Felpel, 1999). It restricts the blood supply to the area by decreasing the size of blood capillaries thereby decreasing hemorrhage and fluid seepage. It is advisable to use low concentration epinephrine (0.01%) for gingival retraction due to its superior effect in keeping the gingival sulcus relatively dry during the impression procedure (Csillag et al., 2007).

British Journal of Pharmaceutical Research, 1(3): 66-87, 2011

Table 9. List of Hemostatic agents

Brand name	Constituent	Action	Available as
Gel Cord/ Gel cord clear (Pascal)	25% Aluminum sulfate Gel	Biologic fluid coagulant	Cartridge-0.32g Syringe-0.75g Jar- 30g
Stat Gel FS (Pascal)	15.5% Ferric sulfate	Styptics	
Racelletcotton Pellets (Pascal)	Epinephrine	Vasoconstrictor	1.15mg and 0.55 mg pellets
Rastringent/ Retraxcotton Pellets (Pascal)	25 % Aluminum sulfate	Biologic fluid coagulant	Solution in bottle
Epidri pellet (Pascal)	Racemic epinephrine HCl	Vasoconstrictor	1.9mg pellet
Hemostatic gel (Pro-option)	20% Ferric sulfate	Styptics	Syringe
Hemostatic solution (Pro-option)	15.5% Ferric sulfate	Styptics	Syringe
Traxodent/ Hemodent (Premier dental products)	15% Aluminum chloride	Biologic fluid coagulant	Syringe
Hemostasyl gel (Kerr)	15% Aluminum chloride	Biologic fluid coagulant	Syringe
ViscoStat clear (Ultradent)	Aluminum chloride gel	Biologic fluid coagulant	1.2 ml syringe
Gingiaid (GingiPak)	8% dl epinephrine HCl	Vasoconstrictor	Syringe
Racestyptine (Septodent)	25 % aluminum chloride, oxyquinol, hydroalcoholic excipients.	Biologic fluid coagulant	Solution in bottle
Astringedent (Ultradent)	15.5% Ferric sulfate solution	Styptics	Bottle/ syringe
Astringedent X (Ultradent)	12.7% Iron Solution Containing Equivalent Ferric sulfate and Ferric Subsulfate	Styptics	Bottle/ syringe
ViscoStatWintermint (Ultradent)	20% Ferric sulfate gel	Styptics	Syringe
ViscoStat Clear (Ultradent)	20% Aluminum chloride gel	Biologic fluid coagulant	Syringe
QuickStat FS (Vista)	15.5% Ferric sulfate gel	Styptics	Syringe

3.3 Hemostatic Agents

Hemostatic agents are used in dentistry for hemorrhage control and wound protection (Mc Bee and Koerner, 2005). These are drugs which arrest more serious bleeding from cut or lacerated capillaries and arterioles.

British Journal of Pharmaceutical Research, 1(3): 66-87, 2011

Some of the examples are:

i. Thrombin- It is prepared from mammalian pro-thrombin, acts by accelerating the clotting of blood. It is available in powder form and mixed with saline. It should be applied locally and never injected.

ii. Gel Foam- It is also known as gelatin sponge and is available as a powder or porous sheet. The hemostatic properties of absorbable gelatin sponge can be improved by soaking it in a thrombin solution before application (Felpel, 1999).

Table 10. Salivary stimulants

Stimulants	Type	Example	Key ingredients
Mechanical (Masticatory) Stimulants	Sugarless gums	Biotene Eclipse Orbit Airwaves Trident, Xylifresh	Xylitol, Sorbitol, Mannnitol, Aspartame, Acesulfame K
	Sugarless tablets	Salix	Carboxymethylcellulose/ hydroxypropylmethylcellulose
Chemical Stimulants	Solutions	Mouth-Kote	Alcohol free Mucopolysaccaharide Sol with citric acid
		Optimoist	Citric acid
Electrical Stimulation		Salitron	Intra-oral electronic stimulator of saliva
Pharmacologic Stimulant	Drugs	Salagen (PilocarpineHCl)	Cholinergic agonist
		Evoxac (CevimelineHCl)	Cholinergic agonist
Oral moisturizers		Water	
	Solutions	Salivart Oralube Xero-Lube Moi stir Glandosane Aqwet	Carboxymethyl cellulose and hydroxyethyl cellulose
		Orex	Carboxymethylcellulose with flouride
	Gel	Plax Oral Balance	Water-glycerin agent Glycerate polymer

3.4 Sialogogues

Xerostomia may result from disease states (Sjogren's syndrome, rheumatoid arthritis, diabetes insipidus, pernicious anemia), from radiation, as a side effect of a wide variety of drugs, or from natural aging. Edentulous patients suffering from xerostomia may experience

difficulty in using dentures and an increased incidence of intraoral candidal infection (Felpel, 1999). Sialogogues are the agents which activate muscarinic cholinergic receptors of the parasympathetic nervous system to increase salivary flow in patients with xerostomia (Tripathi, 2008b).Various agents can be used as salivary stimulants (Table 10). All commercially available preparations have a limited duration of action, making frequent application necessary. Agents such as sugar free gum or candies and lozenges containing citric acid sorbitol, mannitol or xylitol may be recommended. According to Boucher, making a conscious effort of consuming at least eight glasses of water, juice or milk daily is the most important measure to relieve dry mouth (Zarb and Bolender, 2004a). Pilocarpine and Bethanechol have been reported as potentially effective sialogogues for xerostomic patients in a study on patients with dry mouth following cancer therapy (Gorsky et al., 2004). Carboxy methyl cellulose based artificial saliva demonstrated moderate effects in reducing dry mouth-related symptoms with more significant effects appearing in patients whose residual secretory potency was severely compromised (Oh et al., 2008).

3.5 Anti-sialogogues

These agents are used to decrease salivary secretion by cholinergic antagonist action. They decrease salivary secretion by inhibiting the action of myo-epithelial cells in the salivary glands thus producing a dry field. Methantheline and Propantheline (synthetic atropine derivatives) are few examples of anti-sialogouges, with Propantheline being 5 times more potent. Clonidine (0.2mg) an antihypertensive drug has been found to be as effective as methantheline (50 mg) in reducing salivary flow (Wilson et al., 1984). For thedesired reduction in salivary flow, the oral administration of atropine, scopolamine, or methantheline and propantheline should precede the clinical procedure by 1to 2 h, half to 1 h, or one-half an hour, respectively. Medications with anti sialogogic effect include (Rosenstiel et al., 2006b); probanthine (7.5 to 15 mg), robinul (1 to 2 mg), saltropine (0.4 mg) and antipasbentyl (10 to 20 mg). Anticholinergic drugs are contraindicated in patients with glaucoma, prostatic hypertrophy, severe gastrointestinal disorders (ulcerative colitis, obstructive disease, intestinal atony), and myasthenia gravis (Felpel, 1999).

3.6 Gum Paints

Gum paints are the combination of antiseptics and tanning agents which precipitate proteins but do not penetrate cells thereby affecting only the superficial layer making it mechanically stronger and decreases exudation. They have germicidal, fungicidal, anesthetic and healing properties. When applied, they provide a soothing, cooling and an astringent effect. All these preparations contain Choline salicylate, Tannic acid, Cetrimide, Thymol, Camphor, Cinnamon oil, Iodine and Alum (hydrated potassium aluminumsulfate). 'Zingisol' containing 2% Zinc Sulfate is used to control bleeding gums. The patient is advised to apply 3-4 drops on finger and massage 3-4 times a day. 'Sensoform' gum paint (Warren) contains tannic acid, glycerine and potassium iodide and is applied on affected area several times with the cotton applicator for the treatment of stomatitis, inflammation and bleeding gums. It also decreases sensitivity and increases gingival resistance against infections. 'Stolin' gum paint (dr. reddy's)15ml contains cetrimide 0.1 % w/v, tannic acid 2 % w/v, zinc chloride 1 % w/v. 'Sensorok' gum astringent with zinc sulfate is used for gum massage 2-3 times daily. Other commonly available brands include Gumex and Pyastringent, Payogum and Pyosan.

British Journal of Pharmaceutical Research, 1(3): 66-87, 2011

3.7 Denture Cleansers

It must be emphasized that improper care of dentures can have detrimental effects on the health of the denture supporting tissues. Maintenance of adequate denture hygiene is essential to minimize and eliminate adverse tissue reactions. It must be an integral component of post insertion patient care (Zarb and Bolender, 2004b). Following are the requirements of an ideal denture cleanser:

- Should be non toxic
- Easy to remove and harmless to the patient
- Be able to dissolve the denture deposits such as calculus
- Exhibit bacteriocidal and fungicidal effect
- Should have long shelf life and inexpensive
- Harmless to the denture base materials, denture teeth as well as soft liners

Commonly available denture cleansers are available in powder and tablet form and include:

a) Oxygenating cleansers- overnight immersion of dentures in alkaline peroxide solution is a safe and effective method.
b) Hypochlorite cleansers- immersion of the dentures in a solution of one part of 5% sodium hypochlorite in three parts of water followed by light brushing is advisable.
c) Dilute mineral acids.
d) Abrasive powders and pastes.
e) Enzyme containing minerals (proteases).

Commercially available denture cleansers include Kleenex, Stain Away, Polident, Triclean, Efferdent.

3.8 Denture Adhesives

Denture adhesives augment the same retentive mechanisms already operating when a denture is worn. They consist of keraya gum, tragacanth, sodium carboxyl methyl cellulose, polyethylene oxide, flavouring agents, antimicrobial agents and plasticizers. They enhance retention through optimizing interfacial forces by increasing the adhesive and cohesive properties and viscosity of the medium lying between the denture and the basal seat and eliminating voids between the denture base and the basal seat (Zarb and Bolender, 2004c).

They are supplied in powder and paste form. Method of application is as follows:

(1) The powder is sprinkled on the wetted denture base and after the excess powder is shaken off; the prosthesis is inserted and seated firmly.
(2) Placement of thin beads of adhesive is recommended in the incisor and molar regions in case of cream type. An anteroposterior bead should be placed along the midpalate in the maxillary unit.

Commercially available denture adhesives are Fixodent, Poligrip, Cushion grip, Rigident, SeaBond wafers, Secure, Effergrip and Staydent.

British Journal of Pharmaceutical Research, 1(3): 66-87, 2011

3.9 Oral Protective Agents

These agents are finely powdered, inert and insoluble. They afford physical protection to the mucous membrane thus are used for apthous ulcers and gingival inflammation. All these gel preparations should be applied 2-3 times daily. The Lignocaine based preparations contain Lignocaine hydrochloride, Benzalkonium and Choline salicylate. Examples are Dentogel, Dologel and Emergel. Dentasep, Dentonex-M, Maghex-M and Metrogyl DG gel are examples of metronidazole and chlorhexidine preparations. Oraguard B and Mucopain are gels containing Benzocaine as the active ingredient. Petroleum jelly is also used successfully as an oral protective agent.

3.10 Demulcents

These are inert substances which sooth the inflamed and denuded mucosa by preventing contact with air or irritants in the surrounding. They can be applied as thick colloidal and viscid solutions in water. Commonly used agents are Gum Acacia and Gum Tragacanth. These are used as suspending agents for indiffusible powders, emulsifying agents for oils and in lozenges. Glycerin (50-75%) in water acts as a popular vehicle for gum paint(Tripathi, 2008c).

4. CONCLUSION

All the pharmacological agents mentioned are used either before commencement of the treatment, during the treatment or at the post treatment duration. Judicious use of these agents yield good results and have a positive effect in the success of any prosthesis. Therefore, a prosthodontist should have sound knowledge of the benefits and drawbacks of these agents in achieving the desired results.

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Gary M. Radz, DDS

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The Key to the Perfect Impression

Gary M. Radz, DDS*

There appears to be universal agreement that far too many inadequate and unreadable impressions are being sent to dental laboratories.[1-3] This creates daily frustration for the technicians as they try to fabricate a clinically acceptable restoration with less-than-adequate information.

All too often, the dentist will blame the impression material. However, impression materials are among the most developed and reliable of all dental materials.[1] Currently, many excellent choices are available.

More often than not, the fault lies with us, the dentists. We may be overlooking essential details, such as the proper handling of the soft tissue during tooth preparation or management of the soft tissue immediately before taking the impression. If correct technique is used and appropriate attention paid to the management of the soft tissue, the chance of capturing a clinically acceptable impression is dramatically increased.

Many simple techniques and beneficial materials can be applied to help the dentist properly manage the soft tissue, thereby helping to obtain a more ideal impression.

SOFT-TISSUE MANAGEMENT DURING TOOTH PREPARATION

In an ideal world, excellent soft-tissue health would be a prerequisite for predictable impressions. Inflamed tissues will bleed more readily and exhibit increased crevicular fluid flow, rendering moisture control more difficult.[4] However, the reality of private practice does not always provide the opportunity to consistently have ideal soft-tissue health. Despite having less-than-ideal conditions, the capture of an excellent impression is still possible.

During tooth preparation, it is critical to minimize, if not eliminate, soft-tissue trauma. This trauma will create fluid flow, making it more difficult to manage the area when the time comes to take the final impression. There is general agreement that during tooth preparation, the soft tissue should be mechanically displaced using a gingival retraction cord.[2,3,5] A single cord of the appropriate size is placed to deflect the soft tissue from the path of the rotary instrument, thereby decreasing the opportunity to mistakenly touch the tissue. Inevitably, this is not possible 100% of the time, but this technique will certainly minimize the amount of trauma created during tooth preparation.

TISSUE MANAGEMENT FOR FINAL IMPRESSION

The use of a two-cord technique is a time-proven and effective way to properly deflect and control the soft tissue in order to capture the margin of the tooth preparation in its entirety.[1-7] During the tooth preparation, the clinician will leave in place the initial cord (or replace it if damaged during preparation), and then position a second cord on the first. Research has demonstrated that this second cord should remain for 4 minutes before the final impression is taken.[8] After this time span, the top cord is pulled and the final impression taken. Use of this technique consistently produces excellent impressions.

Another option is the use of a single-cord technique. This method can work well with tooth preparations that terminate supragingivally or at the tissue height. In today's age of all-ceramic restorations, we frequently find that the placement of subgingival margins is not always necessary.

With this technique, the cord used to displace the tissue during tooth preparation is kept in place (or replaced if damaged) for the final impression. Often, this technique will work very well, provided the clinician maintains control of the soft tissues and the related fluids in the area.

The placement of retraction cord is frequently uncomfortable for the patient. In areas of less-than-ideal soft-tissue health, it can lead to more bleeding. Recently, the introduction of gingival retraction pastes has provided dentists with a more comfortable and less traumatic option. These pastes are placed in the gingival sulcus and are stiff enough to physically displace the soft tissue and allow for better exposure of the preparation margin. Also, these products have aluminum chloride, which will provide for localized hemostasis.

These materials work best with preparations located at the height of the tissue. Another application that can function well is the use the retraction paste instead of placement of a second retraction cord. Virtually, this is the two-cord technique without the second cord.

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Clinical situations can arise in which the soft tissue is too bulky or too inflamed, hindering visualization of the preparation margin. In these situations, mechanical removal of the soft tissue may be indicated.

The use of electrosurgery or laser surgery provides the opportunity to remove excess soft tissue, which will enable the clinician to see where to place the margin of the final restoration. The tissue removal will also allow for exposure of the preparation margin when it is time to take the final impression.

Gingivectomies with either an electrosurge or laser can be practical ways of dealing with excessive and/or irritated soft tissue. However, the dentist needs to be aware of the concept of biological width.[3] Impinging on the biological width can lead to long-term failure of the final restoration.

FLUID MANAGEMENT FOR THE FINAL IMPRESSION

Crevicular fluids and blood can and will lead to an inaccurate final impression. The dentist must have the area controlled before attempting to take the impression. Several techniques are available for the management of the fluids.

The use of a retraction cord is the first line of defense to control fluid flow. When placed in the gingival sulcus, the retraction cord will physically block crevicular fluids from the preparation margin. In addition, retraction cords can be impregnated with epinephrine, which is an excellent hemostatic agent. It can minimize any bleeding that may be in the preparation area.

The use of electrosurgery or laser surgery is not only effective in eliminating excess soft tissue but also can be used to provide an area of hemostasis. A slight alteration in the settings of these devices can change from a "cutting" setting to a "coagulation" setting. These tools provide a predictable and quick option to control bleeding areas.

Most commonly, bleeding is managed chemically. Ferric sulfate, aluminum chloride, and epinephrine are the most common options. These materials will cause constriction of peripheral blood vessels, resulting in a transient shrinkage of the surrounding tissues.[4]

For years, ferric sulfate has been the most frequently used hemostatic and has been proven to be highly effective in stopping sulcular bleeding.[9] The only issue is its potential to leave an organic black residue on the tooth preparation.[2,4] This is an adverse effect if placing an all-ceramic restoration.

Aluminum chloride, while not quite as effective as ferric sulfate, is another popular option for controlling localized bleeding. Its benefit is that no dark residue remains on the restoration. This makes aluminum chloride the chemical of choice when the final restoration is made of an all-ceramic or indirect composite material.

Another option is epinephrine, which stops localized bleeding through vasoconstriction. While effective, the potential for systemic interactions[4] makes it the least desirable choice. However, when used in combination with a local anesthetic in a 1:50,000 concentration, it can be highly successful at controlling localized bleeding for a short period.

DIGITAL IMPRESSIONS

Digital impression devices have recently became commercially available and are proving to be very effective clinically. While providing a dramatic step in helping to create even better impressions through digital accuracy, these new tools require the clinician to continue applying precise soft-tissue management.

These devices work by capturing digital images of the preparation and surrounding area. If the device cannot "see" the preparation margin, it cannot capture it.

CONCLUSION

A bad impression is rarely caused by the material itself. If great care is not taken to manage the soft tissue during the preparation and in preparation of taking the final impression, inadequate impressions will continue to be sent to the dental laboratories. The good news is that we have many time-proven materials and techniques to help us create great impressions.

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Tissue Management, Gingival Retraction and Hemostasis

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COURSE OBJECTIVES

At the completion of this program, the participant will be able to:

- List the clinical situations where gingival retraction are beneficial in restorative dentistry
- List the different methods of gingival retraction and hemostasis
- List three different types of gingival retraction cord
- List different astringents used in dentistry for retraction and hemostasis

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Dentists, Dental Assistants and Dental Hygienists.

THE ORAL CAVITY IS A DIFFICULT AREA TO TREAT IN RESTORATIVE DENTISTRY because of the constraints of the lips, tongue and cheeks, challenges for access to visualize and manipulate instruments, as well as the position of the teeth that are being treated relative to the gingival tissues — which bleed if improperly managed. While for operative dentistry and single-tooth restorations, the use of the dental dam provides control of the field and access to tooth preparation and restoration, there are many times in restorative dentistry that use of the dental dam is precluded. There are times that caries or non-carious cervical lesions are at or below the free margin of the gingiva — as well as, for fixed prosthodontics, crown or inlay/onlay margins are at or below the free margin of the gingiva and access to them for preparation, impressioning and cementation is impossible without additional techniques to displace the gingival tissues and control gingival hemorrhage and sulcular fluids.

One of the most challenging aspects of crown and bridge is management of the gingival tissues when making an impression. Tissue management includes placing the gingival tissues away from the preparation margins so they can be impressed, combined with providing for hemostasis when the gingival tissues are susceptible to bleeding.[1,2] The rationale for tissue management is a critical aspect of impression making, whether the impression is made with a conventional impression material or by a digital impression technique so that all tooth preparation margins are captured in the impression to assure an excellent marginal fit of a laboratory fabricated restoration.[1,3] From this, the final restoration will be well adapted to the tooth preparation so that when cemented, the restoration will prevent recurrent caries, tooth sensitivity and gingival irritation.

Tissue management is also critical for placement of direct restorative materials, especially for the restoration of Class V lesions. In our practices we have seen a significant increase in Class V cervical lesions. Whether these lesions are carious (Fig. 1) or non-carious cervical lesions (Fig. 2), when these teeth need restoration, the cervical margin can be difficult to access due to both the extent of the lesion and the need for a dry, controlled field when placing the restoration — whether it be composite resin or glass ionomer.


FIG. 1

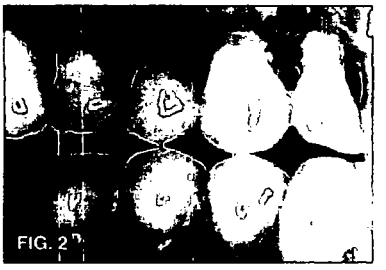


FIG. 2

FIG. 1: Class V carious lesions where gingival retraction will be necessary to prepare and restore. **Fig. 2:** Class V non-carious cervical lesions (NCCL) where gingival retraction would be useful to control the field when restoring.

Table 1
Partial listing of gingival retraction cords

NAME	TYPE	IMPREGNATED	MANUFACTURER
Fas-Tract	knitted	none	Benco
Fas-Tract	knitted	epinephrine	Benco
Crown-Pak	twisted	epinephrine	Gingi-Pak
Gel-Cord	braided	aluminum sulfate	Pascal
GingiBraid+	braided	none	DUX Dental
GingiBraid+	braided	epinephrine/alum	DUX Dental
GingiBraid+	braided	aluminum potassium sulfate	DUX Dental
GingiCord	twisted	epinephrine/alum	DUX Dental
GingiGel	braid	precoated aluminum chloride	DUX Dental
GingiKNIT	knitted	none	DUX Dental
GingiKNIT	knitted	aluminum sulfate	DUX Dental
Hemodent Cord	braided	aluminum chloride	Premier Dental
Knittrax	knitted	none	Pascal
Pascord	twisted	aluminum sulfate	Pascal
Racord	twisted	epinephrine	Pascal
Racord Two	twisted	zinc phenolsulfonate/epinephrine	Pascal
Retrax	twisted	none	Pascal
Roeko Stay-Put Retraction Cord	braided	none	Coltene/Whaledent
Sil-Trax	braided	aluminum sulfate	Pascal
Sil-Trax	braided	epinephrine/zinc phenolsulfonate	Pascal
Sil-Trax	braided	epinephrine	Pascal
Sil-Trax	braided	none	Pascal
UniBraid+	braided	aluminum potassium sulfate	DUX Dental
UniBraid+ (unit dose/precut)	braided	epinephrine	DUX Dental
UltraPak (unit dose/precut)	knitted	none	Ultradent
Z-Twist	twist	aluminum sulfate	Gingi-Pak
Z-Twist	twist	epinephrine	Gingi-Pak
Z-Twist	twist	none	Gingi-Pak

No matter what the circumstance for soft-tissue mangement for restorative dentistry, the goal for managment of gingival tissues requires that the periodontium be in a state of health. As part of any comprehensive treatment plan, especially if a restorative intervention is required and there is need for control of the gingival tissues, that the teeth be cleaned and the periodontium brought to a state of health. With this accomplished, restoration will be more easily accomplished. Management of the gingival tissues for access, visualization, maintaining a controlled field for restoration placement and cementation can be accomplished with a variety of techniques. This article will provide the clinician with an overview of the techniques available for clinical situations that are frequently encountered.

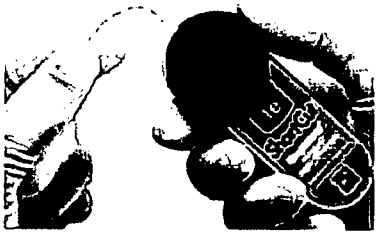
Techniques for Soft-Tissue Management, Displacement Retraction and Hemorrhage Control

Mechanical Methods

Among the first techniques developed and available to clinicians for displacement

FIG. 3

FIG. 4



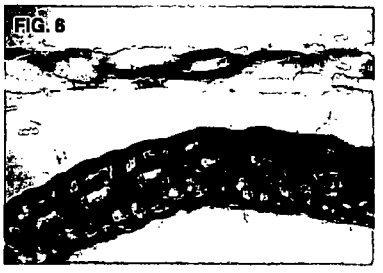


FIG. 3: Dispensing GingiBRAID+ with ShortCut (DUX Dental) click dial dispensing to length desired. **Fig. 4:** Built-in cutter on ShortCut dispenser to cut to length needed. **Fig. 5:** Placement of braided cord for retraction for a Class V carious lesion with a smooth, non-serrated cord placement instrument (Fischer UltraPak Packer, Ultradent). **Fig. 6:** Comparison of braided cord (top) and knitted cord (bottom).

of gingival tissues, especially for crown and bridge impressions, were mechanical displacement. Mechanical displacement refers to physically moving the gingival tissues aside from the tooth/tooth preparation margins to allow for visualization and access for treatment.[1, 2, 4, 5] In many cases, the materials used for gingival retraction can be used by themselves or in combination with other materials and techniques.

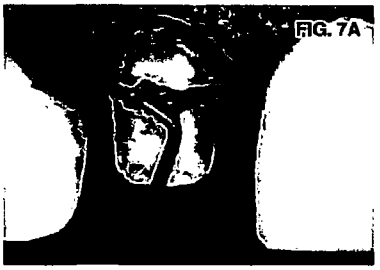
One of the earliest techniques for mechanical displacement of gingival tissues for restoration was the use of the dental dam. Specialized gingival retraction retainers (clamps), when placed, displace the gingival tissues to allow for access for tooth preparation and restoration.[6] The use of gingival retraction clamps has also been described to provide access for scaling and root planing.[7]

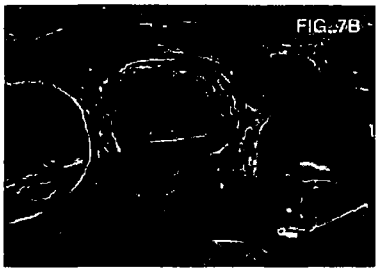
Among the most popular methods of gingival displacement is the use of gingival retraction cord.[1, 2, 4, 5, 8-10] Gingival retraction cords can be woven, braided or twisted in a variety of configurations to provide for different diameters and thicknesses (Table 1). They are typically dispensed from containers or bottles and cut to length. The cord is usually dispensed by pulling the cord from a bottle using a cotton pliers and cutting with a scissors. Hemodent Cord (Premier) has addressed this problem by dispensing its braided and twisted cords in self-cutting plastic dispensing boxes. These techniques have the risk of contamination of the retraction cord. Some recent innovations have addressed this shortcoming of cord dispensing. Unit dose dispensing of retraction cords has been introduced where the chemically treated braided cord is pre-cut and individually packaged in 2-inch lengths (Uni-Braid+, DUX Dental). Of issue is that there is the need for different lengths of cord for different clinical situations and for the various diameters of teeth. There have been no measuring tools as part of the dispensing system, so it is not uncommon to dispense too short a cord, or too long a cord, for the clinical indication. Most clinicians and their chairside dental assistant err by dispensing too long a section of retraction cord that is more difficult to manage when placing the cord into the gingival sulcus. It must then be cut intraorally to the length desired.

This shortcoming in cord dispensing and cutting has been addressed with the introduction of an all-in-one delivery system that combines convenience, efficiency and effectiveness in gingival retraction cord dispensing and cutting.[11] This system, ShortCut (DUX Dental) dispenses the braided gingival retraction cord (GingiBRAID+) by merely turning the click-stop dial of the ShortCut device the number of clicks specific to the length of cord needed. (Fig. 3) Typically 3-4 clicks provides a length of braided cord for an anterior tooth; 4-5 clicks for a premolar; and 5-6 clicks for a molar. Large molars, in this author's experience, require five clicks for the needed length. Once dispensed, the built-in cutter is activated and pushed in with firm pressure, dispensing to the length needed for your clinical procedure. (Fig. 4) The ShortCut device has proven itself to be both durable and easily disinfected. ShortCut is available in braided cord diameters sizes 0, 1 and 2. It is provided as non-impregnated, allowing the clinician to choose the astringent-hemostatic agent, or the GingiBraid+ can be used impregnated with 8% racemic epinephrine/7% aluminum potassium sulfate or impregnated with 10% aluminum potassium sulfate and still allow for soaking in an astringent-hemostatic agent.

The choice of gingival retraction cord has proven itself to be one of personal preference by the clinician. Keep in mind that different cord types offer a variety of properties that to some make them more desirable. Also, as will be reviewed later in this article, many manufacturers have a range of options of non-impregnated and chemically impregnated cords. Some clinicians prefer twisted cords so they can hand-twist the cord to be tighter when placed in the sulcus — and, as the cords untwist, they expand, creating a physical effect of expanding the sulcus for access.

The preference for braided cords relates to their tight and consistent weave. They provide two benefits: First, braided cords for many clinicians are easier to place in the gingival sulcus with packing-placement instruments, both serrated and smooth, non-serrated, because they are solid and can be pushed into place. (Fig. 5) Some braided cords are not only impregnated with astringent-hemostatic agents but are covered with a gel of that reagent (Gel-cord, Pascal; GingiGel Coated Braid, DUX Dental). A braided cord wrapped around an ultrathin copper wire (Roeko Stay-Put Retraction Cord, Coltene-Whaledent) is described as being more stable in the sulcus once placed. Some recent improvements in braided cords (e.g., GingiBraid+) have a modified weave with a unique cotton yarn to allow the cord to have less memory. In this author's hands, this braided cord has offered more precise placement with minimal soft-tissue damage. Also, the change in the yarn used for the braided weave allows the cord to be significantly more absorbent and not split or tear during placement. This superior absorbency contributes to increase absorption of gingival fluids in the sulcus, as well as a swelling effect in the sulcus which contributes to improved retraction for better visualization of margins when making an impression.





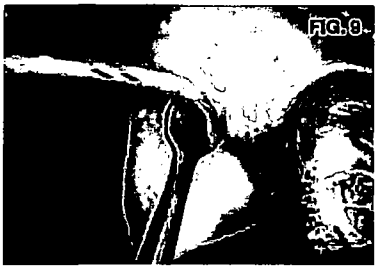


FIG. 7A: Placement of knitted cord (Ultra-Pak, Ultradent) for central incisor crown preparation using a double-cord technique. **Fig. 7B:** Impression demonstrates excellent gingival retraction for making an impression of the subgingival crown margins. **Fig. 8:** Dual-packing blade of TN010 Double Cord Packer (Garrison Dental Solutions). **Fig. 9:** Placement of braided cord (GingiBraid+) for crown preparation.

Knitted cords have increased in popularity. Among the major benefits of knitted cords is their unique knitted weave (Fig. 6), which minimizes unraveling and fraying after cutting and during cord placement. Knitted cords offer easy placement, and they expand when wet, opening up the sulcus greater than the original diameter of the cord.[1,2] The knitting and yarn selection allows for a greater range of knitted cotton cord diameters/sizes. In this author's experience, when using knitted cord, a smooth, non-serrated placement instrument allows for precise placement without pulling the cord out of a gingival sulcus. Also, the range of sizes/diameters allow for placement in both the easy-to-access gingival sulcus and the tighter, healthier gingival sulcus. (Fig. 7)

When describing mechanical displacement of gingival tissues with gingival retraction cords, one would be remiss if there were no mention of retraction cord placement packing instruments. There are many different instruments that have been described.[1] Key to placement of cord with instruments is that the end of the cord packer be thin enough to be placed in the gingival sulcus without damaging the gingival tissue and potentially causing bleeding; and that the angle of the instrument allow for orientation so that cord placement can be accomplished around all surfaces of the tooth. In this author's experience, the use of standard off-angle plastic filling instruments (PFI) is inappropriate due to the thickness of the blade. Also, there is variation in the size, length and shape of the end of the blade of the cord-packing instrument. Most commonly, the clinician will use double-ended instruments. Recently a novel double-ended instrument with multiple orientations of a dual-packing blade (TN010 Double Cord Packer, Garrison Dental Solutions) has been introduced so that the instrument does not need to be twirled to get the end orientation needed (Fig. 8). A good friend, Dr. Bob Margeas, designed this instrument because when using magnification, he found that this design maintains the instrument in the field of view while packing cord around the tooth.

Which are better, serrated or smooth cord-packer blades? For braided and twisted cords, both serrated and smooth cord packers work well (Fig. 9); for knitted cords, smooth cord-packing instruments are less likely to pull the cord from the sulcus during placement (Fig. 10). If you are satisfied with your cord-packing instrument, there is no need to change. If you desire an instrument to manage shortcomings with your current instrument, it would be worthwhile, at the next dental meeting you attend, to seek out manufacturers that provide excellent cord-packing instruments (Table 2).

Recommendations for improved gingival retraction with cord include use of a double-cord technique where a thin-diameter cord is placed to the base of the gingival sulcus without overlap, and cut to be flush within the sulcus. This cord is maintained during the impression to control any bleeding from the base of the sulcus. A second, wider-diameter cord is placed on top of the first cord to achieve tissue displacement. Immediately before making the impression, the cord should be wetted with water so as not to grab and tear the gingival tissues, which can create bleeding. The cord is removed and the impression is made immediately while leaving the first cord in place. Once the cord is removed, the retraction is maintained for only 30 seconds.[1]

Table 2
Partial listing of manufacturers that provide cord-packing instruments

MANUFACTURER	WEB SITE
Garrison Dental Solutions	garrisondental.com
Gingi-Pak	gingi-pak.com
Hu-Friedy	hu-friedy.com
Miltex	miltex.com
Pascal	pascaldental.com
Premier Dental Products	premusa.com
Ultradent Products	ultradent.com

Helpful hint: From this author's experience, if bleeding is persistent when the first cord is removed, continue with the impression, making certain to syringe the impression material within the sulcus. Even with the expectation that the impression will be unsuccessful, this impression will maintain the retraction while allowing for hemostasis. Remove the first impression and *do not* look at it. Immediately make a second impression. The sulcus will still be open and will not be bleeding.

One other method of mechanical displacement for gingival retraction includes making the impression at the same time. The use of copper tubes or copper bands to displace soft tissue for impressions for crown preparations requires that a fitted copper band be cut to shape, contoured and fitted to beyond the crown preparation margins.[4,5,12] The fitted band is filled with an elasomeric impression material, compound or a combination of acrylic resin and then relined with rubber base to simultaneously displace the gingival tissue and make the impression.

Mechanicochemical Methods

A variety of chemical solutions and gels have been recommended for use with gin-

gival retraction cords because of the properties as drugs to act as an astringent or hemostatic agent.[1, 2, 4] In most cases, these drugs are both astringent, causing contraction-retraction of the gingival tissues, and hemostasis, constricting blood flow through coagulation. When these reagents are placed on a retraction cord, they cause a transient ischemia, shrinking the gingival tissue and blood vessel coagulation. Common astringent-hemostatic agents include ferric sulfate, aluminum chloride and racemic epinephrine. As previously stated, gingival retraction cords are available unimpregnated or impregnated with the aforementioned astringent-hemostatic agents, as well as aluminum potassium sulfate, aluminum sulfate, racemic epinephrine and zinc phenolsulfonate/racemic epinephrine, among others. Chemically impregnated cords offer greater sulcus displacement with the combined physical and chemical effect.[1] Also, cord diameter, astringent-hemostatic agent and cord type have a direct effect on the physical properties of the cord.[13] In some cases, both solutions and gel formulations are recommended for direct placement into the gingival sulcus with specialized tips (Astringedent, Ultradent; ViscoStat, Ultradent; Racecord, Septodont) to achieve a hemostatic effect with some ischemic effect before cord placement.

A 20–25% aluminum chloride and 15.5–20% ferric sulfate are among the most popularly used chemical reagents.When used for durations within the gingival sulcus of less than 10 minutes, they cause minimal tissue damage.[1, 2, 14] There has been concern over the use of an 8% racemic epinephrine impregnated cord.[4, 15-18] It has been reported that epinephrine-impregnated cords should be used with care. It has been reported that an 8% racemic epinephrine cord can cause elevation in blood pressure and tachycardia, especially if the gingival tissue is bleeding due to laceration.[16] In fact, it has been demonstrated that no clinical benefit in gingival retraction could be recognized between an epinephrine-containing cord and other cords.[17] A systematic review of the dental literature of cardiovascular effects of epinephrine-containing anesthetic agents and epinephrine-impregnated cords was done to identify any additional risks of adverse cardiovascular outcomes to hypertensive individuals.[18] Although the increased risk for adverse events among uncontrolled hypertensive patients was found to be low, and the reported occurrences of adverse events in hypertensive patients associated with the use of epinephrine in local anesthetics minimal, the quantity and quality of the pertinent literature is problematic.[18]

Table 3
Cordless gingival retraction

PRODUCT	MANUFACTURER
Expasyl	Kerr
GingiTrac	Centrix
Magic Foam Cord	Coltene/Whaledent
Racegel	Septodont
Traxodent	Premier Dental

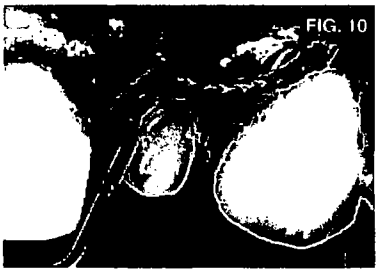


FIG. 10

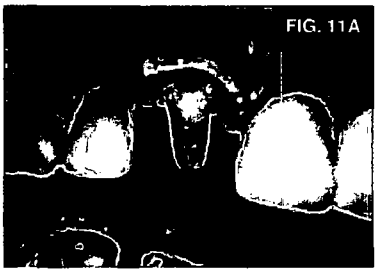


FIG. 11A

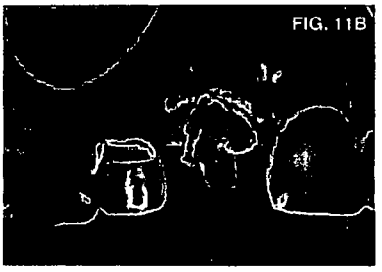


FIG. 11B


FIG. 11C


FIG. 12A

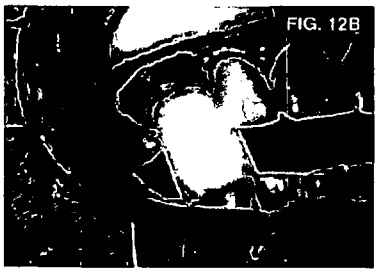


FIG. 12B

FIG. 10: Placement of knitted cord (UltraPak) for crown preparation. **FIG. 11A:** Crown preparation maxillary central incisor. **FIG. 11B:** Placement of GingiTrac paste (Centrix) into gingival sulcus before reseating putty matrix to force paste into sulcus for retraction. **FIG. 11C:** Impression for crown demonstrating the retraction accomplished by the GingiTrac cordless retraction system. **FIG. 12A:** Syringing the retraction paste into the sulcus prior to inserting the compression cap. **FIG. 12B:** GingiCap compression cap placed over the crown preparation to push the paste into the sulcus.

Of special note, the solutions that are used as astringents and for hemostasis are acidic. There has been evidence demonstrating that the use of these products removes the smear layer.[19, 20] There is concern that if the root surfaces beyond the crown preparation margins are exposed to these solutions, there may be an increase in postoperative sensitivity. If, as a clinician, you have this problem, it is recommended that after making the impression and before cementation of the provsisional restoration, the preparations be treated with a desensitizing agent such as Gluma (Heraeus-Kulzer) or Calm-It (Dentsply Caulk).

Cordless Retraction

In most cases, gingival retraction cord is the most effective method for retracting tissue to the depth of the sulcus. Unfortunately, many times on the day of the tooth preparation, gingival bleeding is difficult to control — or, when packing a cord into the sulcus, the tissues start to bleed, making impression difficult or impossible. For this reason, a new class of gingival retraction materials have been introduced (Table 3).

These cordless retraction materials provide for excellent hemostasis and some gingival retraction. Some of the materials incorporate the use of a compression cap to enhance the retraction effects of the material.

GingiTrac (Centrix) was an improvement over the first-generation cordless retraction and tissue-management material, Retrac (Centrix).[21] The technique for GingiTrac is the use of a heavy-viscosity matrix combined with a light-body retraction/hemostatsis paste for single and multiple tooth preparations (Fig. 11) or for single teeth with a compressible closed foam cap (GingiCap, Centrix)[22] (Fig.12). In this author's experience, another paste-like material, Expasyl (Kerr) provides for excellent hemostasis but minimal retraction even when syringed into the sulcus. A poly vinyl siloxane material (Magic Foam Cord, Coltene-Whaledent) not only pro-vides for hemostasis but also, when used with its compression cap, expands the sulcus to allow for easy access for impression making. GingiTrac and Magic Foam Cord are more easily used for impression techniques; Expasyl can be used for impression techniques and for hemostasis during routine restorative procedures. Clinical studies evaluating Magic Foam Cord and Expasyl demonstrated their effectiveness in cordless retraction and control of bleeding during and after the retraction.[23,24] Expasyl was found to cause slightly more inflammation than Magic Foam Cord and UltraPak knitted cord, and Expasyl had a higher rate of postoperative dentin hypersensitivity.[23] Also, both products caused less histologic damage than a retraction cord technique.[25]

Using these cordless retraction techniques provide for a non-traumatic, non-invasive tissue management of the sulcus for fixed prosthodontic impressions. Expasyl offers the additional advantage of hemostasis for routine restorative procedures. For the Retrac and Magic Foam Cord, control of the soft tissue for exposing the margins of the tooth preparation using pressure, astringency and time allows the clinician to get predictable gingival retraction and hemorrhage control. These materials and techniques can be used by themselves or in combination with the use of gingival retraction cord, electrosurgery or laser tissue sculpting when bleeding is difficult to control.

Surgical Methods of Gingival Retraction

The use of specialized devices to reshape and remove gingival tissue to control bleeding and to create access to preparation margins has been shown to be successful.[26-28] The surgical method for gingival retraction and exposure of the margins of the tooth preparation has been referred to as "troughing" or "tissue dilation."[26, 27] The first use of this technique was with electrosurgery.[26, 27, 29] In recent years, the use of laser tissue sculpting for gingival retraction has been described.[28] The trough, soft tissue excision, extends from the height of the free margin of the gingiva to a point 0.3–0.4mm apical to the finish line margin of the tooth preparation. The displacement of the soft tissue is accompanied by hemostasis. Unlike other techniques that provide retraction without removal of the gingival tissue, this technique removes gingival tissue and requires soft-tissue healing. It may be problematic in the esthetic zone where the healing and height of the gingival margin has a direct impact on the esthetics of the gingival tissue. Most manufacturers of lasers have specialized tips and settings for this technique. This author has limited experience with these techniques and would recommend that a clinician interested in the use of lasers for soft tissue management review with manufacturers' representatives and colleagues familar with the use of lasers.

Conclusion

There are a variety of techniques and materials that allow the clinician to manage the gingival tissues during restoration and when making an impression. These include gingival retraction cords, chemical reagents, electrosurgery, laser tissue sculpting, copper tube impressions, hydraulic impressions and non-invasive, atraumatic displacement/hemostatic materials. In most cases, gingival retraction cord is the most effective method for retracting tissue to the depth of the sulcus. The other methods have their advantages and indications. In any case, the control of the soft tissue for exposing the margins of the tooth preparation for restoration and impressioning is critical. It would be worthwhile for the clinician to understand all the choices available.

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1. **Displacement of gingival tissues in restorative dentistry may be necessary for**

a. restoring Class V carious lesions below the free margin of the gingiva.
b. restoring Class V non-carious cervical lesions (NCCL) below the free margin of the gingiva.
c. for fixed prosthodontic impressions where the margin of the crown preparation is below the free margin of the gingiva.
d. all the above.

2. **In this article, the description of tissue management when making impressions for fixed prosthodontics includes:**

a. placing the gingival tissue away from the preparation margins.
b. providing soft-tissue hemostasis when the gingival tissues are susceptible to bleeding.
c. surgically creating a soft-tissue flap to reflect the gingiva from the crown margin to visualize the presence of calculus.
d. a and b.

3. **The rationale for tissue management is a critical aspect of impression making. The rationale includes both conventional impressions with impression materials and using a digital impression technique.**

a. Both statements are true.
b. The first statement is true; the second statement is false.
c. The first statement is false; the second statement is true.
d. Both statements are false.

4. **Tissue management is critical for placement of direct restorative materials, especially for Class V lesions. When teeth with Class V lesions need restoration, the cervical margin can be difficult to access due to the extent of the lesion and the need for a dry, controlled field when placing the restoration.**

a. Both statements are true.
b. The first statement is true; the second statement is false.
c. The first statement is false; the second statement is true.
d. Both statements are false.

5. **The goal of tissue management for restorative dentistry requires that the gingival tissue be in a state of health.**

a. True.
b. False.

6. **Mechanical methods for gingival retraction when restoring Class V carious lesions that are subgingival include all the following EXCEPT:**

a. dental dam (rubber dam) using gingival retraction clamps.
b. gingival retraction cord.
c. wooden wedges.

7. **Gingival retraction cord can be woven, braided or twisted. There is only one diameter of cord available to dentists to use.**

a. Both statements are true.
b. The first statement is true; the second statement is false.
c. The first statement is false; the second statement is true.
d. Both statements are false.

8. **Easy methods of dispensing cord include all of the following EXCEPT:**

a. cord dispensed in self-cutting dispensing boxes (Hemodent Cord).
b. precut, individually packaged cord (UniBraid+).
c. 100-inch-long cords dispensed like thread in a sewing machine (The Long and Short of It).
d. all-in-one delivery with a dispensing device that dispeneses and cuts the cord (ShortCut).

9. **Gingival retraction cord is a very popular method for gingival retraction.**

a. True.
b. False.

10. **Gingival retraction cords are available both chemically treated/impregnated with astringents and hemostatic agents and not impregnated. The benefit of a non-impregnated cord is that clinicians can choose their own hemostatic/astringent to use.**

a. Both statements are true.
b. The first statement is true; the second statement is false.
c. The first statement is false; the second statement is true.
d. Both statements are false.

11. **According to this article, the choice of gingival retraction cord is**

a. because one type is much better than other types.
b. personal preference by the clinician.
c. to save money.
d. to save time.

12. Braided gingival retraction cord can be easily used with what type(s) of cord-packing instruments?

a. Smooth, non-serrated cord-packing instruments.
b. Serrated cord-packing instruments
c. Porous, notched, cardboard single-use flexible cord-packing instruments.
d. a and b.

13. In this article, the type of cord-packing instrument recommended for knitted cords is

a. smooth, non-serrated cord-packing instruments.
b. serrated cord-packing instruments.
c. porous, notched, cardboard single-use flexible cord-packing instruments.
d. b and c.

14. Chemical solutions and gels have been recommended for use with gingival retraction cords. These solutions and gels are drugs that

a. act as an astringent causing contraction-retraction of gingival tissue.
b. are anticoagulents to promote gingival bleeding to flush the gingival sulcus of any bacteria before doing the restorative procedure.
c. are hemostatic to control bleeding when doing the restorative procedure.
d. a and c.

15. All of the following drugs are listed in the article for use either as a hemostatic agent or astringent or both EXCEPT:

a. aluminum chloride.
b. ferric sulfate.
c. racemic epinephrine.
d. citric acid.

16. Chemically impregnated cords offer greater sulcus displacement with a combined physical and chemical effect. Also, cord diameter, astringent-hemostatic agent and cord type have no effect on the physical properties of the cord; you need only one large diameter to accomplish the task.

a. Both statements are true.
b. The first statement is true; the second statement is false.
c. The first statement is false; the second statement is true.
d. Both statements are false.

17. The acidity of astringents and hemostatic agents can remove the dental smear layer. There has been concern that using these agents can cause an increase in dentin hypersensitivity of crown margins and the root surfaces beyond the crown margins and an increase in postoperative pain.

a. Both statements are true.
b. The first statement is true; the second statement is false.
c. The first statement is false; the second statement is true.
d. Both statements are false.

18. Cordless retraction refers to the atraumatic placement of hemostatic and astringent pastes into the gingival sulcus to control bleeding and retract the gingival tissues. There have been clinical studies that demonstrate that these techniques are not effective and should be discarded from our practice of dentistry.

a. Both statements are true.
b. The first statement is true; the second statement is false.
c. The first statement is false; the second statement is true.
d. Both statements are false.

19. The use of lasers and electrosurgery for gingival retraction and hemostasis is a surgical method for controlling the soft tissue. The exposure of margins using these devices is referred to as

a. air abrasion.
b. tissue resorption.
c. troughing.
d. tissue redaction.

20. The use of lasers for gingival retraction is effective in creating a space by tissue excision from the height of the gingival margin to a point 0.2–0.4mm apical to the finish line of the tooth preparation. This tissue displacment is accompanied by hemostasis.

a. Both statements are true.
b. The first statement is true; the second statement is false.
c. The first statement is false; the second statement is true.
d. Both statements are false.

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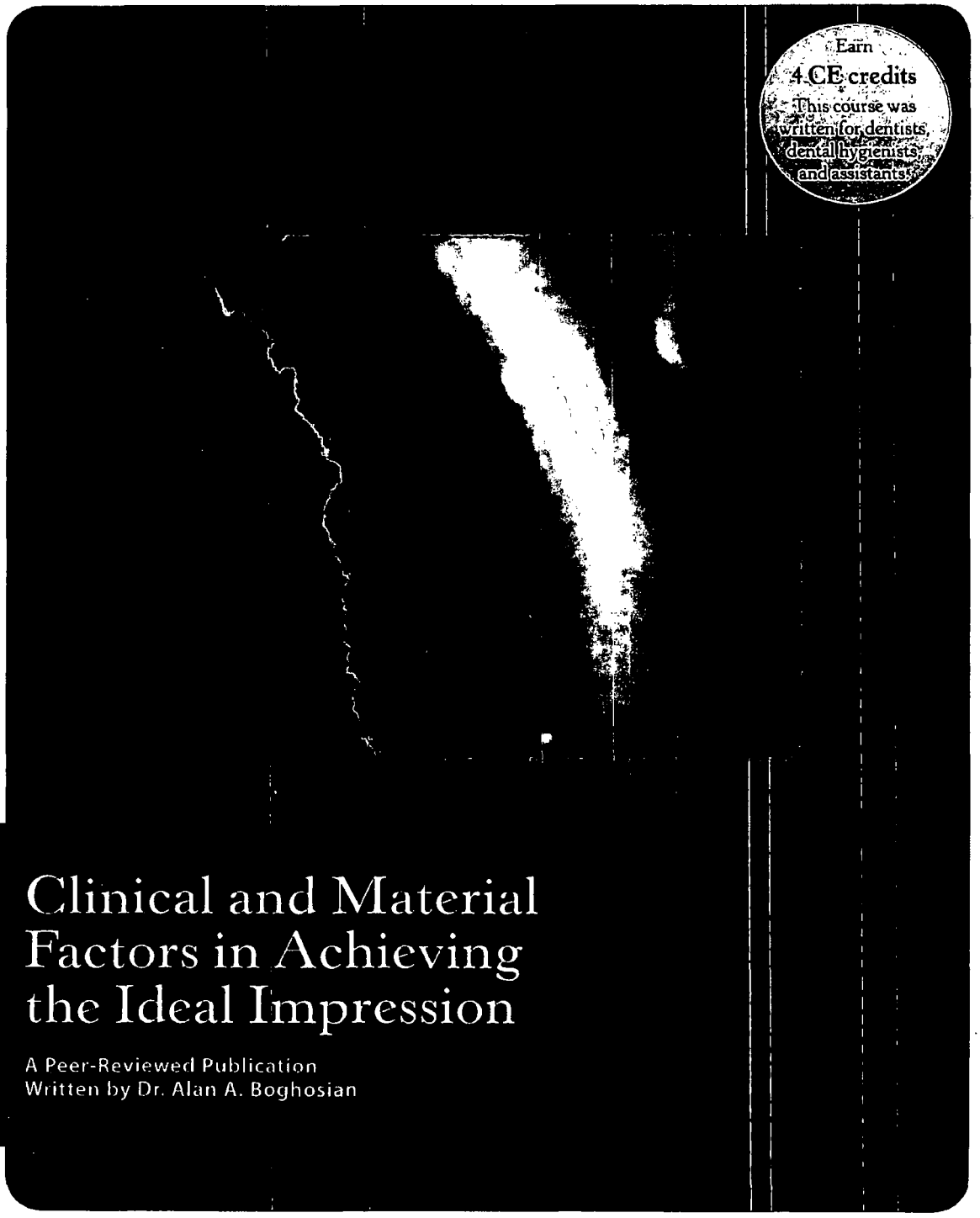

Clinical and Material Factors in Achieving the Ideal Impression

A Peer-Reviewed Publication
Written by Dr. Alan A. Boghosian

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Educational Objectives

Upon completing this course, the reader should be able to do the following:

1. Understand the key factors involved in achieving an ideal impression
2. Be knowledgeable about techniques available for soft tissue retraction and hemostasis
3. Understand the factors involved in tray and impression material selection
4. Be knowledgeable about techniques and materials available that will enhance impression material flow

Abstract

Clinicians report that the impression-taking process is the most stressful restorative procedure. Key factors involved in producing clinically acceptable impressions include managing soft tissue, appropriately selecting tray and impression material, and enabling impression material to flow predictably. Managing soft tissue is the most critical step in obtaining a perfect impression. Tray selection also plays a significant role with tray choice depending on the clinical situation and on the impression material and technique used. The most commonly used elastomeric impression materials are polyether (PE) and vinyl polysiloxane (VPS) chemistries. Appropriate use of either will produce a clinically accurate impression. The material must have an adequate working time and flowability, and have sufficient tear strength to prevent tearing at thin areas at the margin. Using a hydrophilic impression material and a surface modifier will permit enhanced flow and result in a more accurate and detailed impression. In addition, the impression must be dimensionally stable for a reasonable time until it is cast. Achieving clinically acceptable impressions requires clinical expertise and appropriate materials, trays, and techniques.

Introduction

Successful indirect restorations depend on many factors, but chief among them is taking a good impression. An impression that does not precisely duplicate the prepared teeth will produce an inaccurate working model and result in poorly fitting restorations. Clinicians report that the impression-taking process is the most stressful restorative procedure, because of clinical technique and the impression material's inherent properties.

This article will present key factors involved in producing clinically acceptable impressions, including managing soft tissue, selecting tray and impression material, and enabling impression material to flow predictably.

Soft-Tissue Management

Managing soft tissue is the most critical step in obtaining a perfect impression. When surveyed, 48% of key opinion leaders and researchers considered soft-tissue management the single most critical factor in accurate impression-taking.[1] With clinical cases involving deep decay, margin placement is an important consideration. Before any preparation, consider the biologic width.[2] Avoid placing margins too close to bone level, to prevent violating the biologic width.[3,4] Extending restoration margins beyond the biologic width can cause inflammation and, eventually, anatomic changes.[5]

Consider pre-prosthetic crown lengthening if the biologic width has been violated.[6] Also, capturing a preparation's margins is significantly easier if they are not deeply subgingival. Two criteria are critical when taking an impression of equigingival and subgingival preparations: hemostasis and gingival retraction (see Figures 1, 2).

Figure 1. Poor hemostasis resulting in inadequate impression

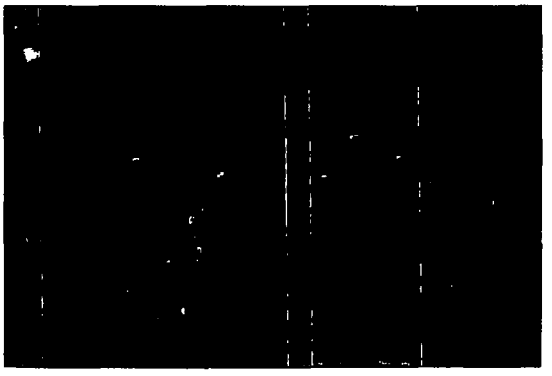
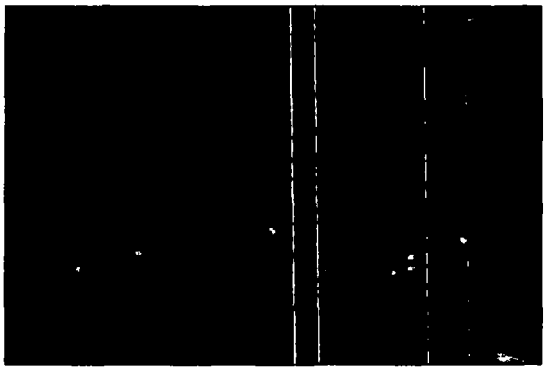


Figure 2. Poor impression with undefined margins



Hemostasis

Several hemostatic agents containing aluminum chloride and aluminum sulfate can arrest and prevent bleeding before an impression is taken. Products containing aluminum chloride include Hemogin-L (Van R), Hemodent™ Liquid (Premier Dental), and ViscoStat Clear (Ultradent). Products

containing aluminum sulfate include Gel Cord® (Pascal) and Tissue Goo™ (Clinician's Choice Dental).

To control slight-to-moderate bleeding, I have found that aluminum chloride and aluminum sulfate are suitable. To control moderate-to-severe bleeding, ferric sulfate and ferric chloride are more effective. Products containing ferric sulfate include FS Hemostatic™ (Premier Dental), and ViscoStat and ViscoStat Wintergreen (Ultradent). An ideal hemostatic agent is ferric chloride (ViscoStat Plus). It can be more effective than ferric sulfate and is potentially less irritating to dentin and pulpal tissues because of its higher pH (2.3 compared to 1.0). However, ferric chloride can tarnish stainless steel.

Gingival retraction

Gingival retraction enables accurate recording of preparation margins and the gingival sulcular area. The most common way to retract the gingiva is with retraction cord.

In addition to classical methods of gingival retraction, newer chemical systems are now available. Silicone polymer retraction materials and materials composed of high-viscosity clay include Magic FoamCord (Coltene Whaledent) and Expasyl ™(Kerr Corporation).

Magic FoamCord is a vinyl polysiloxane material that is syringed around the prepared tooth margins. The material generates hydrogen gas, which expands the sulcus. However, when preparation areas are fairly subgingival, the material may not provide enough retraction force, and it lacks a hemostatic agent.

Expasyl™ contains aluminum chloride for hemostasis. Its putty-like consistency provides sufficient retraction for conservative subgingival preparations, and it can effectively control slight-to-moderate bleeding. However, its viscosity may not provide enough retraction for deeper subgingival preparations.

Although other methods are available — such as rotary curettage, electrosurgery, and lasers — they remove tissue rather than retracting it, and all alternatives but lasers have other drawbacks.

Rotary curettage can be difficult to control and is not recommended for thin, friable gingival tissue. Electrosurgery is similarly contraindicated with friable tissue and in patients with pacemakers. Lasers have produced good results with management of gingival tissue and in postoperative healing. They not only produce an excellent visible path to the margin but also provide outstanding hemostasis.

Gingival retraction using retraction cord is the most widely accepted method. To avoid trauma, as a rule of thumb, use the thinnest cord that adequately retracts tissue. Using a nonimpregnated cord lets you select the hemostatic medicament. If using preimpregnated cord, first soak with a hemostatic agent to improve hemostasis.[7] Before removing cords, soak them with water to help prevent tissue damage and ease placement. Of prosthodontists who responded to a 1999 national survey, 98% said they used gingival retraction cord and 48% said they used double cords.[8]

Single-cord technique

This technique involves a single retraction cord placed in the sulcus and removed just before taking the impression. The single-cord technique is effective if the margins are supragingival or equigingival. It may not be as effective if the margins are subgingival, because the gingival tissue rapidly collapses back over the margins when the cord is removed (see Figure 3). This prevents the flow of impression materials apical to the margin.

Figure 3a. Placement of single retraction cord

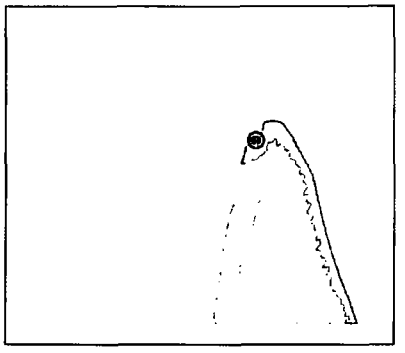
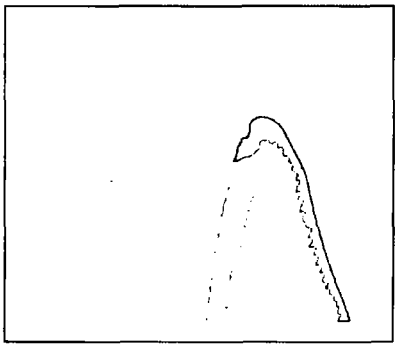


Figure 3b. Tissue collapse following removal of single-cord



Double-cord technique

This technique uses two layers of cord of differing thicknesses. It can prevent tissue collapse and bleeding, helping to achieve perfect impressions. However, careful technique is required to avoid tissue damage. In the case of a shallow sulcus or friable tissue, use only one cord.

Figure 4a. Preparation and adjacent gingiva

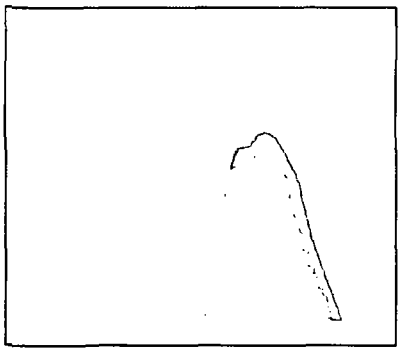


Figure 4b. Placement of first retraction cord

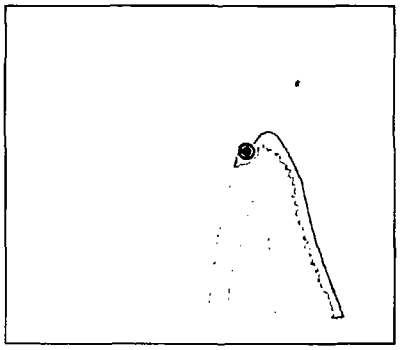


Figure 4c. Placement of thicker second retraction cord

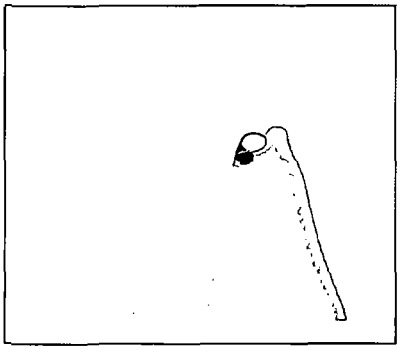
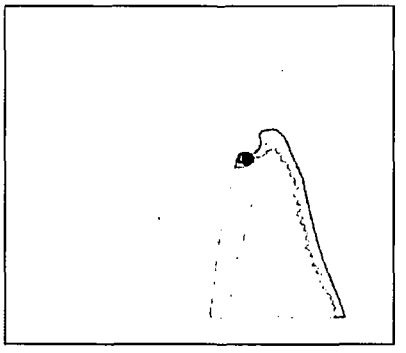


Figure 4d.Soft tissue after removal of the thicker retraction cord prior to impression taking



The following steps describe the use of the double-cord technique:

Step 1. Using a microbrush, apply a small amount of ViscoStat Plus around the entire margin to arrest slight bleeding or to prophylactically prevent bleeding during cord placement.

Step 2. Soak a thin-diameter retraction cord (Ultrapak, Ultradent; GingiBraid, Van R) in an appropriate hemostatic agent. Then place the cord subgingivally around the tooth to obtain apical retraction. The first cord acts as a gingival seal and prevents tissue-adhesion bleeding when the second cord is removed before taking the impression. Completing final margination after placing the first retraction cord protects the gingiva from potential damage by rotary instruments.

Step 3. After finalizing the margins, soak a second, larger-diameter (No. 2) retraction cord in the hemostatic agent. Place this around the preparation to create further lateral and apical retraction.

Step 4. Allow the cords to remain in place long enough for full retraction to occur and to prevent relapse when you remove the second cord (usually after four to five minutes).[9] Then remove the second cord and take the impression, keeping the first cord in place to prevent crevicular seepage and bleeding (see Figure 4). If the first cord does not come out with the impression, be sure to retrieve it from the sulcus before dismissing the patient.

Tray Selection and Impression Technique

Tray selection plays a significant role in taking accurate, detailed impressions. Base your tray choice on the clinical situation and on the impression material and technique used. Choose from stock plastic and metal trays (perforated and unperforated) and custom-fabricated trays.

Custom trays are the most reliably accurate. They also produce consistently accurate impressions of implant-fixture sites,[10] use less impression material, and are more comfortable for patients. But regardless of the clinical case or the impression technique and tray used, prevent prepared teeth from touching the tray to avoid ill-fitting crowns.

Complete-arch (full-arch) technique

When taking an impression on fewer than four teeth, you can use a stock (metal or plastic) or custom tray. But to ensure successful impressions when preparing more than four to six teeth, strongly consider using a custom tray. A properly constructed custom tray will enable optimal impression–material flow (see Figure 5).

Figure 5a. Custom tray

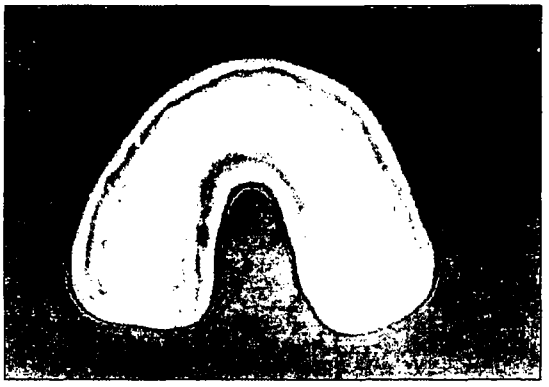


Figure 5b. Accurate impression for implant case

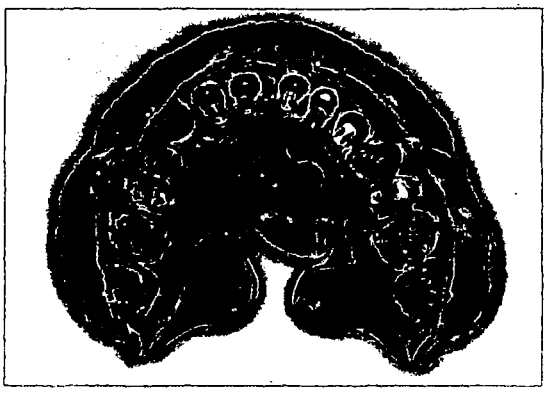
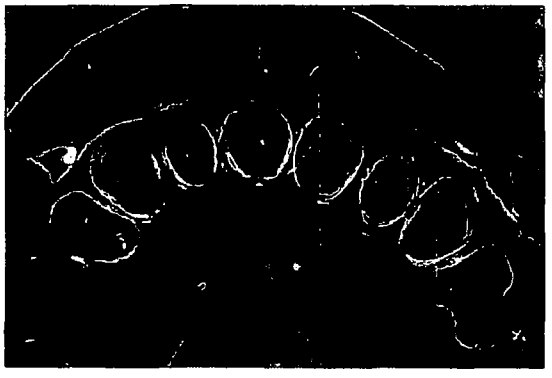


Figure 5c. Accurate multi-preparation impression



Closed-bite (double-arch) technique

The closed-bite impression is the most technique-sensitive of all impression techniques. If used correctly, it can save time and reduce occlusal adjustments on crowns. It is ideally suited for one or two prepared posterior teeth that are adjacent to unprepared teeth. These impressions, when appropriately taken, can provide dimensional and marginal accuracy[11,12] (see Figures 6, 7, 8).

Figure 6. Quad tray (Clinician's Choice Dental)

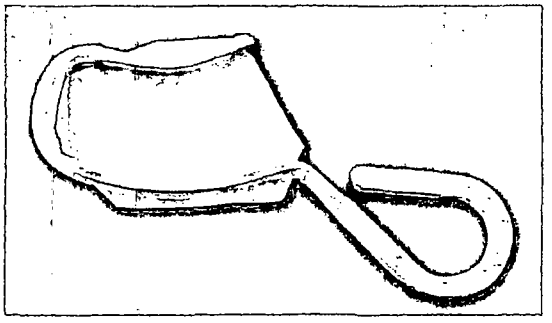


Figure 7. Incorrect impression using closed-bite technique

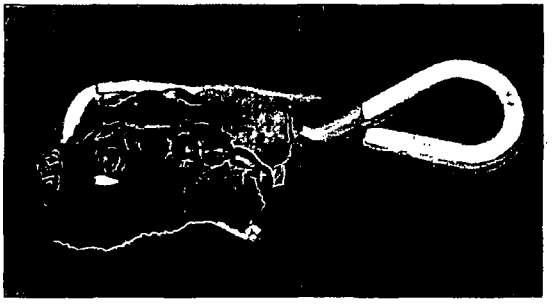
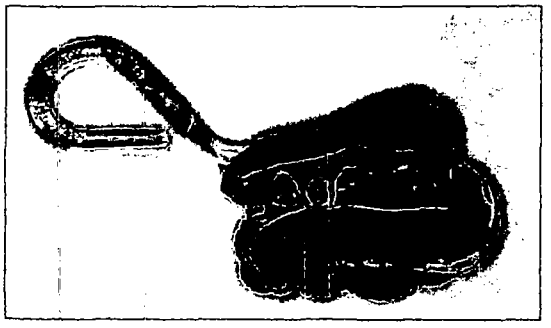


Figure 8. Correct impression using closed-bite technique



Use a rigid metal closed-bite tray with low sidewalls and a wide buccal-lingual distance. If the patient has a narrow palate, a tray with higher sidewalls could impinge and flex, causing improperly fitting restorations. Use fast-set impression material only if you can syringe and seat the tray in 20 seconds or less. Otherwise, use regular-set impression material. Use a tray material with a low strain-in-compression.

Impression Material Properties

Requirements for Impression Materials

The most commonly used elastomeric impression materials are polyether (PE) and vinyl polysiloxane (VPS) chemistries. Appropriate use of either will produce a clinically accurate impression. However, be aware of several physical-property and clinical-handling requirements.

A precision elastomeric impression material must accurately replicate the details of the prepared teeth. The detail reproduction test in International Standards Organization (ISO) document 4823 and American Dental Association (ADA) specifications requires a light body impression material to replicate a 20-micron line. The material must have an adequate working time and flowability. The impression must be dimensionally stable for a reasonable time until it is cast. In addition, the material must have sufficient tear strength to prevent tearing at thin areas at the margin.

An impression material's set hardness is measured by the strain-in-compression test. The tray material's strain-in-compression properties should correspond to the selected tray type. Full-arch impressions can be more easily retrieved from the mouth when using less rigid setting-tray materials, whereas exceedingly rigid setting-tray materials are ideal for use with the closed-bite impression technique.

When selecting an impression material, consider patient comfort. Choose materials that have as short a setting time as clinically appropriate, are easy to remove, and smell and taste pleasant. I will discuss these properties in the next section.

Working time

An impression material's working time critically depends on temperature. Addition silicones (VPS) are more sensitive to temperature changes than PE. Intraorally, VPS impressions have 66% less working time, and PE impressions 50% less working time than at the lower room temperature used as the ISO standard for testing.[13] This reduced working time affects how long the material can flow to capture all clinical details and margins (see Table 1).

Table 1. Working time and temperature

Adapted from ADA Professional Product Review Vol. 2 Issue 3.

Use fast-set material when preparing only one or two teeth. Use regular-set impression material when preparing more than two teeth, to increase working time, or if working in a warmer environment. When using a double-mix impression technique, syringe the wash material around the teeth and then immediately seat the tray. If the wash material starts to set before the tray is placed, the tray material could drag the wash and create voids.

If a putty material is selected as the tray material and is mixed too long, it will set before the tray is seated, causing recoil and resulting in inaccurate dies and tight-fitting crowns.

To lengthen working time for large restorations, refrigerate the impression material. Lowering its temperature will significantly increase working time without jeopardizing its physical properties.

Mix putty quickly, using fingertips as much as possible to avoid heat transfer from the palms. While you are syringing the prepared teeth, your assistant can simultaneously dispense impression material into the tray to provide maximum working time for the viscosity of both materials.

Strain-in-compression

Strain-in-compression measures how hard an impression material sets up, and ranges from 0.8% to 20%. Strain-in-compression is an important consideration in tray selection and impression technique. When taking a full-arch impression, use a tray material with a strain-in-compression above 3.5%. This improves patient comfort during retrieval, especially when undercuts and pontics are present. When using the closed-bite impression technique, use a stiffer setting-tray material with a strain-in-compression below 2%, because the impression material becomes the extension of the tray.

Elastic Recovery (Compression Set)

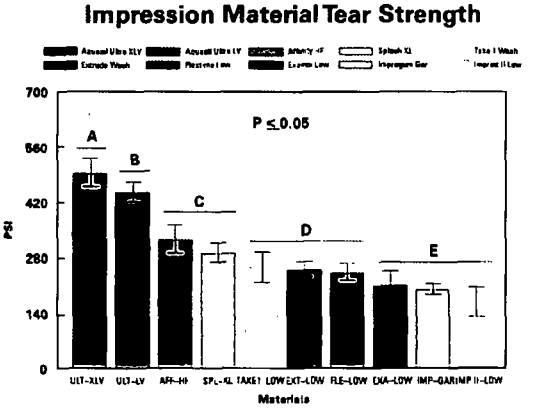
The ability of an impression material to recover to the same shape and dimension after being deformed is tested in elastic recovery. When a set impression is removed from the mouth, the material is stretched and compressed from undercuts. Vinyl polysiloxane materials with values greater than 99% have the greatest elastic recovery. Tests of polyether elastomers show that they average around 97% recovery. The higher the value, the better, but note that polysulfide materials having the lowest elastic recovery at 95% can perform well clinically. Differences in clinical performance might be seen with implant transfer type impressions, where a high degree of elastic recovery may perform better.

Tear Strength

A measurement of tear strength is not included in the suite of physical property tests in the American National Standards Institute/American Dental Association (ANSI/ADA) specification No. 19[14] or ISO 4823 specifications.[15] Lautenschlager and Boghosian investigated the tear strength of low-viscosity impression materials using specimens with notches the size of the average thickness of impressions (220 microns). We found Aquasil Ultra XLV to have the highest tear strength in this study.[16] Tear strength alone should not be the only criteria when choos-

ing a product for clinical use. However, if you experience frequent tearing, selecting a material with higher tear strength could be very helpful providing all other properties are satisfied (see Table 2).

Table 2. Tear strength



Hydrophilicity and wettability

The degree of hydrophilicity of a material is tested using a contact angle goiniometer. A small droplet of water or other liquid is placed on a surface, and the angle formed between the liquid-solid interface is referred to as the contact angle. A material with a lower contact angle is more wettable and hydrophilic. Modern vinyl polysiloxane impression materials have significantly increased hydrophilic properties over their predecessors, with measured contact angles as low as 7 degrees measured in 10 seconds.

While contemporary impression materials demonstrate highly hydrophilic behavior, the dentin on which these materials are syringed lack the same degree of hydrophilicity. Contact angles of more than 70 degrees have been reported on dehydrated dentin surfaces[17] (see Figure 9). The flow of the impression material, especially subgingivally, is limited because of the disparity between the dentin and the impression material contact angles.

Surface modifiers

In the same survey mentioned above, 57% of key opinion leaders and researchers stated that their greatest need was for an impression material that could predictably flow subgingivally, thus eliminating voids in the sulcus and at the margins.[18] Predictable flow of impression material can be attained by applying a surface modifier to dentin and other intraoral surfaces to increase the wettability. Surfactants used as surface modifiers (surface treating agents) or as topical agents on impression materials also improve wettability and reduce voids in impressions.[19]

B4™ Pre-Impression surface optimizer (DENTSPLY Caulk) is a surface modifier that has been found to wet out dentin and improve contact angles of dentin to hydrophilic VPS (Aquasil Ultra Smart Wetting® impression material). To decrease the contact angle of dentin as shown in Figure 9a, first apply B4™ surface optimizer to the surface (see Figure 9b).

Figure 9a. Contact angle of water on dentin

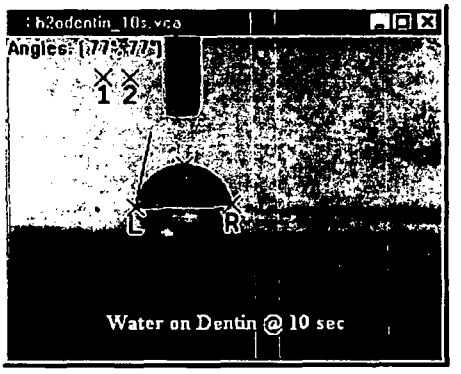
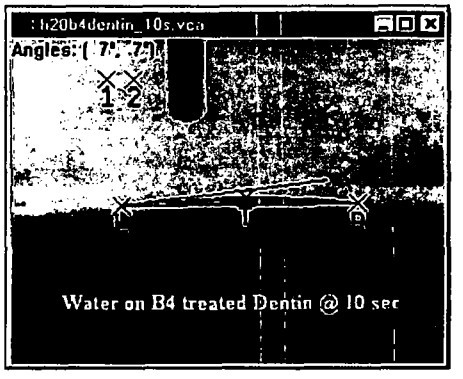


Figure 9b. Contact angle of water on B4™ surface optimizer treated dentin



Lowering the surface tension by applying B4™ surface optimizer helps the impression material flow better (see Figure 10). Figure 11 compares the application of 1.0cc of Aquasil Ultra XLV impression material syringed onto a surface with and without B4™ surface optimizer. Note the enhanced flow achieved on the right side. Enhanced impression material flow is seen on dentin with B4™ surface optimizer pretreatment (see Figure 12).

Figure 10a. Preparation with dry dentin

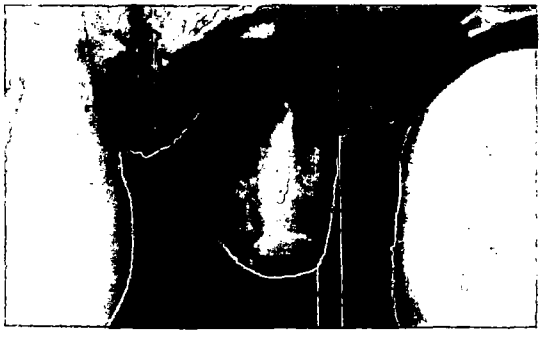


Figure 10b. Preparation after application of B4™ surface optimizer

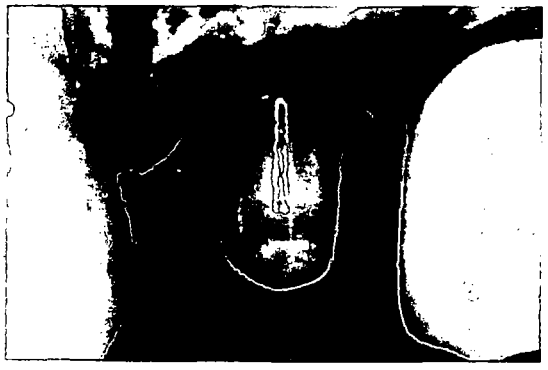


Figure 11. Surface flow with and without B4™ surface optimizer

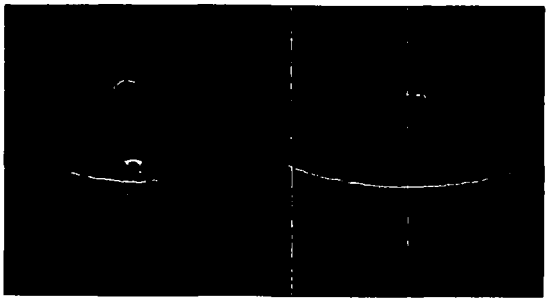
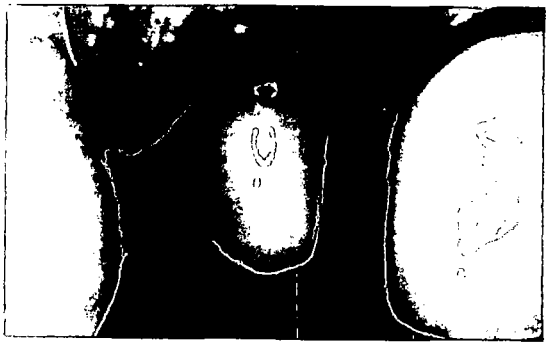


Figure 12a. Impression material flow without B4™ surface optimizer

Figure 12b. Impression flow following application of B4™ surface optimizer



The use of B4™ surface optimizer with Aquasil Ultra impression material does not interfere with the replication of the 20-micron line, as described in ADA and ISO detail reproduction testing. Higher-detail reproduction resolution was tested using 1,200 grooves/mm holographic gratings. Prior to taking an impression, a film of B4™ surface optimizer was applied to the grating surface. The impression was cast in epoxy and examined with a scanning electron microscope. The ruled lines in most areas throughout the surface showed equivalent detail compared to a replication without the B4™ surface optimizer pretreatment (see Figure 13). In conclusion, application of B4™ surface optimizer will substantially increase the flow of impression material on dentin and other intraoral surfaces, while not affecting on surface detail reproduction.

Figure 13a.
SEM of diffraction grating at 10,000x

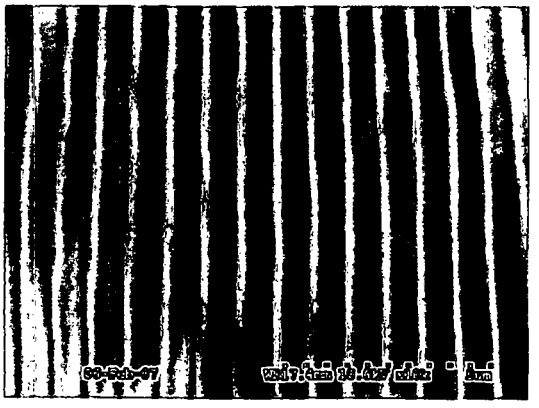
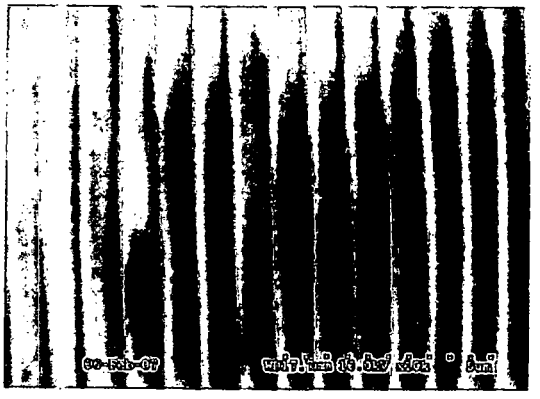


Figure 13b.
SEM of diffraction grating 10,000x after B4™ surface optimizer application



Summary

Achieving clinically acceptable impressions requires clinical expertise and appropriate materials, trays, and techniques. Several considerations are essential: properly managing

tissues before taking the impression, not exceeding the impression material's working time, and following proper protocols. Using a hydrophilic impression material and a surface modifier such as B4 will permit enhanced flow, allow time-efficient syringing of wash material, and result in a more accurate and detailed impression.

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Author Profile

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The author of this course was involved in the development of B4, in which he has a commercial interest.

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Questions

1. Clinicians report that the impression-taking process is _____.
   a. the simplest part of a prosthetic procedure
   b. the most stressful restorative procedure
   c. not critical to results
   d. none of the above

2. The most critical step in obtaining a perfect impression is _____.
   a. creating a bevel in the preparation
   b. preparing the tray
   c. using an etchant first
   d. managing soft tissue

3. The biologic width should be considered _____.
   a. after the preparation is completed
   b. before any preparation has begun
   c. only in patients with periodontal disease
   d. none of the above

4. If the biologic width has been violated, _____.
   a. inflammation can occur
   b. anatomic changes can occur
   c. pre-prosthetic crown lengthening should be considered
   d. all of the above

5. Hemostasis and gingival retraction are critical in taking an impression of _____.
   a. a subgingival or equigingival preparation
   b. any preparation
   c. a subgingival or supragingival preparation
   d. none of the above

6. Hemostatic agents used include _____.
   a. aluminum sulfate
   b. ferric sulfate and ferric chloride
   c. aluminum chloride
   d. all of the above

7. Ferric chloride _____.
   a. can be more effective than ferric sulfate
   b. is potentially less irritating to dentin than ferric sulfate
   c. has a higher pH than ferric sulfate
   d. all of the above

8. Methods for gingival retraction include the use of _____.
   a. retraction cord
   b. polymers and pastes such as Expasyl™
   c. lasers and rotary curettage
   d. all of the above

9. According to the article, the most common method of gingival retraction is the use of retraction cord, and many clinicians use the double-cord technique.
   a. True
   b. False

10. Using the thinnest retraction cord that will adequately retract tissue will _____.
    a. help avoid trauma to the tissue
    b. not be satisfactory
    c. avoid the use of too much material
    d. result in a poor impression

11. The single-cord technique for gingival retraction may not be as effective if the margins are subgingival, because the gingival tissue can rapidly collapse back over the margins when the cord is removed.
    a. True
    b. False

12. Using a double-cord technique for gingival retraction _____.
    a. can help achieve a perfect impression
    b. can prevent bleeding
    c. can prevent tissue collapse
    d. all of the above

13. The choice of tray material should be based on the _____.
    a. impression material
    b. technique used
    c. clinical situation
    d. all of the above

14. Custom trays _____.
    a. are the most reliably accurate
    b. are an unnecessary extra step
    c. are more comfortable for patients
    d. a and c

15. According to the article, a stock tray should be strongly considered if more than four to six teeth are being prepared.
    a. True
    b. False

16. The most technique-sensitive impression method for preparations is the _____.
    a. open-bite technique
    b. closed-bite technique
    c. plaster of paris technique
    d. a and c

17. The most commonly used impression materials are _____.
    a. polyethers
    b. vinyl polysiloxanes
    c. polysulfides
    d. a and b

18. ISO testing and ADA specifications require a light body impression material to replicate _____.
    a. a 20-micron line
    b. a 30-micron line
    c. a 40-micron line
    d. a 60-micron line

19. An impression material must have _____.
    a. adequate working time
    b. adequate flowability
    c. dimensional stability after setting
    d. all of the above

20. The strain-in-compression test measures _____.
    a. an impression material's flowability
    b. an impression material's set hardness
    c. an impression material's reproducibility
    d. none of the above

21. Full-arch impressions can be more easily retrieved from the mouth when using less rigid setting-tray materials.
    a. True
    b. False

22. Intraorally, VPS impressions have _____ less working time and PE impressions _____ less working time than at the lower room temperature used as the ISO standard for testing.
    a. 36%; 45%
    b. 66%; 50%
    c. 66%; 55%
    d. 75%; 60%

23. A regular set impression material is recommended _____.
    a. when preparing more than two teeth
    b. to increase working time
    c. when working in a warmer environment
    d. all of the above

24. The ability of an impression material to recover to the same shape and dimension after being deformed is tested in _____.
    a. elastic deformity
    b. elastic recovery
    c. plastic recovery
    d. none of the above

25. A material with a lower contact angle is more wettable and hydrophilic.
    a. True
    b. False

26. Modern vinyl polysiloxane impression materials have significantly increased hydrophilic properties when compared to their predecessors, with measured contact angles as low as _____ measured in _____.
    a. 3 degrees; 5 seconds
    b. 5 degrees; 10 seconds
    c. 7 degrees; 10 seconds
    d. 7 degrees; 15 seconds

27. Applying a surface modifier to dentin and other intraoral surfaces to increase wettability _____.
    a. can lead to attainment of predictable flow of impression material
    b. improves contact angles of dentin to hydrophilic impression materials (VPS)
    c. has no effect on the end result
    d. a and b

28. Using B4™ surface optimizer will_____.
    a. substantially increase the flow of impression material on dentin
    b. substantially increase the flow of impression material on other intraoral surfaces in addition to dentin
    c. not affect surface detail reproduction
    d. all of the above

29. Using a hydrophilic impression material and a surface modifier will allow time-efficient syringing of wash material and will result in a more accurate and detailed impression.
    a. True
    b. False

30. Considerations essential for achieving clinically acceptable impressions include _____.
    a. following proper protocols
    b. not exceeding the impression material's working time
    c. properly managing tissues prior to impression taking
    d. all of the above

ANSWER SHEET

Clinical and Material Factors in Achieving the Ideal Impression

Name: Title: Specialty:

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Requirements for successful completion of the course and to obtain dental continuing education credits: 1) Read the entire course. 2) Complete all information above. 3) Complete answer sheets in either pen or pencil. 4) Mark only one answer for each question. 5) A score of 70% on this test will earn you 4 CE credits. 6) Complete the Course Evaluation below. 7) Make check payable to PennWell Corp.

Educational Objectives

1. Understand the key factors involved in achieving an ideal impression
2. Be knowledgeable about techniques available for soft tissue retraction and hemostasis
3. Understand the factors involved in tray and impression material selection
4. Be knowledgeable about techniques and materials available that will enhance impression material flow

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Please evaluate this course by responding to the following statements, using a scale of Excellent = 5 to Poor = 0.

1. Were the individual course objectives met? Objective #1: Yes No Objective #3: Yes No
   Objective #2: Yes No Objective #4: Yes No
2. To what extent were the course objectives accomplished overall? 5 4 3 2 1 0
3. Please rate your personal mastery of the course objectives 5 4 3 2 1 0
4. How would you rate the objectives and educational methods? 5 4 3 2 1 0
5. How do you rate the author's grasp of the topic? 5 4 3 2 1 0
6. Please rate the instructor's effectiveness 5 4 3 2 1 0
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8. Do you feel that the references were adequate? Yes No
9. Would you participate in a similar program on a different topic? Yes No
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4.	Ⓐ	Ⓑ	Ⓒ	Ⓓ		19.	Ⓐ	Ⓑ	Ⓒ	Ⓓ
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6.	Ⓐ	Ⓑ	Ⓒ	Ⓓ		21.	Ⓐ	Ⓑ	Ⓒ	Ⓓ
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8.	Ⓐ	Ⓑ	Ⓒ	Ⓓ		23.	Ⓐ	Ⓑ	Ⓒ	Ⓓ
9.	Ⓐ	Ⓑ	Ⓒ	Ⓓ		24.	Ⓐ	Ⓑ	Ⓒ	Ⓓ
10.	Ⓐ	Ⓑ	Ⓒ	Ⓓ		25.	Ⓐ	Ⓑ	Ⓒ	Ⓓ
11.	Ⓐ	Ⓑ	Ⓒ	Ⓓ		26.	Ⓐ	Ⓑ	Ⓒ	Ⓓ
12.	Ⓐ	Ⓑ	Ⓒ	Ⓓ		27.	Ⓐ	Ⓑ	Ⓒ	Ⓓ
13.	Ⓐ	Ⓑ	Ⓒ	Ⓓ		28.	Ⓐ	Ⓑ	Ⓒ	Ⓓ
14.	Ⓐ	Ⓑ	Ⓒ	Ⓓ		29.	Ⓐ	Ⓑ	Ⓒ	Ⓓ
15.	Ⓐ	Ⓑ	Ⓒ	Ⓓ		30.	Ⓐ	Ⓑ	Ⓒ	Ⓓ

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Minimally Invasive Tissue Management for Restorative Procedures

A Peer-Reviewed Publication
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Educational Objectives

1. Know the factors and considerations in the placement of direct and indirect restorations.
2. Understand the reasons and pre-requisites for the successful sub-gingival placement of restoration margins.
3. Be knowledgeable concerning the various methods of gingival retraction that are available, and factors in selecting a method.

Abstract

The clinical success and longevity of restorations depend on a number of factors, including the initial accuracy of the restoration. Factors attributed to restoration accuracy have included the degree of clinical expertise; properties of impression, stone and die, and restorative materials; and the conditions under which impressions are taken and restorations completed. When restorations are placed with sub-gingival margins, it is essential that the operative site is clear of debris, dry and that the margins are accessible. This requires gingival retraction, which can be carried out using a number of methods, including retraction cord, copper bands, rubber dams, electrosurgery, and lasers, as well as polymers and pastes. Selection of the appropriate method depends on clinical demands and preferences, the individual patient, and consideration of the potential advantages and disadvantages. Ideally, gingival retraction should be quick, user-friendly, patient-friendly, painless, and inexpensive. The use of modern techniques and materials has made possible minimally-invasive and tissue-friendly gingival retraction that preserves periodontal health while enabling clear, dry access to sub-gingival margins.

Introduction

The clinical success and longevity of restorations depend on a number of factors. Although recurrent or secondary caries has been found to be a major reason for the replacement of existing restorations,[1] the materials and techniques employed at the time of restoration are key considerations in determining longevity and clinical success for both direct and indirect restorations. Factors attributed to restoration accuracy, depending on the type of restoration (direct or indirect), have included the degree of clinical expertise; properties of impression, stone and die, and restorative materials; and the conditions under which impressions are taken and restorations completed.

Restoration accuracy and longevity

Indirect restorations

Indirect restoration accuracy is influenced by a number of material and technique considerations. Impression material, setting accuracy, flow, temperature and humidity, mixing, disinfection, and time-to-pour following impression-taking have all been investigated. Polyether impressions have been shown to absorb water; their post-impression dimensional stabilities – and therefore the accuracy of the model – were found in an in vitro study to decrease with increasing humidity and higher temperatures.[2] Other studies, however, have found that the presence of water does not adversely affect dimensional accuracy of either polyether or polyvinylsiloxane impression materials, but found that polyether has a greater likelihood of producing superior impressions when water is present.[3] Studies have also found that use of appropriate agents for disinfection immersion results in polyether, polyvinylsiloxane, and addition-cured silicone impressions that have a clinically-acceptable accuracy post-immersion.[4,5] Hand-mixing and cartridge-mixing have been shown to affect shrinkage of set impressions over time, with more shrinkage occurring at extended time intervals prior to model and die-pouring.[6] Another investigation found that the investment material and number of sprues used influences the dimensional accuracy of cast restorations.[7] In addition to these considerations, the selection of restorative material must take into account occlusal forces, any paranormal habits, and the space available for the restoration vis-à-vis material strength and depth/volume. (Table 1)

Table 1. Considerations – direct and indirect restorations

Direct
- Biologic width
- Esthetics
- Restorative material(s)
- Occlusal forces and paranormal habits
- Dry, clean and accessible field for restoration placement
  - — Gingival retraction for detailed impression
  - — Hemostasis
- Technique

Indirect
- Biologic width
- Esthetics
- Restorative material(s)
- Occlusal forces and paranormal habits
- Impression material properties
- Temperature, humidity
- Disinfection of impressions
- Mixing method
- Elapsed time prior to model-pouring
- Dry, clean and accessible field for impression-taking and restoration placement
  - — Gingival retraction for detailed impression
  - — Hemostasis
- Technique
- Investment material, number of sprues

Supra-gingival restoration margins may be considered preferable for periodontal health but are frequently esthetically unacceptable and/or may be impossible due to pre-existing hard-tissue loss. As a result, restorations are placed with margins sub-gingivally in the gingival sulcus – the objectives are to achieve a long-lasting restoration that

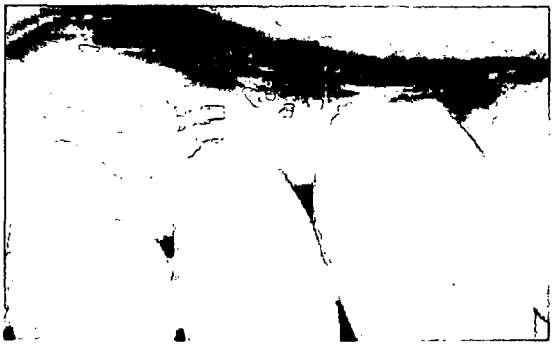
optimizes esthetics, has good marginal accuracy, maintains biologic width, and preserves periodontal health.

While the properties and selection of materials are important, margins that are free of debris, are accessible, and which impression materials can flow over and around, are a pre-requisite for detailed and accurate impressions and, ultimately, clinically-acceptable indirect restorations. Investigators have also found that the width of the gingival sulcus influences impression accuracy, with a sulcus width of more than 0.15 mm resulting in accurate impressions, and those less than 0.10 mm resulting in variable outcomes.[8]

Direct restorations

Similar considerations exist for direct class V restorations with respect to restorative material selection and technique, as well as esthetics and hard-tissue loss pre-determining sub-gingival placement of restorative margins. These, too, should respect biologic width, periodontal health, esthetics, and marginal accuracy.

Figure 1. Sub-gingival Class V carious lesion



It is critical when placing composite restorations that the field is dry to enable placement of the restoration and curing of composites. Successful placement of direct composite restorations is not possible without adequate curing. Furthermore, the degree of cure of the composite material is a determinant for leakage and marginal breakdown; one in vitro study has shown that enhanced curing reduces marginal breakdown and increases resistance to wear.[9] Gingival retraction and isolation of the operative site are essential for sub-gingival direct restoration placement and a biologically and esthetically compatible form.[10]

Gingival retraction and soft-tissue management

Regardless of all other considerations, accurate recording and restoration of sub-gingival margins is imperative for direct and indirect restorations. Optimal gingival retraction is essential.[11] Appropriate retraction enables clear visualization of the prepared tooth's sub-gingival margin; allows for accurate impression-taking apical to the margin with adequate impression material bulk between the sulcular wall and the tooth; controls crevicular seepage and bleeding; and, depending upon the preparation design, may help provide access to sub-gingival hard-tissue that must be treated due to caries or retentive/esthetic considerations.[12]

A number of retraction methods have been used, including retraction cords with and without medicaments, rotary curettage, copper bands, rubber dams, electrosurgery, lasers, and, recently, polymers and pastes. Each method offers the clinician the ability to perform gingival retraction, with selection of the appropriate method depending on clinical demands and preferences, the individual patient, and consideration of the potential advantages and disadvantages. Ideally, gingival retraction should be quick, user-friendly, patient-friendly, painless, and inexpensive – and importantly, tissue-friendly to preserve periodontal health.

Retraction cord

Retraction cords have been used for several decades and have traditionally been the most popular method. As recently as 1999, a survey of prosthodontists found that 98 percent of respondents used gingival retraction cords, with 44 percent of them using a double-cord technique.[13]

When used appropriately, retraction cord offers a quick, familiar, and inexpensive retraction method. It can be carried out with or without the addition of hemostatic agents, using either a single-cord or a double-cord technique. The double-cord technique uses two cords packed successively, with the first cord remaining in place while the impression is taken, prior to being removed. This technique is used for troughing around the preparation, to help ensure a detailed impression as well as an adequate biologic width of the final restoration.[14] It employs two knitted cords of different diameters and is considered safe and effective, provided periodontal health is good. However, it has also been recommended that where possible, the finish lines should be placed supra-gingivally when using this method.[15] With the single-cord technique, a single retraction cord is placed in the sulcus and if an impression is being taken, the cord is removed prior to this occurring. A disadvantage of the single-cord technique is that if preparation margins are in a deep sulcular area, the gingival soft-tissue can collapse over the margins making accurate restoration placement or impression-taking impossible.

The use of gingival retraction cord is technique-sensitive and requires expertise. Problems encountered include the parting of cord fibers, shredding, and cord damage or displacement when using the packing instrument or while using a bur at the margin.[16] Tissue damage may also occur, with friable thin gingival tissue particularly susceptible and subject to tearing. While packing the cord, there is a risk of damaging the epithelial attachment and/or exacerbating gingival recession and bleeding. Retraction cord use can result in tissue recession, and the double-cord technique may cause unpredictable tissue recession and patient

discomfort.[17] A 2007 investigation has found that acute, gingival tissue damage occurs with use of retraction cords, with demonstrable increases in the levels of tumor necrosis factor (alpha) (TNF-alpha) in the gingival crevicular fluid. Nonetheless, the same study also found that the damage healed clinically within two weeks.[18]

The use of hemostatic agents with retraction cords helps prevent gingival bleeding that may occur during packing or removal of the cord[19] and helps maintain a clear, dry operative site for cord-packing and impression-taking. Hemostatic agents in retraction cords include epinephrine, aluminum chloride, and ferric sulfate and, depending upon the particular cord, it may have been pre-treated or soaked at the time of placement.[20,21] Aluminum chloride has been found to be more commonly used than epinephrine: 33 percent of respondents in one survey reported side effects associated with epinephrine use, the most common being an increased pulse rate, with 24 percent reporting side effects from other medicaments used with retraction cords.[22] Use of epinephrine provides prolonged gingival vasoconstriction, but the use of aluminum chloride and ferric sulfate has been associated with hyperemia and bleeding upon cord removal.[23] However, epinephrine use is problematic in patients with cardiovascular disease and may interact with cardiovascular medications used to control the disease.[24]

Copper bands and impression copings

The use of copper bands, as well as impression copings for cast restorations, results in isolation of the site and obviates the need for gingival retraction using retraction cord or other techniques. As with retraction cords, copper bands have been used for a number of decades. Their use requires selection of copper band size, and careful trimming and fitting of the copper band prior to impression-taking. (Figure 2) Copper bands are inexpensive, readily-available, and with appropriate use are unlikely to result in tissue damage and recession. However, this method is technique sensitive, and the sharp margins of the copper band may exacerbate gingival bleeding; the bands do not incorporate a hemostatic agent and can cause patient discomfort without the use of local anesthesia.

Figure 2. Copper band

Cast impression copings function similarly to copper bands, fitting over the preparation finish line. They do not require trimming, nor do they have the sharp margins associated with copper-band use; they can capture margins and provide accurate, detailed impressions without using gingival retraction. However, they must be individually fabricated, involving an extra step.[25] By their very nature, cast impression copings are only used for indirect restorations, and both these and copper bands are unsuitable for direct restorations.

Rubber dams

Rubber dams help prevent operative-site exposure to oral micro-organisms and intraoral fluids. By using modified retention and a modified technique with placement of the rubber dam apical to the retainer after the retainer has been positioned on the tooth, rubber dams have been found to be effective in providing gingival retraction and thorough isolation of Class V restorative sites with sub-gingival margins, and help avoid damage to periodontal tissues.[26,27] This technique is intended for class V restorations and is unsuitable for impression-taking and indirect restorations.

Rotary curettage

Rotary curettage uses burs to create a trough in the sulcus around the finish line. It can result in bleeding at the site, requires local anesthesia to prevent patients from experiencing discomfort, and can be used for both direct and indirect restorations.

Electrosurgery

Electrosurgery is a modified cautery technique, utilizing an electric current passed to fine wire contacts that removes soft-tissue and creates a trough in the gingival sulcus adjacent to the finish line. One study found no difference in tissue response at four, eight, and twelve weeks between electrosurgery and bur (rotary curettage) methods.[28] A separate study found both electrosurgery and rotary curettage produced unpredictable results.[29] With clinical expertise, this method offers predictable troughing and tissue responses, with good exposure of margins for impression-taking and restorative techniques. It has also been shown to provide for more impression material bulk in the sulcus than a bur method.[30] Electrosurgery requires local anesthesia, and in addition to exposing the finish line and creating a trough, it also helps prevent bleeding at the site (Figures 3 and 4).

Figure 3. Gingival bleeding, sub-gingival preparation margin

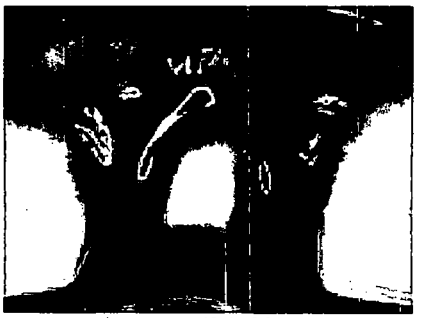


Image courtesy of Dr. Ian E. Shuman

Figure 4. Use of an electrosurgery tip (Bident) to expose margins, stop bleeding

Image courtesy of Dr. Ian E. Shuman

Lasers

The introduction of dental lasers has offered dental professionals many options in operative techniques, including their use as a gingival retraction method. Lasers produce a high-energy, collimated beam of light that is converted into thermal energy. They predictably vaporize tissue at 100 to 150 degrees Celsius, create an adequate trough and retraction that permits detailed and accurate impressions, and preserve biologic width. (Figures 5, 6, and 7) Erbium-based lasers are absorbed on the surface and the Nd:YAG series energy is absorbed deeper in the tissues.[31] A third type of laser, the diode laser (Odyssey, Vivadent), is also utilized for soft-tissue procedures. Their use results in minimal or no intra-operative and post-operative discomfort, and is not associated with tissue recession seen with the use of the double-cord gingival retraction method. In addition, lasers offer hemostasis and can be used in many patients without anesthesia.[32,33] In comparing the use of a pulsed Nd:YAG laser with retraction cord soaked in either aluminum chloride or ferric sulfate, it has also been found that the laser's use resulted in less bleeding, less tissue inflammation, faster healing than either retraction cord, and was painless, simple, and convenient. Laser use is suitable for both indirect and direct restorations in offices that have laser units.[34] In a survey of laser users, 79 percent of respondents indicated that they used lasers for gingival retraction/troughing.[35] Lasers, such as the Waterlase™ YSGG Laser (Biolase), also offer the potential to complete the hard-tissue preparation and soft-tissue management with one instrument and in some cases without the use of anesthesia.[36]

Figure 5. Crown preparation with bleeding, sub-gingival margins prior to impression-taking

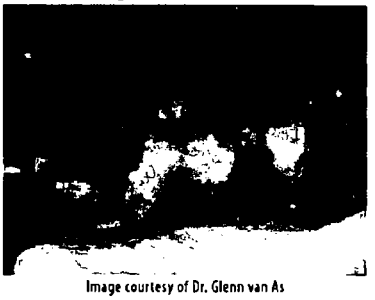


Image courtesy of Dr. Glenn van As

Figure 6. Use of a diode laser (Odyssey, Vivadent)

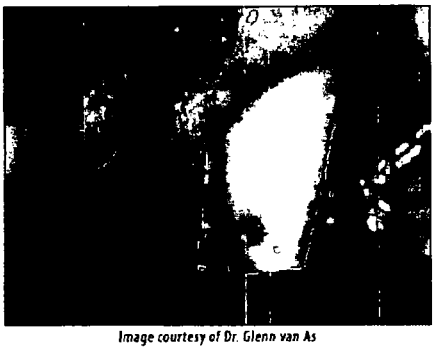


Image courtesy of Dr. Glenn van As

Figure 7. Final impression showing clear margin details

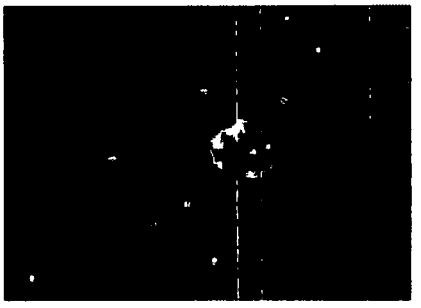


Image courtesy of Dr. Glenn van As

Polymers and pastes

Polymers and pastes have also been recently introduced as gingival retraction methods. Studies have shown that the use of polymers with a sponge-like texture cut into 2-mm strips is an effective method. The polymer swells when exposed to moisture and gently pushes the gingival tissue away from the finish line, enabling detailed impression-taking. In addition, it was found that the gingivae returned to a normal position within twenty-four hours. [37] Merocyl strips were found to be effective at expanding gingival tissue and exposing the margins of preparations for impression-taking.[38]

A recent technique uses a paste (Expasyl™) that provides for gingival retraction and hemostasis. Expasyl™ consists of an organic, clay material (kaolin), mixed with aluminum chloride as a hemostatic agent. The paste is thick, firm, and viscous to enable easy and quick tissue displacement, and the aluminum chloride controls bleeding simultaneously. It is injected directly into the sulcus from a pre-loaded syringe at a recommended rate of 2 mm per second, using even pressure. (Figure 8) If necessary, this can be followed by gently tamping on the paste with a plastic instrument or cotton pellet to ensure the paste is fully in the sulcus. The paste is left in the sulcus for one to two minutes if the tissue is thin, or three to four minutes if the soft-tissue is thicker. After this time, the sulcus will be expanded, and the paste should be removed by gently rinsing and then drying the site prior to impression-taking or restoration placement. (Figure 9a and b)

Figure 8. Expasyl™ injected into the gingival sulcus

Figure 9a. After Expasyl™ removal

Figure 9b. After Expasyl™ removal

Once the material has been applied and absorbs moisture, there is no chemical reaction, material expansion, or trauma to the tissue; hemostasis is achieved, and the material should be isolated from additional moisture, such as saliva. If necessary, the process can be repeated without traumatizing the tissue.

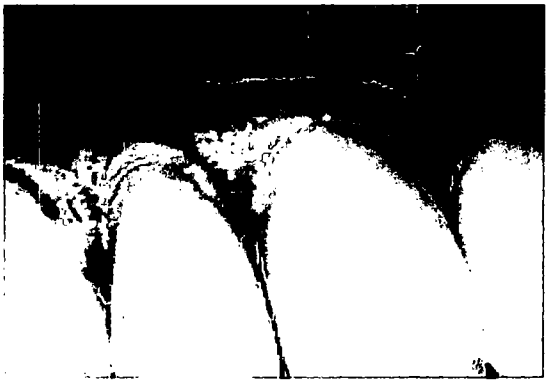
This paste system is suitable for gingival retraction prior to impression-taking (Figure 10) and final indirect restoration placement. Gingival retraction will last for four minutes after the Expasyl™ has been rinsed and removed from the site.

Figure 10. Final impression with clear margin details

It can also be used prior to direct Class V restoration to prevent gingival seepage and bleeding, and to widen the sulcus, enabling a composite of the appropriate dimension to be placed and cured. (Figures 11 and 12)

Figure 11. Expasyl™ placement

Figure 12. Final direct composite restorations



Gingival retraction cord, electrosurgery, and laser surgery are more-traditional options. However, these result in varying degrees of tissue trauma, depending on clinical experience. The risk of gingival recession and bone resorption, linked to damage to the epithelial attachment, is eliminated using the minimally-invasive tissue management offered by the paste retraction method.[39] It has been found to reduce chairside time required for retraction prior to impression-taking and restoration placement, and reduces soft-tissue trauma as well.[40,41] Time savings of up to 50 percent have been reported with its use.

A polyvinylsiloxane expandable gingival retraction paste is available (Magic FoamCord Gingival Retraction System). This is also applied around the preparation margins using a pre-loaded syringe. After syringing the material around the margins, a cap (Comprecap) is used over the material and tooth – this is used to apply pressure for 5 minutes to obtain gingival retraction. The impression is

Table 2. Comparison of gingival retraction methods

	Application method	Traumatic to tissue	Requires pressure	Requires tray or cap	Provides hemostasis	Time taken
Retraction cord	Packing into sulcus	Yes	No	No	Yes/No	Up to 5 minutes
Copper band	Trim and apply band	Yes	No	No	Yes, by isolating site	Up to 5 minutes
Rubber dam	With clamp/floss	No	No	No	Yes, by isolating site	Up to 5 minutes
Rotary Curettage	Direct	Yes	No	No	No	Up to 5 minutes
Electrosurgery	Direct	Yes	No	No	Yes	3 to 5 minutes
Laser surgery	Direct	Yes	No	No	Yes	3 to 5 minutes
Gingival retraction paste						
Expasyl™	Syringe	No	No	No	Yes	2 to 4 minutes
Magic FoamCord	Syringe	No	Yes	Yes	No	5 minutes
GingiTrac™	Syringe	No	Yes	Yes	Yes/No	5 minutes

taken after the paste has been removed. This paste does not contain a hemostatic agent, and hemostasis must be obtained prior to applying the paste and cap.

A third gingival retraction paste system (GingiTrac™) also uses a pre-loaded syringe to apply the paste around the margins. The paste contains an astringent, and if necessary a hemostatic agent can be applied prior to the application of GingiTrac™. For single tooth use, a cap (GingiCap™) is used to apply pressure for up to 5 minutes after the paste has been applied. The cap is first filled with the paste, then placed over the tooth and paste syringed around the margins. (Figures 13 and 14) For multiple tooth preparations, a plastic tray is first used with a firm paste matrix over which the GingiTrac™ paste is syringed before the tray is placed over the arch and held in position for 3-5 minutes. For both single tooth and multiple tooth preparations, gingival retraction is achieved through the application of pressure prior. The paste is removed prior to impression-taking.

Figure 13. Application of retraction paste and cap

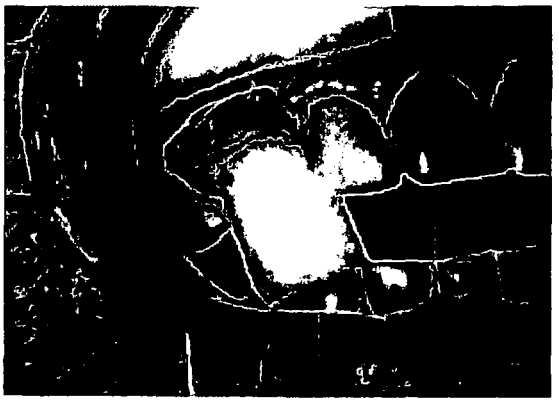
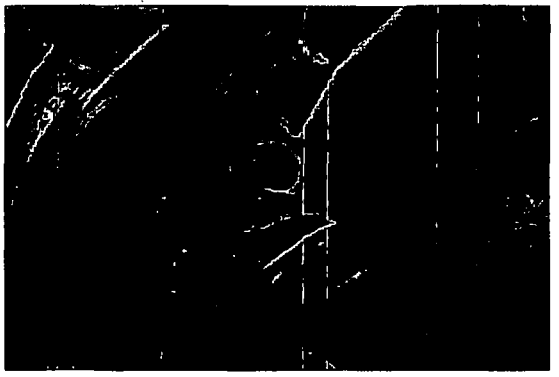


Figure 14. Preparation margins after removal of paste and cap.



Summary

The multi-faceted benefits and indications of tissue management render it an important process in assessing clinical success. Traditional gingival retraction methods include retraction cords, copper bands, electrosurgery and more recently laser surgery. In addition, pastes have been introduced that function as gingival retractors. Depending upon the paste system used, the time taken is typically 2 minutes for paste not requiring use of caps or a tray matrix (Expasyl™) and up to 5 minutes for paste systems using caps or trays to apply pressure (Magic FoamCord; GingiTrac™) In selecting a method for tissue management during restorative procedures, it is incumbent upon clinicians to consider the advantages and disadvantages of each method, the individual case and patient, and to strive for minimally-invasive methods that optimize the procedural site for impression-taking and restoration placement, while at the same time preserving periodontal health. Recent innovations have made minimally-invasive soft-tissue management an achievable reality during restorative procedures.

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Author Profile

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Questions

1. Considerations in the longevity and clinical success of restorations include _____.
   a. the materials employed
   b. the techniques employed
   c. the presence of a HEPA filter
   d. a and b

2. _____ is a factor in determining post-impression dimensional stability of impressions.
   a. Humidity
   b. Impression flow
   c. Mixing of impression material components
   d. All of the above.

3. Supra-gingival restoration margins _____.
   a. are preferable to sub-gingival restoration margins under all circumstances
   b. may be esthetically unacceptable
   c. may be impossible due to pre-existing hard-tissue loss
   d. b and c

4. Margins that are accessible and free of debris are a pre-requisite for detailed and accurate impressions.
   a. True
   b. False

5. Both direct and indirect restorations should respect _____.
   a. biologic width
   b. periodontal health
   c. esthetics
   d. All of the above.

6. _____ is a determinant for leakage and breakdown of composite margins.
   a. The choice of cavity liner
   b. The degree of cure of the composite material
   c. Using an impression material
   d. None of the above.

7. Appropriate gingival retraction _____.
   a. enables clear visualization of sub-gingival margins
   b. allows for accurate impression-taking
   c. controls crevicular seepage
   d. All of the above.

8. Gingival retraction methods include the use of _____.
   a. gingival retraction cord
   b. polymers and pastes
   c. lasers
   d. All of the above.

9. A 1999 survey found that _____ of prosthodontists use gingival retraction cord.
   a. 35 percent
   b. 63 percent
   c. 98 percent
   d. 100 percent

10. Retraction using gingival retraction cord can be carried out _____.
    a. with or without the addition of hemostatic agents
    b. using a double-cord or single-cord technique
    c. more quickly than any other gingival retraction method
    d. a and b

11. The double-cord gingival retraction technique _____.
    a. is considered safe and effective provided periodontal health is good
    b. is clinically-proven to be the least time-consuming method of gingival retraction
    c. involves the use of two retraction cords placed into the gingival sulcus, one after the other
    d. a and c

12. The use of copper bands is _____.
    a. expensive, redundant and still always requires the use of retraction cord
    b. inexpensive, technique sensitive, and with appropriate use unlikely to result in tissue damage or recession
    c. the most popular method, used routinely in the dental office
    d. a and c

13. A modified rubber dam technique that involves placing the rubber dam apical to clamps after these are placed, is suitable for _____.
    a. crown and bridge preparation margins
    b. crown and bridge, and Class V restoration, preparations
    c. only Class V restorations
    d. None of the above.

14. With clinical expertise, electrosurgery offers _____.
    a. predictable troughing
    b. a predictable tissue response
    c. good exposure of margins
    d. All of the above.

15. Electrosurgery _____.
    a. exposes the preparation margins
    b. helps prevent bleeding at the site
    c. never requires anesthesia
    d. a and b

16. Lasers expose gingival margins by _____.
    a. abrading tissue
    b. vaporizing tissue
    c. eroding tissue
    d. None of the above.

17. At 150° Celsius, gingival soft-tissue is _____.
    a. molten
    b. calcified
    c. vaporized
    d. All of the above.

18. Lasers used for gingival retraction _____.
    a. offer hemostasis
    b. may be able to be used without anesthesia
    c. are suitable for both direct and indirect restorations
    d. All of the above.

19. A recently introduced paste (Expasyl™), used for gingival retraction, _____.
    a. is applied using a pre-loaded syringe
    b. provides hemostasis
    c. contains epinephrine
    d. a and b

20. The use of hemostatic agents in gingival retraction paste containing kaolin (Expasyl™) _____.
    a. is contraindicated
    b. controls bleeding
    c. ensures that pressure and hemostatic agents will be used to control bleeding
    d. b and c

21. Expasyl™ should remain in the sulcus while an impression is being taken.
    a. True
    b. False

22. Kaolin-containing gingival retraction paste _____.
    a. absorbs moisture after application and reacts chemically until it is removed
    b. does not react chemically after being applied
    c. absorbs moisture after application, and after this there is no chemical reaction
    d. is contraindicated if moisture is present

23. Polyvinylsiloxane gingival retraction paste _____.
    a. is applied using a pre-loaded syringe
    b. requires the application of a cap over the paste and pressure for gingival retraction
    c. does not contain a hemostatic agent
    d. All of the above.

24. Some of the gingival retraction pastes discussed in the article should remain in place while an impression is taken.
    a. True
    b. False

25. GingiTrac™ gingival retraction paste _____.
    a. is applied using a pre-loaded syringe
    b. requires the application of pressure for gingival retraction
    c. can only be used for single tooth preparations
    d. a and b

26. If using GingiTrac™, a tray loaded with a heavy matrix _____.
    a. is used with multiple-tooth preparations
    b. is never necessary
    c. involves the use of composition that must be heated prior to use
    d. a and c

27. Concerning the three paste methods for gingival retraction discussed in the article, _____.
    a. all contain a hemostatic agent
    b. all are equally quick to use
    c. all use pre-loaded syringes
    d. All of the above.

28. Expasyl™ has been found to be minimally-invasive, as have Magic FoamCord and GingiTrac™, and to eliminate the risk of damage to the epithelial attachment.
    a. True
    b. False

29. In assessing the various methods of gingival retraction, it is incumbent upon clinicians to _____.
    a. consider the advantages and disadvantages of each method
    b. consider the individual case and patient
    c. use a slow method to ensure adequate gingival retraction
    d. a and b

30. Recent innovations have made minimally-invasive tissue management during restorative procedures _____.
    a. achievable
    b. no longer a consideration
    c. take more time
    d. None of the above.

ANSWER SHEET

Minimally Invasive Tissue Management for Restorative Procedures

Name:			
Title:	Specialty:		
Address:		E-mail:	
City:		State:	ZIP:
Telephone: Home ( )		Office ( )	

Instructions to obtain dental continuing education credits: 1) Complete all information above. 2) Complete answer sheets in either pen or pencil. 3) Mark only one answer for each question. 4) Successful completion of this course will earn you 4 CEUs. 5) A blank duplicate answer sheet may be copied for additional course participants.

Mail completed answer sheet to
Academy of Dental Therapeutics and Stomatology
P.O. Box 116, Chesterland, OH 44026
(216) 398-7822

For IMMEDIATE results, go to www.ineedce.com and click on the button "ENTER Answers Online." Answer sheets can be faxed with credit card payment to (216) 255-6619, (440) 845-3447, or (216) 398-7922.

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1. How would you rate the objectives and educational methods?
   5 4 3 2 1 0
2. To what extent were the course objectives accomplished?
   5 4 3 2 1 0
3. Please rate the course content.
   5 4 3 2 1 0
4. Please rate the instructor's effectiveness
   5 4 3 2 1 0
5. Was the overall administration of the course effective?
   5 4 3 2 1 0
6. How do you rate the author's grasp of the topic?
   5 4 3 2 1 0
7. Do you feel that the references were adequate?
   Yes No
8. Do you feel that the educational objectives were met?
   Yes No
9. If any of the continuing education questions were unclear or ambiguous, please list them.

   _____

10. Was there any subject matter you found confusing? Please describe.

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11. Would you participate in a program similar to this one in the future on a different topic? Yes No
12. What additional continuing dental education topics would you like to see?

    _____

1.	Ⓐ	Ⓑ	Ⓒ	Ⓓ		16.	Ⓐ	Ⓑ	Ⓒ	Ⓓ
2.	Ⓐ	Ⓑ	Ⓒ	Ⓓ		17.	Ⓐ	Ⓑ	Ⓒ	Ⓓ
3.	Ⓐ	Ⓑ	Ⓒ	Ⓓ		18.	Ⓐ	Ⓑ	Ⓒ	Ⓓ
4.	Ⓐ	Ⓑ	Ⓒ	Ⓓ		19.	Ⓐ	Ⓑ	Ⓒ	Ⓓ
5.	Ⓐ	Ⓑ	Ⓒ	Ⓓ		20.	Ⓐ	Ⓑ	Ⓒ	Ⓓ
6.	Ⓐ	Ⓑ	Ⓒ	Ⓓ		21.	Ⓐ	Ⓑ	Ⓒ	Ⓓ
7.	Ⓐ	Ⓑ	Ⓒ	Ⓓ		22.	Ⓐ	Ⓑ	Ⓒ	Ⓓ
8.	Ⓐ	Ⓑ	Ⓒ	Ⓓ		23.	Ⓐ	Ⓑ	Ⓒ	Ⓓ
9.	Ⓐ	Ⓑ	Ⓒ	Ⓓ		24.	Ⓐ	Ⓑ	Ⓒ	Ⓓ
10.	Ⓐ	Ⓑ	Ⓒ	Ⓓ		25.	Ⓐ	Ⓑ	Ⓒ	Ⓓ
11.	Ⓐ	Ⓑ	Ⓒ	Ⓓ		26.	Ⓐ	Ⓑ	Ⓒ	Ⓓ
12.	Ⓐ	Ⓑ	Ⓒ	Ⓓ		27.	Ⓐ	Ⓑ	Ⓒ	Ⓓ
13.	Ⓐ	Ⓑ	Ⓒ	Ⓓ		28.	Ⓐ	Ⓑ	Ⓒ	Ⓓ
14.	Ⓐ	Ⓑ	Ⓒ	Ⓓ		29.	Ⓐ	Ⓑ	Ⓒ	Ⓓ
15.	Ⓐ	Ⓑ	Ⓒ	Ⓓ		30.	Ⓐ	Ⓑ	Ⓒ	Ⓓ

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TISMGT0705PAT

Pharmaceutical Chemistry Journal *Vol. 40, No. 7, 2006*

SEARCH FOR NEW DRUGS

LOCAL HEMOSTATICS (A REVIEW)

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Translated from Khimiko-Farmatsevticheskii Zhurnal, Vol. 40, No. 7, pp. 9 – 15, July, 2006.

Original article submitted March 9, 2006.

Information on the hemostatic agents of local action, which are most widely used in leading countries of the world, is summarized. The mechanisms of action of various local hemostatics are considered and possible variants of their combinations in particular ready-to-use drugs are presented.

This review is intended to generalize data concerning the use of drugs with various structures and mechanisms of action, as well as their combinations for the arrest of local bleeding. Local hemostatics can be, albeit quite conditionally, classified into the following groups:

(1) Agents producing vasoconstrictive and proaggregant effects;

(2) Compounds inducing the transition of blood proteins into solid state and reducing vessel permeability by means of protein denaturation;

(3) Compounds stimulating the aggregation and adhesion of formed elements and accelerating fibrin formation;

(4) Plasma coagulation factors;

(5) Fibrinolysis inhibitors;

(6) Combined preparations.

A close classification was proposed by Krylov et al. [1]. Drugs of the first group decrease the blood flow via collateral ways (bypass channels, which provide blood flow in cases of thrombosis). This group is represented by adrenaline (epinephrine), vasopressin, desmopressin, terlipressin, and pituitrin.

Epinephrine finds rather limited use as a hemostatic, predominantly in dentistry. The hemostatic properties of this compound are related to the action upon α_1 adrenoreceptors of vessel walls, which produces vasoconstriction and stimulates blood platelet (thrombocyte) aggregation that leads to a decrease in hemorrhage [2]. Epinephrine is mostly used as a component in various solutions, pastes, gels, etc., and is rarely use in pure form. Disadvantages of this drug are the short time of action (5 – 10 min) and restricted field of possible applications (several manipulations in dentistry, skin transplantation, endoscopic arrest of bleeding from veins in the gastrointestinal tract (in combination with cyanoacrylates) [3], and low specific activity.

Vasopressin has been used as a vasoconstrictor for the treatment of portal hypertension and related complications, beginning from the 1970s. However, it was soon established that the use of this hemostatic in about half of cases is accompanied by side effects, including serious heart rhythm violations, myocardial infarction, and acute disturbances in cerebral circulation [4]. The interest in this group of hemostatics was restored due to the implementation of terlipressin – a synthetic vasopressin analog, which has increased half-elimination time that makes unnecessary continuous intravenous infusion.

Another important feature in the drug pharmacokinetics is the slow biotransformation of terlipressin into vasopressin in tissues, which facilitates the creation of its high local concentration (at a low concentration in the overall blood flow, which reduces the risk of undesired systemic effects) [5].

Desmopressin is a derivative of vasopressin, which (i) stimulates the release of endogenous factor VII, Willebrand's factor and tissue plasminogen activator, (ii) increases platelet adhesion, and (iii) reduces hemorrhage duration [6]. This compound is effective in patients suffering from hemophilia A, Willebrand's disease, and inherited or acquired platelet dysfunction, as well as in cases of acetylsalicylic acid (or some other antiaggregant) overdose [7]. Desmopressin is available in the form of spray for the arrest of nasal bleeding.

Pituitrin, comprising a mixture of oxytocin and vasopressin, is used for the treatment of hemorrhage accom-

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0091-150X/06/4007-0353

panying esophageal varicose vein dilatation [8, 9]. A close hemostatic action is produced by serotonin [10 – 12]. In addition to the vasoconstrictive action, epinephrine, vasopressin, and serotonin stimulate platelet aggregation. A common disadvantage of drugs representing this group is a relatively short hemostatic action and low specific activity.

The group of local hemostatics reducing vessel permeability by means of blood protein denaturation, which is accompanied by their transition into the solid state, contains a large subgroup of inorganic metal compounds. Among these, the most interesting agents are the salts of lead (acetate), bismuth (basic nitrate and subgallate), zinc (oxide and sulfate), copper (sulfate), silver (nitrate), and iron (feracryl). The drug kataluhem, containing aluminum chloride hexahydrate and katamin AB (alkyldimethylbenzylammonium chloride), exhibits hemostatic and antibacterial effects and is used in dentistry [13].

The international pharmaceutical market offers a number of mineral hemostatics, which are widely used in dentistry for the arrest of bleeding, including rascstiptin or septodont (containing aluminum chloride and hydroxyquinoline sulfate), imodent (containing 21.3 % aluminum chloride), rastrigent (25 % aluminum sulfate solution), and stasis (aqueous iron sulfate solution). These drugs are rather expensive and did not find wide use in Russia. Pastes containing zinc chloride and 5 – 10 % copper sulfate solutions were used for the arrest of bleeding accompanying trophic gingivitis [14]. Another widely used hemostatic preparation is the Moncel solution (containing 20 % iron sulfate). The presence of subsulfate groups and the low pH of this solution induce protein denaturation and favor the occlusion of blood vessels [15].

The aforementioned hemostatic feracryl is an incomplete iron salt of polyacrylic acid, which contains 0.05 – 0.5 % of iron. Being an acid polyelectrolyte, feracryl forms insoluble polycomplexes with various proteins (including blood proteins) at pH 2.9 – 4.0. A method has been developed and successfully used for the endoscopic introduction of this compound in cases of esophageal gastroduodenal hemorrhage of various genesis. Feracryl is used as aqueous and alcohol solutions with concentrations from 1 to 10 %, as well as in the form of a hemostatic plaster. This plaster exhibits stable activity and does not produce local irritation and autoallergic action. It was reported that feracryl also possesses antibacterial properties [16]. Iron-containing polyacrylic acid was also used as a basis for a hemostatic glue composition (hemocompact), which is used in the clinic [17].

A special position among protein hemostatic agents belongs to collagen, which is one of the main structural proteins in the organism. In cases of vessel damage, subendothelial collagen interacts with its principal receptors on thrombocytes. This interaction leads to thrombocyte activating and spreading over subendothelium. The adhesion stage is followed by the aggregation of activated thrombocytes and the creation of an active surface for the stimulation of plasma hemostasis that leads to fibrin formation [18 – 21].

Hemostatic collagen preparations are available in the form of powders (aviten), solutions (collost), fibrous mass (collastipt), and fibrin-collagen pastes and sponges (collastat, tachotop, conbutec-2, digispon, super-4, androxon, bcriplast, hemostatic collagen sponge, stimul-oss, gentacol, collagresorb) [22 – 29]. Collagen preparations are an indispensable hemostatic aid in various surgical operations, treatment of postoperation and traumatic wounds, and arrest of bleeding.

In order to stimulate the phospholipid-dependent blood coagulation process and increase the adhesion of formed blood elements, a hemostatic composition (thrombocol) has been developed on the basis of a collagen plate impregnated with thrombocytes. Thrombocol showed high hemostatic activity and was successfully used for hemorrhage arrest in surgery and dentistry [30]. Another complex preparation, based on collagen and hydroxyapatite (representing a mixture of powder, granules, and ceramic fragments) was proposed for hemorrhage arrest and the treatment of wounds of various etiology (in particular, in bones) [31]. Much interest was also attracted to the creation of hemostatic preparations based on gelatin (a product of partial hydrolysis of collagen, contained in cartilage and bone tissues of animals). Homeostatic gelatin preparations can be in the form of powder, pastes, gels, pads, and sponges.

Considerable research effort was devoted to the development of hemostatic preparations based on polysaccharides, in particular, cellulose. A highly oxidized cellulose patented in [32] can be used as a nontoxic hemostatic agent possessing antimicrobial and wound-healing properties. Cellulose and its derivatives have been used for a long time in the form of sponges (sterispan, spongostan, gelfoam, spongipost, spongel, surgical) [33 – 35]. Cellulose sponge was successfully used for the treatment of moderate uterine bleeding during cesarian section and tooth extraction operations [36]. Oxycellodex is a mixed hemostatic preparation comprising oxidized glucose powder with 20% of polyglucin, which is intended for the treatment of bleeding from small blood vessels and capillaries. The film of oxycellodex applied onto the surface of an organ dissolves within one to two weeks, not increasing the wound healing time. The mechanism of its hemostatic action is related to the stimulation of platelet aggregation, followed by the formation of an erythrocyte – hydroxycellulose thrombus possessing adhesive properties [37]. A mixture of viscose with crystalline mirabilite was used to obtain a cellulose-based sponge, which exhibited high adsorption capacity, good mechanical strength, and the ability to retain shape [38 – 40].

The use of cellulose-based hemostatic preparations has certain limitations. They cannot be used for drying and swabbing purposes after bleeding arrest. Once this goal is achieved, such hemostatics have to be removed from the regions surrounding damaged bones, bone marrow, optic nerves, and chiasm. Otherwise, the swelling of cellulose can lead to dangerous compression of these structures. Such preparations are not intended for the arrest of bleeding from large vessels [41, 42].

Extensive investigations into the hemostatic properties of chitin and chitosan began more than three decades ago [43]. A mechanism of the hemostatic action of chitosan is related to the ability of its positively charged molecules to attach to negatively charged membranes of blood cells, which leads to cell aggregation and plasma homeostasis activation. It was found that chitosan from shrimps adheres well to wounds and induces rapid blood coagulation even in patients suffering from hemophilia. A series of wound dressings based on collagen – chitosan complexes with various antiseptic drugs has been developed (collachit, collachit FA, collachit Sh, etc.), which are now widely used for hemostatic and wound healing purposes [44].

A promising direction of research is the development of polymeric materials based on algic acids. It was shown that pronounced hemostatic properties are inherent in zinc alginates [45]. The hemostatic properties of alginates are related to their ability to accelerate the polymerization of fibrin monomers — the final stage of blood coagulation — due to the carboxy groups in algic acid molecules [46]. The mechanisms of the hemostatic action of alginates include, in addition to gel formation upon contact with blood, the ability to favor the aggregation of blood formed elements (in particular, erythrocytes). The most widely used alginate based hemostatics are sorbsan, caltostat, sorbalgon, salgitex, and xamalgan [47]. Successful applications of alginate-based hemostatics were reported in otorhinolaringology [48], dentistry [49], proctology [50], and skin transplantology [51].

Hemostatic preparations may also contain the aforementioned hydroxyapatite cyanoacrylate, as well as synthetic polymers. To the present, various hemostatic compositions involving synthetic polymers have been created, a typical example being offered by gelevin — a powder adsorbent based on poly(vinyl alcohol (PVA) [52]. Gels with hydroxyapatite can be used for the treatment of bleeding from bone tissues [53]. Good hemostatic properties with minimum side reactions were reported for the polysaccharide polymer N-acetylglucosamine, which was recommended for wide use in various fields of surgery [54]. The results of experiments on pigs [55] showed that a synthetic polyethylene-based hydrogel can be used as an effective local hemostatic in laparoscopic nephrectomy.

Local hemostatics belonging to the group of cyanoacrylate glues have been developed in the USA (sitman), Germany (histacryl), Japan (aronalf), and Russia (M-1 – M-3, MK-2, M-6. etc.) [56, 57]. These preparations are based on monomer esters of cyanoacrylic acid. Since the polymerization of cyanoacrylates proceeds without volume changes, these hemostatics can be used as fillers of tissue defects. The mechanism of their action consists in creating a mechanical barrier for blood flow, which is related to the high adhesive properties. The polymer is not decomposed and the film is retained on the organism. Cyanoacrylate preparations were recommended for use in vascular and thoracic surgery [58]. Good hemostatic properties were also reported for a hydroxyacrylic glue containing cyanacrylate [59], which was recommended for use in dentistry – in particular, in patients receiving warfarin [59]. Recently, a glue composition created on the basis of acrylate latex was reported to be effective in abdominal operations [60]. Attempts to use poly(tetrafluoroethylenes) as hemostatics in surgical operations involving small vessel showed that the hemostatic effect is less pronounced compared to that of powdered gelatin, oxidized cellulose, and microcrystalline collagen [61].

Historically, the concept of using a blood clot for blocking hemorrhage from parenchymatous organs was formulated at the beginning of the 20th century. Blood preparations possess pronounced hemostatic properties, are readily sterilized, retain this activity for a long time, and exhibits fully decomposition (resorption) in tissues of the organism. In attempts to achieve local hemorrhage arrest by introducing various blood coagulation factors into wounds, numerous experiments were performed using thrombin-containing preparations [62]. In addition to the conversion of fibrinogen into fibrin, thrombin is a powerful activator of platelet aggregation and adhesion [63]. Because of the intense prothrombogenic action, thrombin is used only as a local hemostatic, in particular, to arrest hemorrhage from small vessels, capillaries, and parenchymatous organs (in patients with cerebrocranial traumas, after operations on the liver, kidneys, and other parenchymatous organs, and in cases of bleeding from the bone cavity, gum, etc.). Thrombin solutions prepared from donor blood is used in ophthalmology, in particular, during vitrectomy operations in the prophylaxis and treatment of intraoperative hemorrhage [64]. Local introduction of thrombin, as an alternative to surgical operation, can be used for the treatment of pseudoaneurism [65]. Thrombin powder can be used in dentistry for the treatment of local hemorrhage in patients with inherited and/or acquired defects in the blood coagulation system [66].

Thrombin is effective for the treatment of various hemostasis disorders except for the cases of acute hypo- and afibrinogenemia (in cases of blood coagulation dysfunction, solutions are less effective than powdered forms). Patented thrombin-containing hydrogel [67] was proposed for hemorrhage arrest. In order to prevent rapid thrombin leaching by the bloodstream, it was suggested to introduce thrombin into collagen and gelatin pastes and sponges [68 – 72] and to impregnate textile carriers [73]. In recent years, an original system was developed in which a thrombin layer is sandwiched between fibrinogen films [74 – 76]. It was reported that a hemostatic system for rapid arrest of mixed hemorrhage cases was created by thrombin and fibrinogen immobilization on a bioadsorbable unwoven material [75].

A hemostatic effect with a mechanism close to that of thrombin action is produced by the poisons of some snakes (*Botrops atrox*, *Notechs csutaius*, *Oxuranus scutellatus*) and by filtrates of *St. aureus* cultures used a basis for the preparations of botropase, reptilase, hemocoagulase, stipven, crotolase, batroxobin, and staphyllocoagulase [77], representing nonphysiological thrombin activators. Botropase only splits fibrinopeptide A from fibrinogen molecule, which

leads to the appearance of a fibrin monomer and the development of a weak thromboplastin activity. Reptilase converts fibrinogen into fibrin and, in addition, activates factors II, VII, X, and XIII.

The addition of thrombin to fibrin led to various effective local hemostatic preparations such as fibrin cotton, fibrin sponge, fibrin paper, fibrin foams, and fibrin films [78]. Also widely used in medicine are fibrin glues (biocol, besiplastP, bosil, hemasil, APR, quicksil, tissel, and tissucol) [79 – 81]. The typical fibrin glue consists of two components delivered in separate flasks, one containing thrombin with a source of calcium ions and the other containing fibrinogen, fibrinolysis inhibitor, and factor XIII [82]. The contents of two flasks are dissolved and immediately mixed on a wound. Under the action of thrombin and calcium, fibrinogen converts into fibrin, the fibrin clot is stabilized by factor XIII, and the fibrinolysis inhibitor prevents decomposition of the clot by plasmin.

Local hemostatic preparations can make use of natural factors of the blood coagulation system [83]. It was established that factor VIIA is capable of effectively arresting hemorrhage [84]. An effective hemostatic preparation was obtained by applying fibrinogen, thrombin, and factor XIII onto the surface of cellulose fibers [85]. There are local hemostatics (not widely used) based on the tissue factor thromboplastin; this group includes hemostazin, pulmin, and clauden, which are obtained by extraction from thromboplastin-rich tissues such as lung, liver, and brain [86, 87]. With allowance for the role of thrombocytes in primary thrombus formation, it was suggested to use dry thrombocytes as a hemostatic agent [88].

A hemostatic effect can be achieved both by using activators of fibrin formation and by introducing fibrinolysis inhibitors such as ε-aminocaproic acid and aprotinin [21, 89]. It was demonstrated that ε-aminocaproic acid preparations can be successfully used in patients suffering from hemophilia [90]. Capramin — a hemostatic fluid preparation based on ε-aminocaproic acid — is used in dentistry in the course of manipulations such as tooth extraction, mineral deposit removal, and cavity preparation. Aprotinin-based hemostatics are used in thoracic, cardiovascular [91], and spinal surgery [92]. Local application of aprotinin can be used to arrest postoperative hemorrhage in neurosurgery [93].

Tranexamic acid produces hemostatic action close to that of ε-aminocaproic acid. In particular, tranexamic acid was more effective than ε-aminocaproic acid in liver transplantation [94]. Mouthwash with a tranexamic acid solution provides effective hemorrhage arrest upon tooth extraction, even in patients receiving warfarin [95]. A hemostatic collagen sponge proposed in [23] contained donor blood plasma, amben, and calcium chloride.

There is a large group of combined preparations that contains either mixtures of hemostatics from different groups or mixtures of hemostatics with some other drugs, usually antibiotics [96]. For example, the introduction of amicacin (antibiotic) into a fibrin glue composition provides effective prophylaxis against local infection development, while retaining good hemostatic properties [97]. A collagen sponge impregnated with epinephrine increases the hemostatic properties of the initial preparation without increasing the risk of side effects. A fibrin glue composition modified by adding taurolidine (cytostatic) is used for the treatment of malignant cerebral tumors (glyomas) in nonoperable patients [98]. Collagen plates impregnated with fibrinogen and rifampicin (antibiotic) were successfully used for healing spleen traumas [99].

Another representative of combined preparations is tachocomb, representing a collagen plate with lyophilized fibrin glue components (fibrinogen, thrombin, aprotinin, riboflavin). Tachocomb was originally intended to arrest hemorrhage parenchymatous organs [100, 101] during operations on liver [42, 102, 103], pancreas [104], and spleen [105] and in neurosurgery [106, 107] and cardiology [108]. However, now this preparation is also successfully used for the plastic reinforcement of surgical sutures [109] and the reduction of comissure processes [110. It was reported that tachocomb plates could be used in operations on lung tumors [111], during kidney transplantation [112], and in the treatment of hemorrhoidal veins. A unique property of tachocomb is the ability to stimulate angiogenesis in underlying tissues, which significantly accelerates regenerative processes.

Algic acid salts are used in the production of materials employed for the arrest of local capillary-parenchymatous hemorrhage. These preparations have the form of a cotton with immobilized calcium ions or thrombin and fibrinogen (Gram I and II, respectively) [113]. It was also proposed to use films based on alginate and PVA with hemostatic additives (AlCl3, capralin AV, CDC) [114].

The hemostatic caprofer represents a carbonyl complex of iron(III) with ε-aminocaproic acid in physiological solution [115, 116]. The interaction of this complex with blood leads to the formation of a clot that tightly adheres to the wound surface [117]. In addition, caprofer accelerates the regeneration and epithelization processes, favors the formation of granulation tissues, and produces antiedemation and antiinflammatory effects. This preparation was also used in otorhinolaringology [118], dentistry [119], and surgery (operation on lungs) [120], and it was effective in arresting hemorrhage from parenchymatous organs [121, 122]. In recent years, caprofer was successfully used under battlefield conditions for the arrest of hemorrhage from gunshot wounds and during abdominal operations [124].

Under the conditions of violated blood coagulation system function, an effective local hemostatic action is provided by polycapran [125], which represents a cellulose N-oxide modified with ε-aminocaproic acid.

It was suggested to use gelatin in combinations with dry plasma, glucose, and antibiotics. This preparation (gelplastan) exhibits procoagulant and adhesive properties [126]. Gelatin sponge preparations spongostan, gelform, gelaspon, and hemoscpt are prepared from dry purified gela-

tin foam and possess a homogeneous porous structure [127]. Experiments demonstrated effective combined use of gelform and fibrin glue for local hemostasis in laparoscopic nephrectomy [128]. The same operation was performed using a gelatin sponge impregnated with thrombin [129]. Gelatin sponges were also successfully used in vascular [130] and general surgery [131]. A gelatin sponge with thrombin effectively arrested hemorrhage, exhibited good adhesion to a wound surface, and did not cause side reactions; in order to increase the antimicrobial effect it was proposed to additionally modify the gelatin sponge with furacilin and gentamicin [132]. A hemostatic gelatin sponge containing formalin, calcium chloride, and an antiseptic component was described in [133].

A new cellulose-based fiber containing fibrinogen, thrombin, and factor XIII, which is capable of rapidly absorbing blood plasma and activating thrombus formation in wounds, was proposed in [134].

A promising direction of development is related to the fabrication and use of hemostatic preparations based on textile carriers [20, 135], in particular, tricots of textured polymer and cotton fibers, mixed cotton – viscose, and polyester fibers. Domestic hemostatic dressings on textile carriers include coletex, activtex, and hemotex. For example, a hemotex pad consists of two layers: the first, protective (atraumatic) and hemostatic layer comprises a perforated circular-weaving tricot with immobilized iron(II) salts; the second layer is made of an unwoven cotton – viscose canvas [30]. The hemostatic pad of activex represents a textile carrier with immobilized ε-aminocaproic acid. Activex AKF contains ε-aminocaproic acid and furagin, which are immobilized on a textile base impregnated with a special biocompatible polymer. Being wetted, the polymer forms a gel from which the drug components are gradually and uniformly delivered to the wound. This preparation possesses both hemostatic and antimicrobial properties. Analogous structure and properties were reported for activex Fhem, which contains feracryl and furagin [136].

To summarize, there are many single-component and combined preparations possessing hemostatic activity and intended for local application. All such products have certain limitations and are intended for use in various clinical conditions. The specific pharmacological activity was tested under various conditions (in patients with different diagnoses, in different experimental models, and in various organs and tissues). We believe that, along with the development of new products, it would be expedient to perform comparative evaluation of various local hemostatics under identical experimental model conditions. Such comparative tests would provide useful information concerning the character of action of the existing preparations and indicate the promising directions of further search for effective local hemostatics.

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Dominic Stewardson

Trends in Indirect Dentistry: 5. Impression Materials and Techniques

Abstract: A fundamental pre-requisite for the construction of satisfactory indirect restorations is the ability to record an accurate and detailed impression of the dental structures. Knowledge of the key properties of the available impression materials and their handling behaviour is necessary if they are to be used effectively. A variety of techniques can be employed in different situations, each of which can be highly successful, but only if attention is paid to the detail of their execution and the clinician is aware of their individual limitations and pitfalls. Where imperfections occur, an appreciation of how they have been caused, and the strategies to take to prevent them will lead to greater success in impression taking.

Clinical Relevance: Current materials exceed our needs in terms of accuracy and stability, and yet the impressions produced are frequently flawed. By realizing why faults occur, being aware of the range of techniques available and having an understanding of the behaviour of materials, clinicians can achieve the quality in their impressions that is possible and necessary to provide excellence in indirect restorations.
Dent Update 2005; 32: 374-393

Until the advent of intra-oral scanning and computer-aided manufacturing techniques, the construction of indirect restorations required a model or cast to be made, this being an accurate three-dimensional facsimile of the mouth and teeth. To create a cast, a mould or impression of the oral structures is obtained. The quality of the subsequently produced restoration depends first on having an accurately fabricated cast, which in turn depends on the ability of the impression to record the dimensions of the target objects faithfully. Dimensional accuracy is therefore the most fundamental property needed in an impression material. While there are many further steps in the manufacture of an indirect restoration at which errors and inaccuracies can occur, it is the dentist's responsibility to provide the technician with high quality impressions and records with which to work and, should returned restorations be ill-fitting or have defects, the clinician should first examine his or her own technique for flaws before looking elsewhere for possible culprits.

	Polysulphide	Condensation Silicone	Polyether	Addition Silicone
Polymerization shrinkage (%)	0.4–0.45	0.4-0.6	0.2-0.25	0.14-0.17
Percentage recovery	97-95	98-97	98.5-98	99.9-99.6
Tear strengths (MPa)	0.5	1.6	2.0	2.4

Table 1. Properties of elastic impression materials. Low viscosity formulations quoted first.

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Key properties

Which is the best impression material for indirect restorations? The choice is between:

- The inaccurately termed hydrocolloids (reversible – Agar, and irreversible – Alginate) and
- The elastomers: polysulphide, polyether and the silicones (type 1 condensation-cured; type 2 addition-cured).

Dimensional accuracy is dependent on the changes occurring as the material sets. Shrinkage occurs as the molecules move together to form polymer chains, and form cross linkages. There is also some

shrinkage as the material cools on removal from the warm mouth (Table 1). Although the polyethers and addition silicones achieve the highest dimensional accuracy, all of these materials (even alginate with a specific technique) are capable of *sufficient* dimensional accuracy for use in making indirect restorations.

Dimensional stability

As well as being able to record accurately, it is clearly desirable for the material to maintain that accuracy for a convenient length of time, ie the material should have good dimensional stability, or at least one should know for how long the impression will be sufficiently accurate so that it can be used intelligently, and how storage conditions may affect its stability. Polysulphide and type-1 silicones produce water and ethanol, respectively, during their polymerization. This results in their shrinkage, with over half of the total shrinkage occurring in the first hour after removal. Although the distortion occurring is not as severe as in the hydrocolloids, it is advisable to pour these materials quickly – within 48 hours in the case of polysulphides.[1] For type-1 silicones the recommended times range from 30 minutes[2] to within 6 hours.[1] The polymerization of polyethers and type-2 silicones involves an addition reaction with no volatile by-products being created, and their polymerization shrinkage is very small. The chemistry of the polyethers, however, encourages water absorption and swelling, and so they must be stored dry until casting. They should also be shielded from strong sunlight during storage. Reversible hydrocolloid, when set, is composed mainly of water (85%) and will swell or shrink as it absorbs or releases water, according to its environment. Even when stored in 100% humidity, it must be poured within one hour to prevent clinically unacceptable distortion occurring.[3] Alginate is similarly affected but to a lesser degree; comparable storage for up to two hours is advised before pouring. However, disinfection by immersion will affect dimensional stability.

Hydrophilicity

As the mouth is a wet environment, a moisture-loving material would be expected to work better in the presence of blood and saliva. The hydrocolloids are truly hydrophilic and can produce detailed impressions in a wet field. The polyethers are hydrophilic in that they will absorb moisture, but still require an essentially dry field to capture detail. The other elastomers are hydrophobic and do not readily wet surfaces, ie they have no natural tendency to flow across prepared teeth. This makes it difficult for the casting material to wet and flow into the set impression material, and may give rise to voids or loss of detail in the produced casts. To combat this, manufacturers of the addition silicones have added surfactants to lower surface tension, creating the *so-called hydrophilic silicones*.[4,5] It is important for clinicians to understand what this means in terms of the use of such materials. The degree of hydrophilicity is often quoted in terms of contact angle measurements. This refers to a test which essentially involves placing a drop of water on to the set surface of the material, and examining the shape formed after a fixed time period. On materials which are difficult to wet, the drop will be well rounded, and a high contact angle is created (Figure 1). Conventionally, angles greater than 90° define a hydrophobic material; less than 90° indicates hydrophilicity. Unfortunately for the clinician, test results from different manufacturers are rarely comparable as there are many test variables which are not standardized between different test laboratories. Also, testing the set material is only an indication as to which impressions are easiest to cast. Testing the unset material, which has been less frequently undertaken (because it is a more difficult test to perform) gives a better assessment of the likely wetting behaviour in the mouth.[6] The only practical benefit of increasing the hydrophilicity, however, is likely to be an improvement in the quality of casts, as studies suggest that the quality of impressions obtained clinically is unrelated to the surface activation of the material; the other material characteristics exert a greater influence on quality.[7,8] Despite their name, hydrophilic impression materials will not compensate for poor moisture control!

Figure 1. Contact angles of a water droplet on a hydrophobic and a hydrophilic surface.

Detail capture

Elastomeric impression materials are required to record detail down to 20µ.[9] Such discriminatory ability is probably more than is required for indirect restorations, especially when it is considered that die-stones are only required to reproduce detail down to 50µ. However, these materials are successfully used to create replicas for microscopic examination of tissues and biological samples where there is a need to see structures considerably smaller than 20µ in size.

Permanent deformation

Impressions of the mouth will need to be withdrawn from tooth and tissue undercuts, and therefore must be sufficiently elastic to deform as they exit undercuts but then return to their original shape. Although international standards define the maximum permissible permanent deformation, manufacturers frequently refer to the converse, ie percentage recovery. Not surprisingly, highly-filled materials have slightly less elastic recovery than lower viscosity formulations. The addition silicones achieve over 99% recovery, and the type 1 silicones and polyethers reach between 98% and 99%. Flexibility is measured by strain in

	Polysulphide	Condensation silicone	Polyether	Addition silicone
Handling	Very sticky	Easy removal Protect hands while mixing	Sticky	Easy removal Reaction affected by some latex gloves. Protect hands while mixing
Taste	None	None	Bitter	None/some flavoured
Smell	Sulphurous odour	None	None	None/some scented
Colour	Usually brown	Wide variety	Limited	Wide variety
Setting time	Long – 10 minutes	4-6 minutes. Variable set times available	Fast	4-6 minutes Variable set times available Sensitive to temperature
Die plating	Silver	Usually not possible	Silver	Silver or Copper
Toxicity	Low	Very low	Some reactions reported in past[10,11]	Very low
Cost	Least expensive	Moderately expensive	Moderately expensive	Most expensive

Table 2. Additional impression material characteristics.

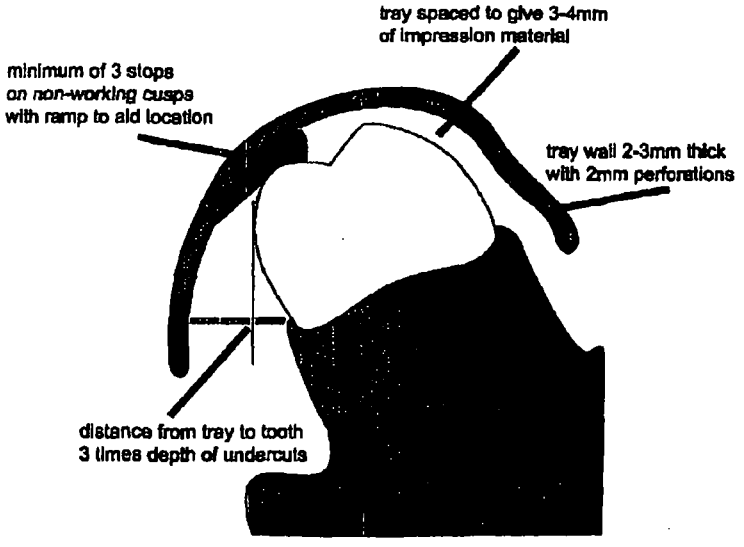

Figure 2. Features of a good individual tray, with particular reference to inclined teeth.

compression, the percentage change in length of a sample under a specific load. The polysulphides are more flexible than the other elastomers, among whom the condensation silicones are slightly more flexible than the type 2 silicones or polyethers of similar consistency. Where significant undercuts exist which need to be recorded, for example on tilted teeth, an addition silicone is less likely to distort on removal than the other materials. However, as it is also a stiff material when set, it could be difficult to disengage physically. To overcome this, a tray should be selected which allows an adequate bulk of material in the area – three times the depth of the undercut (Figure 2). A very rigid material may be indicated when it is crucial to prevent distortion of the relative positions of dies, as is the situation with implant restoration, but it may prove difficult to remove where moderate tissue undercuts are present. It may also be impossible to remove such an impression from a cast

with the same undercuts without dies and/or teeth breaking off in the process. The dentist should be alert to these potential problems and consider blocking out such undercuts clinically with cotton wool or waxes. Retrieved impressions should be cut back to remove material which reproduces these undercuts, prior to sending to the laboratory.

Tear strength

An impression should be able to record detail in narrow spaces such as the gingival crevice and preparation features like slots and grooves. It therefore needs to be strong in thin section if it is to be withdrawn intact from these sites. Polysulphides have recorded the highest tear strengths but, because they also have poor permanent deformation characteristics, they are not very reliable for recording areas of thin section. The type 2 silicones and the polyethers both have high tear strengths but there is little difference between them and the type 1 silicones. The hydrocolloids have much lower tear strengths. There are several other desirable characteristics to be considered when choosing an impression material as listed in Table 2.

Impression technique

As implied above, any of these materials has sufficient inherent accuracy for them to produce high quality restorations. Realizing their potential depends on the clinician understanding the material's properties and behaviour, and handling it so that any deficiencies are minimized. With the high quality of materials available to dentists over the past 40 years, technique is a much bigger factor in determining success or failure in indirect work than are material differences.

Irreversible hydrocolloid and polysulphides will not be considered in this section. Most UK dentists are now using silicones or polyether, as they are more user and patient friendly than polysulphide. Those who are using reversible hydrocolloid are most likely to be specialist practitioners well versed in its use.

Figure 3. A poorly executed two-stage putty wash impression. Only a section of the putty has been covered by the wash, and the tray has not been fully seated, which resulted in a stepped cast.

Putty/wash technique

Two-stage

Since elastomers shrink on polymerization, it follows that using a small volume of material will reduce the net effect of the shrinkage on the accuracy of the impression. Only a closely adapted custom tray would allow a small volume to be used. An alternative approach was proposed for the condensation silicones which allowed cheaper, time-saving stock trays to be used. A heavily filled 'putty' version, which therefore has reduced shrinkage, is effectively used to convert the stock tray into a close-fitting custom tray. As a second step, a lightly filled (higher shrinkage) material (the wash) is placed inside this 'tray' and re-seated. Very little of this low viscosity material is needed, hence little net shrinkage occurs, while good detail is recorded by its ability to flow more readily than the high viscosity putty. However, there are some problems with this technique. With such a close adaptation of the putty to the teeth, there is little space in which the wash material can flow, and the trapped material makes it difficult to reseat the tray (Figure 3). This leads to an uneven thickness in the wash, and uneven shrinkage. More importantly, the build-up of hydrostatic pressure acts to push the set putty and the walls of the tray outwards. When the impression is removed, the putty recoils and the resulting dies, which may appear flawless, will be narrower than the preparations, and the crowns made on these dies are unlikely to seat easily on the teeth.[12]

The use of more rigid (specifically metal) trays reduces the recoil from the tray but, to reduce the recoil which will occur in the set putty, modification of the putty must be made to allow release of the pressure. The putty should be generously cut back in the depths of the sulci (and palate in the upper arch), and several buccal and lingual sluices cut to

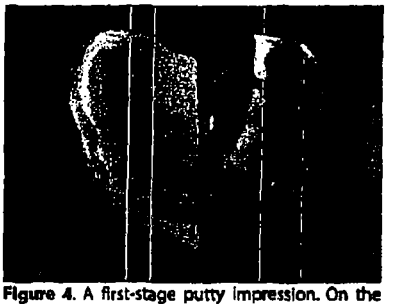

Figure 4. A first-stage putty impression. On the right side the impression has been marked to show where trimming has been carried out to remove the sulcus depths, and create several sluices. The interdental collets will also be removed to allow easy, positive re-seating.

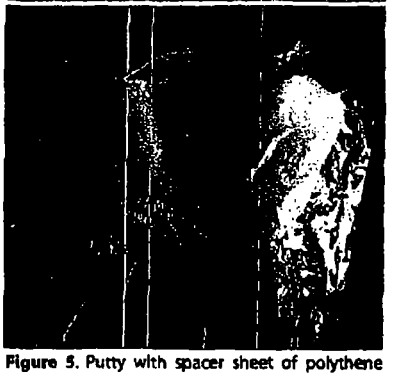

Figure 5. Putty with spacer sheet of polythene prior to taking first-stage of two-stage impression.

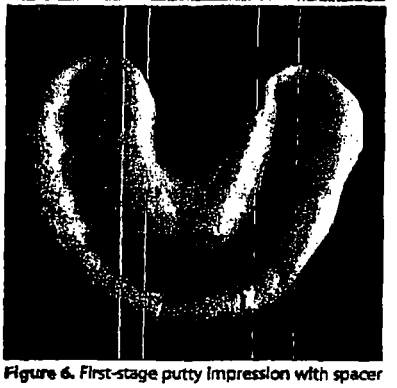

Figure 6. First-stage putty impression with spacer removed.

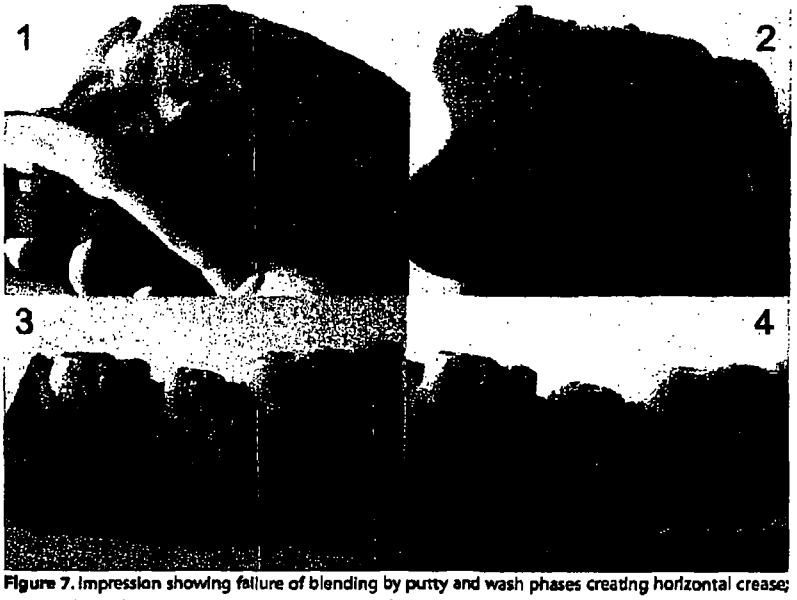

Figure 7. Impression showing failure of blending by putty and wash phases creating horizontal crease; arrowed (1) and in cross-section (2). Resulting die shows corresponding ridge on preparation surface (3, 4), with similar drag defects on adjacent teeth.

provide escape channels for the wash. The interdental collets should also be removed, and the modified putty impression replaced to check that it can be easily relocated (Figure 4). It may be thought that, if the first-stage putty impression is taken before any tooth preparation is performed, sufficient space will be created locally around that tooth. However, for this to be an effective method of overcoming recoil, the operator would have to place the exact volume of light body required to fill this space into the putty. Any excess would be unable to escape from the surrounding close-fitting putty, leading again to outward displacement of the putty and tray and/or difficulty seating the impression. Any flow of the light-bodied material which occurred across nearby teeth would create a step in the impression at the limit of its flow. A quicker method of creating room for the wash material to escape is to place a thin sheet of polythene over the putty as the first-stage is put into the mouth (Figure 5). On removal from the mouth, the polythene is discarded. This provides a thin space allowing movement of the wash in the second stage, and prevents the putty material passing interdentally or to the full sulcus depth (Figure 6). Spacer sheets can be purchased which have a raised pattern designed to increase the surface area for adhesion of the putty and wash. Bonding of the two phases does not appear, however, to be a problem as long as the putty surface has been carefully cleaned of saliva etc., and dried.

One-stage

Decreasing the number of steps should increase efficiency, and placing both materials in the tray for a one-stage impression is therefore an attractive option. Although seating difficulties are overcome, recoil of flexible trays still occurs. With such a contrast in the viscosities of the two materials, the wash may be pushed away by the putty, resulting in drags below undercut areas such as the axial surfaces of teeth and inclined preparations; critical areas (slots, grooves, finish margins) may be recorded by the putty alone which is less able to record fine detail. Where margins are extended into the gingival crevice, the unset putty will act to close up the gingival crevice, pushing out the wash and giving poor definition of essential margin detail. In the two-stage technique described previously, while the first putty phase is recorded, the crevice can be held open by retraction cord. At the second wash step, the pressure build-up occurring as the impression is re-seated tends to drive the wash into the opened crevice and clearer recording of the margins occurs.

A defect which, in the author's experience, occurs more with type 2 rather than type 1 putty/wash impressions and is not often recognized by the clinician, is failure of the two viscosities to blend fully. This manifests as a crease in the completed impression on the axial surfaces of teeth, frequently on the prepared teeth (Figure 7). This may be as a result of the relative differences in the surface tensions of the two viscosities, or it may be because the setting reaction of addition silicones starts earlier than for condensation silicones or polyethers, which means it develops elasticity quickly, and this effect is accelerated at increased temperature.[13] On placing the wash around the teeth, the material against the warm tooth will start to polymerize while the bulk of the wash still appears fluid. When the putty is applied, this partially set skin may be displaced or distorted, forming a crease. Since the wash is applied first to the prepared tooth, this effect is more likely to occur there. It is advisable, therefore, always to chill the wash material. Conversely, once apparently set, addition silicones need to be given longer to complete the reaction fully or distortion may occur on removing the impression. Although more steps are involved in a two-stage technique, it can be completed with a minimal increase in time. As the purpose of the first stage is only to create a custom tray, the putty impression can be removed before it has fully set, and this stage can be carried out at the start of the appointment while awaiting anaesthesia. Some practitioners make use of the putty taken before tooth preparation as a matrix with which to make a provisional restoration. This avoids the need for a separate impression with which to create a temporary restoration, and can also save time in temporization compared with the time taken to trim crown forms. However, any methacrylate type compounds, eg bis-acryl or methacrylate temporary crown materials, and also bonding resins which come into contact with addition silicones,

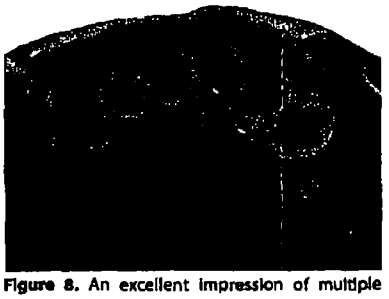

Figure 8. An excellent impression of multiple units achieved by careful preparation, moisture control, and gingival displacement. An individual tray with stops was indicated and a heavy and light combination of silicones used. Produced by a final year dental student (by kind permission of Ms E Hopkins).

will contaminate the platinum-containing catalyst and impede the setting of, and the bonding to, the light body silicone, so the putty must be carefully cleaned with alcohol to remove any temporary crown material residue.

Some laboratory studies suggest that the dies produced with single stage impressions are more dimensionally accurate than those from two-stage techniques.[14,15] Unfortunately, one can also find evidence that one-stage is superior[16,17] and that there is no significant difference in accuracy between the techniques.[18] Accuracy, however, is only one determinant of quality. Where margins extend into or close to the gingival crevice, the clear recording of the margins is also critical to producing acceptable restorations, and a careful two-stage technique can give superior marginal definition and avoid drag formation.

Heavy/light

The technique most often used with addition silicones is that originally devised for the condensation silicones, namely, one-stage putty and wash. Using any putty will give rise to recoil problems in non-rigid trays, and the potential offered by the superior material properties of the addition silicones will not be realized. Since the setting shrinkage of type 2 silicones is less than half that of the type 1 silicones, a less heavily filled material can be safely used in bulk in a stock tray placed simultaneously with a lighter viscosity material to capture detail. This gives the dentist the convenience of a single-stage method without its disadvantages; distortion of plastic trays is reduced, and the viscosities of the two materials are closer, which reduces drags and improves blending of the two phases. The lower viscosity material is not as readily displaced from the gingival crevice, permitting good margin definition, and the higher viscosity material can record detail better than a putty can (Figure 8). The heavy material is generally sufficiently thixotropic not to run out of the tray, but it requires some effort to express enough material from an automix syringe to fill a tray quickly. Automatic mixing machines introduced in the past few years overcome this problem; their extra cost must be weighed against the risks of repetitive strain injury! The polyether materials are not formulated as putties as they would be too rigid to use, and are used in a heavy/light combination, or in a single medium body viscosity – otherwise known as a monophase technique.

Monophase

The advantages of making impressions with a medium-bodied presentation are that the possible co-ordination problems of using two mixing guns and the need to stock more than one material are avoided, and there is no conflict between different viscosities. However, as this one material is not as heavily filled as the high viscosity described above, polymerization shrinkage will increase slightly, and it will have increased flow compared with the heavy tray material. For these reasons, it is probably safer to use monophase materials in a custom tray, which reduces volume and contains them better than would a stock tray. However, the thicker consistency compared with a light- or very light-bodied material may limit the ability of medium-bodied materials to flow into intra-coronal features or the gingival crevice.

Tray selection

The influence of the tray on the creation of a successful impression has been touched on in the preceding sections. However, the importance of correct tray selection is often overlooked. Clinicians will consider many other possible sources of failure when restorations do not fit, and may change their impression material, but rarely think of their tray. Trays should be as rigid as possible and not all disposable trays will resist deformation while loading heavy-bodied materials.[19,20] Metal trays offer the greatest rigidity but should be used with caution with polyether and type 2 silicones – if there are significant tissue undercuts the tray may need to be cut off, which is a lengthy, laborious and very traumatic procedure for the patient!

Custom trays can improve the chances of producing an accurate impression because they can offer greater rigidity, and allow control of the thickness of impression material. An optimum thickness (approximately 2–4 mm) of material[21] will provide the best compromise between having enough bulk of material to minimize the permanent deformation caused by removing the material from undercuts, and the need to reduce the volume so as to minimize the effect of shrinkage (and reduce cost)(Figure 2). Trays made from self-curing acrylics require a delay of 24 hours to allow complete polymerization before use, while light-curing materials can be safely used almost immediately. Both should have a thickness of 2–3 mm to ensure sufficient rigidity.[22,23] Impression materials adhere better to the light-curing composite tray materials and adhesion is also helped if, during manufacture, the spacer wax is covered with metal foil before the tray material is applied.[24] Requesting a custom tray is not the end of the matter. An even distribution of material can only be obtained if the tray is precisely positioned, and this control of position requires either luck, or the incorporation of stops in the tray which can guide the clinician in seating it. If the rationale for having a custom tray spaced is accepted, it is illogical not to have stops. They should give at least three widely spaced supports to the tray, offer very positive seating, and be on non-critical areas, ie non-functional cusps of unprepared teeth, edentulous areas or the palate. If a ramp is created leading to the stops, it will help direct the tray into position as the impression is seated.[25] When a custom tray is indicated, a putty/wash combination must not be used for several reasons:

Figure 9. Electrosurgical tip for gingival troughing.

- First, it is illogical since the purpose of the putty is to fill the large space of a stock tray and minimize the volume of the wash material – a custom tray is shaped to minimize impression material volume.
- Secondly, a close-fitting tray containing putty will be very difficult to seat without setting up enormous stresses in the putty, and
- Thirdly, most of the previously mentioned problems associated with the putty-wash technique will persist.

A custom tray will not always give a significantly better outcome clinically than a stock tray. A stock tray will suffice when:

- The stock tray is of a rigid type;
- The shape of the patient's arch conforms to that of the tray, ie an even thickness of impression material can be accommodated in the completed impression;
- Only one or two single units are being restored;
- Stops are placed as described;
- Overextensions are removed – these may prevent outflow of impression material at the peripheries and contribute to recoil (as can happen when a lower tray is used in the upper arch);
- The chosen materials (preferably avoiding putties) are used correctly.

On the other hand, where several units or a bridge are being constructed, the impression is required to deliver not only accurate individual dies, but also to reproduce the spatial relationships between the units. An individual tray is more likely to achieve this extra level of accuracy, and the extra cost will be recouped in less adjustment time and less material used.

Retention of the impression in the tray as it is removed is essential. Trays for elastomers should be perforated with holes of at least 2–3 mm diameter, to allow material to escape and lock on to the outer surface of the tray, and have an appropriate adhesive coating extending on to the outer surface. These are contact adhesives and, in the case of the silicones, need to be painted on at least 7–15 minutes before use.[28] If insufficient time is allowed for the solvents to evaporate, the adhesive will act more as a lubricant. Removing any impression made with an elastic material (this includes alginate) should be as rapid as possible. They are all visco-elastic, which means that, if pulled gradually or rocked out of the mouth, they will deform. With quick removal they will behave more elastically and not distort. Where the prepared teeth are tilted relative to the rest of the teeth, the impression should be brought out along the line of the prepared tooth to minimize any excessive strain and distortion of the impression of the preparation. With marked tilting, a correctly shaped custom tray should be used.

Tissue management

The most frequent visible fault identified in impressions received in laboratories is poor margin definition.[27] This may be owing to poor preparation, but is mostly attributable to inadequate displacement of the gingivae when the restoration is extended close to or below the gingival crest. Without an open gingival cuff, the precise extent of the margin will not be recorded, and the technician has to guess where to finish the restoration. Where sufficient depth exists, recording the shape of the tooth surface below the margin will help the technician to create a natural emergence profile, avoiding sudden changes in direction from the root to the restoration, which results in over-contoured margins which will encourage plaque retention.[28,29] For the elastomeric impression materials, the crevice needs to be opened to 0.2–0.3 mm to allow accurate detailed reproduction.[30,31] This can be achieved by surgical widening or mechanical displacement with or without chemical adjuncts.

Surgical widening

This entails removing the lining of the gingival crevice and can be accomplished using an electrosurgery unit, a rotary instrument, or with a laser.

Electrosurgery, or more accurately radiosurgery since the instrument emits high frequency radiowaves (3–4 MHz), produces rapid heating and cell destruction in the immediate vicinity of the electrosurgery probe as the radio waves pass through the tissue owing to the high resistance of the gingival tissue. A specific probe, which has an insulated tip from which extends a short metal projection, is available for some machines (Figure 9). This design helps to prevent contact with the adjacent teeth as a result of the insulation, and the short tip limits the depth of its use in the crevice. The heat generation helps to cauterize the cut tissue and reduces bleeding, but care must be taken to keep the tip moving whilst activated (0.7 m/sec is suggested) in order to prevent an excessive temperature rise; at least 5 seconds should be allowed before working in the same area again.[32] Touching the teeth, or metal restorations, with the electrosurgical probe can cause rapid heating and damage to the pulp. Rotary gingival curettage, also known as gingitage or gengitage, achieves removal of the crevicular lining with a high-speed diamond or ceramic bur directed around the tooth within the gingival crevice, usually at the same time as the preparation margin is prepared.[33] So-called soft lasers can vaporize superficial tissues and have also been used to widen the gingival crevice surgically for impression taking.[34]

Common concerns with all of these destructive techniques are whether recession of the gingivae will occur, and what potential there is for permanent damage to the tissues. A number of studies have compared these modalities, and each one has been shown to be at least equal, if not superior, to the others.[33-39] This conflicting evidence suggests that any differences between these techniques are likely to be clinically insignificant, *when they are used correctly*. There is, however, great potential for significant damage with all three. Overheating of the tissues with electrosurgery or laser can cause pulp death and alveolar bone necrosis. Rotary gingival curettage involves the least cost in new

equipment and allows the dentist to use an instrument with which he/she is very familiar. Nevertheless, in the interproximal areas, there is a high probability of contacting the adjacent tooth surfaces and permanently marking them. This is likely to encourage caries, and cause sensitivity. All of these methods should be avoided where the gingivae are thin and friable, as significant recession may then be likely.

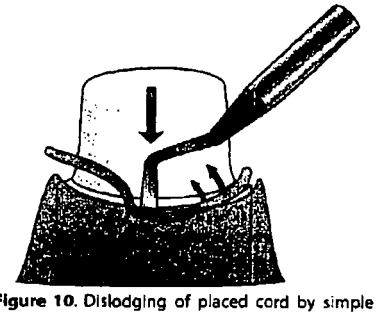

Figure 10. Dislodging of placed cord by simple vertical packing technique.

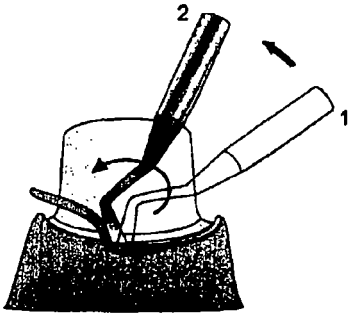

Figure 11. Rotating the packing instrument as the cord is seated helps to keep the earlier packed cord in place.

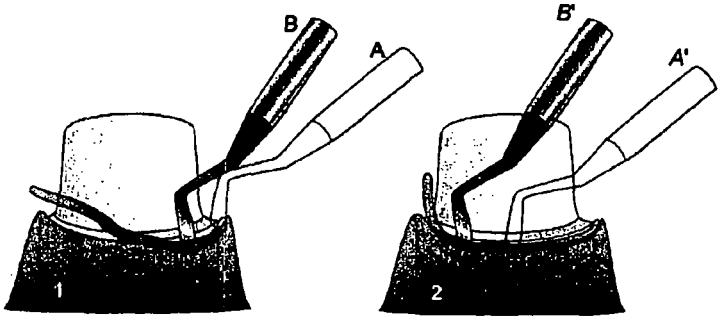

Figure 12. Using two instruments, walk around the tooth, to hold seated cord in place.

Mechanical displacement

Rather than destroy tissue to create space in the crevice, the natural elasticity of the gingivae can be exploited and the crevice temporarily widened by inserting a material into it. Cords are convenient for this purpose as they can be produced in varying diameters and are readily cut to length. Made from absorbent cotton strands, they can soak up crevicular fluids or can hold haemostatic agents *in order to provide a dry field. Twisted* cords have a tendency to unravel during placement, so knitted or braided cords are preferable. Either a single- or a double-cord technique can be used. If a marginal gap of 0.2–0.3 mm is required then, realistically, the clinician should aim to open the crevice by at least 0.3–0.4 mm to allow for some closure to occur while the impression is being placed. Therefore, with one cord, the largest diameter should be chosen which can be inserted *with gentle pressure* into the crevice. This provides displacement of *the gingival cuff. The pressure of the cord,* possibly supplemented by haemostatic solutions, creates a dry field locally. Additional lengths can be placed if there is a large bulk of gingivae to be pushed back. Before mixing the impression material, the teeth are washed and dried and the cord, which should be moistened to prevent tearing of the crevice lining, gently removed. It is essential to wait for 10–15 seconds to see if any bleeding now occurs. Placing the impression material immediately after removing the cord will not prevent such *bleeding, so it makes sense to see if further* applications of haemostatic agents are required before wasting time and money on an impression which will be flawed. In the two-cord technique, the functions of haemostasis/drying and displacement are divided between the two cords. A *narrow* cord is placed first to ensure a dry field but, as it is to stay in place during the impression taking, needs to be cut fairly precisely to the size of the periphery of the tooth. A second, thicker cord is placed on top to open up the crevice, and only this is removed before the impression material is placed. To use two cords requires more depth in the crevice, and so some operators use suture material as their first cord. It also takes more time, but gives greater control of the critical marginal area, and so is particularly useful where an impression of multiple units is being obtained or where persistent gingival bleeding occurs. Retraction cords should not be reserved solely for the impression stage. With the gingivae deflected, the margins can be seen and prepared more accurately, and the tissues are protected from bur damage which can add to the problems of achieving haemostasis. It may also be easier to place cord prior to margin cutting. Cords can themselves be harmful. A recent study suggests a direct effect on fibroblasts;[40] of more importance is direct trauma resulting from excessive force leading to recession. Common sense should guide the practitioner – thin, tight gingivae indicate narrower cords and lighter inserting force; wider diameters and greater pressure where the tissue is tougher. Baharav *et al.*[41] suggest that 4 minutes is needed to achieve an adequate displacement width, while longer times give no further benefit. It would seem sensible not to leave cord in longer than 10 minutes if working on multiple teeth, as this may lead to recession. Once cord is removed, the gingivae can rapidly close up, possibly within 30 seconds[42] therefore, if control of bleeding delays the taking of the impression, replacing the cord may be necessary.

Cord placement method

- Explore the gingival crevice around the anaesthetized tooth with a narrow flat plastic instrument – this will help indicate the appropriate diameter of cord to be used. It will also identify where the cord can be easily and securely anchored and so act as

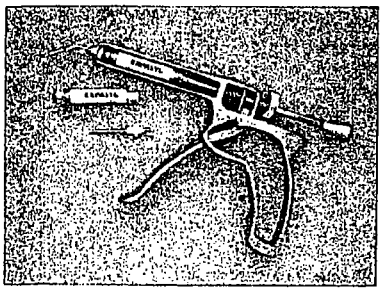

Figure 13. *Expasyl* gingival displacement equipment.

a reliable starting point from which to start cord packing.

- ☐ Cut a suitable length of cord and moisten with water or an astringent solution.
- ☐ Secure one end in the chosen anchor site using a narrow flat plastic instrument or preferably with a specifically designed cord packing instrument. Magnification will help to ensure that the cord is being pushed into the crevice and not against the gingivae or preparation margin.
- ☐ Simply packing vertically will tend to pull in the cord on either side, causing it to rise out of the crevice behind the packer (Figure 10). Rolling the instrument in the direction one is packing helps to avoid this (Figure 11); as does the use of two packers, where one instrument holds down the cord while the other packs the next section, stepping around the tooth (Figure 12). However, this is a more difficult technique to master.
- ☐ Inspect the preparation to ensure the margins can all be seen – place additional cord if required.
- ☐ Leave the cord for at least 4 minutes, but do not allow the tooth to dehydrate.
- ☐ After sufficient time, wash and dry the tooth before gently removing the cord (top cord in the two-cord technique). Washing, and especially forceful air-drying after cord removal, can encourage bleeding.
- ☐ Check the crevice for adequate displacement and watch for bleeding which can occur after a few seconds. Clear any coagulum and debris carefully with a CPITN probe. If necessary, dry the crevice with a gentle stream of air.
- ☐ If the conditions are right, proceed to the impression – if not, correct the situation; don't waste your expensive impression material.

Haemostatic agents

Pressure alone may not stem gingival bleeding, and it is not uncommon to apply an astringent liquid into the crevice and on to the cord before it is placed. These compounds are usually solutions of metal salts – chlorides and sulphates of aluminium and iron. The most effective astringent, ferric sulphate, is also the most aggressive in its effect on the tissues and can temporarily stain the gingivae black for 24–48 hours. They are all quite acidic,[43] and have the potential to etch dentine, opening its tubules, which may lead to sensitivity and allow bacteria to enter.[44] They also have a terrible taste, and must be placed with care. Some are presented as gels which can give greater control. Concerns over possible inhibition of the setting reaction of addition-cured silicones by the sulphate-containing astringents appear unfounded. Where this inhibition has occurred, it is thought that sulphur-containing additives from latex gloves rubbed on to the teeth have been responsible.[45]

Adrenaline solutions and impregnated cords are not recommended as they have the potential to cause serious systemic effects.[46] Using local anaesthesia has been shown to improve the quality of subsequent impressions.[47] This may be due to the haemostatic effect of the adrenaline contained in the solution when injected locally, but may also be because, once the gingivae are anaesthetized, retraction cords can be more effectively placed and vital teeth adequately dried without causing discomfort.

Expasyl (Kerr UK Ltd, Peterborough, UK) is an alternative mechanical displacement method. Consisting of a blend of kaolin(china clay) with the astringent aluminium chloride, it is presented in cartridges with a dedicated syringe and disposable wide bore delivery tubes (Figure 13). After tooth preparation, the thick, putty-like material is injected into the gingival crevice, which is thereby dilated. After 5 minutes it is removed by water spray, the preparation is dried and impression material can then flow into the opened and dried crevice. This has the distinct advantage of being probably the

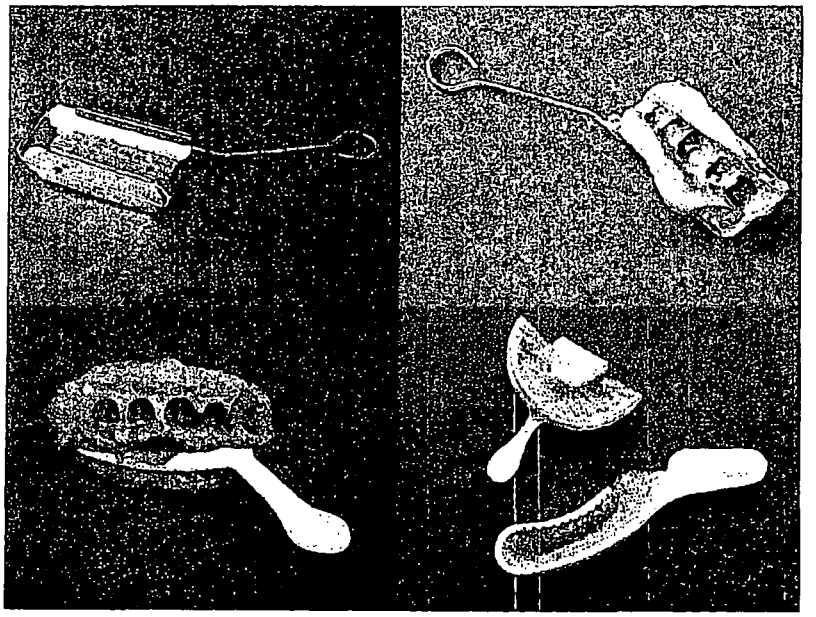

Figure 14. Metal (top) and plastic dual arch trays.

least traumatic, and therefore painless, displacement technique, and does not require additional anaesthesia for its use. However, it may not be sturdy enough to cope with thick gingivae, and cannot easily be used to protect the tissues while margins are being prepared.[48]

Gingival health

Problems of gingival bleeding and concerns about recession will be minimized if the gingivae are free from inflammation. This will be the case when the patient has good oral hygiene and any existing restorations have well-fitting and contoured margins. Dentists should not have to battle against bleeding gums to try and achieve decent impressions. Patients have increasing expectations regarding their dental care but, in turn, must be made aware of the impact poor gingival health will have on the quality of restorations and their responsibility to maintain that health. They also need to appreciate that provisional restorations may be required to allow effective cleaning and a return to stable tissue conditions before they can be provided with first class dentistry.[49]

Dual-arch impression

Also known as closed bite, triple tray or double arch impression, this method has been in use in the US for about five decades, but is still not widely used elsewhere. Various designs of trays are available which aim to achieve the simultaneous recording of the prepared tooth/teeth, the opposing teeth, and their intercuspal relationship (Figure 14). It offers several practical advantages over the traditional method. Less material is needed, it is quicker because both arches are recorded at the same time, and patients have been shown to prefer this technique over traditional full-arch impressions.[50] Laboratory investigations show that dies have comparable accuracy compared to those obtained from full-arch impressions,[51-52] and that the quality of restorations produced is at least equal to that which can be obtained with conventional full-arch impressions.[50,53] Both plastic and more rigid metal trays are available for posterior quadrants and the anterior sextant. No clear superiority has been demonstrated between either, nor between different viscosities of silicone.[52,54] However, if the patient's alveolae or palate contacts the tray on closing it will be distorted, giving an inaccurate result. As the plastic trays are more flexible, the patient may not notice the distortion and not alert the dentist. With any new technique there is a learning curve; this applies to the dentist and possibly even more so to the technician, so initial results may be inferior.[55] The impressions are shallow, and this makes them difficult to pour, and mounting can be problematic without specific cast relators. This method is not recommended for all situations, but where appropriate yields very good results, and has some real advantages.

Indications and requirements for dual-arch impressions are as follows:

- One or two units bounded by intact and opposed teeth;
- Stable, reproducible and obvious intercuspal position;
- Co-operative patient able to close directly into intercuspal position on request;
- Tray does not contact axial tooth surfaces, or the adjacent tissues on closure;
- In quadrant trays, there is space for the connector bar behind the last molars;
- Technician familiar with the specific pouring and mounting procedures.

A checklist for the dual-arch technique includes the following:

- Check that the tray can be placed into the appropriate position with the tray sidewalls out of contact with the tissues, ie is the tray wide enough?;
- Check that the patient can close with the tray in place, ie no contact. (This is best done before anaesthesia so the patient can identify any obstruction);
- Check that the patient can close repeatedly into intercuspal with tray in place, ie not contacting teeth on opposite side;
- Complete tooth preparation and cord placement if required;
- Apply adhesive to tray but not the gauze;
- Dry prepared tooth and remove cord – check haemostasis;
- Assistant fills top and bottom of tray (heavy or monophase) while the dentist syringes impression material around prepared tooth (light or monophase);
- Orient and seat tray over arch with prepared tooth;
- Ask patient to close (into intercuspal position) and maintain closure until instructed to open. Check correct closure using reference teeth noted previously;
- Once completely set, ask patient to open quickly and forcefully. Dentist completes removal from other arch.

Alternative techniques

Reversible/irreversible technique

While the dual-arch method is popular in the US, the use of irreversible with reversible hydrocolloid has been used in Sweden to fabricate indirect restorations with similar survival rates as those made with other impression materials.[56] Suggested in 1951 by Schwartz,[57] the combined use of reversible and irreversible hydrocolloid can produce casts of sufficient accuracy and detail on which to make indirect restorations.[58] A low viscosity reversible hydrocolloid is syringed over all the teeth to record fine detail, and an alginate in a stock tray is placed over it to contain the wash and fill the tray. The wash material is simple to keep fluid in a small heated water bath, ready for use. This method allows the operator to use inexpensive materials and gain the benefits of reversible hydrocolloids' hydrophilic properties and accuracy; using alginate as the tray material avoids the need for expensive bulky water-cooled trays. Poor dimensional stability and low tear strength are still a concern, and specific alginates formulated for this technique should be used to avoid the two materials separating on removal as can happen if a conventional alginate is used.

Injection techniques

The principal claimed advantage of the two-stage putty/wash method is that the low viscosity material can be driven in to the gingival crevice by the set putty, enhancing the definition of the margins. There is still the risk that the build-up of pressure which causes this may give rise to the problems of recoil. To avoid this, Lococo[59] described his hydrodynamic impression technique whereby a high viscosity silicone material is first used to obtain an impression of the teeth. Channels are cut into this, leading to the teeth to be prepared. After preparation and gingival displacement, the tray is reseated and a light-bodied material is

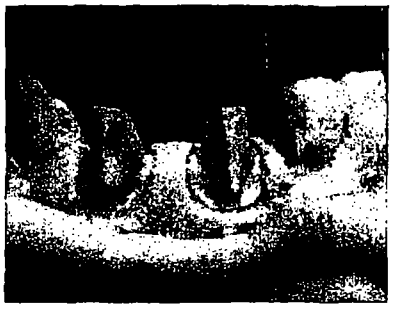

Figure 15. Extreme example of dies produced from impression with vertical drags as a result of poor flow of putty phase.

then injected through one hole until the excess is seen escaping from the other. The force of injection acts to push the wash material into the crevice, opening it further. Similar approaches have been described by Schoenrock[60] in his laminar impression technique using a dual-arch tray, and by Millar[61] with a full arch tray where the injection hole is sited over the occlusal surface of the prepared tooth with a buccal relief hole.

Matrix impressions

Despite improvements in material properties, capturing marginal detail can still be a problem which has inspired some alternative solutions. We need a material which has sufficient viscosity to be directed into the crevice and displace it (while being able to record detail), but then we need to prevent it from being displaced and the crevice collapsing, as more impression material is placed to record the rest of the arch. The now largely abandoned copper ring technique achieved some of these goals – the gingivae were displaced by a trimmed metal tube and the viscous thermoplastic compound, which was the impression material. An overall impression of the arch was made over the copper ring, usually in alginate, to relate the prepared tooth to the rest of the teeth. Improvements on this technique included substituting elastomers for the inflexible compound and alginate, and using plastic crown forms which are easier to adjust as the matrix.[62,63] Livaditis[64] has further extended this concept by using an initial impression of the prepared teeth taken in rigid occlusal registration type polyether. This is trimmed to the gingival margins and is then used as a matrix to carry a higher viscosity material which, as it is seated, drives the unset material into the gingival crevice. Once set, a third impression is taken in a conventional tray with a lower viscosity material over the matrix, which joins all three elements together. Martignoni,[65] in his 1990 text, describes using a putty silicone matrix and provisional restorations trimmed as before to carry a silicone foam which again is driven into the crevice, and held under pressure. In this case, however, the purpose is to achieve gingival displacement only; a conventional impression technique is then followed to produce the working cast. Recently, Coltene (Coltene/Whaledent Ltd, Burgess Hill, West Sussex, UK) have produced *Magic FoamCord*, which uses the same principle of a silicone which expands on setting to open the crevicular space prior to the working impression. It is syringed around the gingival margins, and then an appropriately sized cotton wool 'thimble' is positioned over the tooth and pressed down by the operator, and then by the patient's opposing teeth for five minutes. For multiple preparations, it is suggested that a putty in a sectional tray be used to provide the additional force. The action of the expanding foam and the pressure applied to the carrier opens the crevice atraumatically.

Troubleshooting

Impression pulling out of the tray

Increase the retention with more perforations of appropriate size and paint on the adhesive at least 5 minutes ahead. If there are deep tooth or tissue undercuts gripping the impression, block them out with soft wax or cotton wool.

Persistent bleeding

If persistent bleeding is the result of general inflammation of the tooth's gingivae:

- Provide a provisional restoration with good margins;
- Ensure that the patient can and will keep the area plaque free; and
- Delay impression taking for at least 10 days.

If, on the other hand, it is the result of bur damage, insert cord before preparing subgingival margins to deflect the gingivae. Local measures will usually cope with isolated bleeding points. Try burnishing a very small cotton wool pledget or microbrush soaked in ferric or aluminium sulphate directly against the site. Papillary injections of local anaesthesia can temporarily halt bleeding and are particularly useful if some oozing starts at the moment of placing the impression. The two cord technique gives better moisture control than a single cord.

Margin defects

These are more commonly seen with the one-stage putty wash method.

Horizontal ridges

These are not obvious unless deliberately looked for, and are often seen on the buccal/lingual side of prepared teeth when a one-stage putty wash technique has

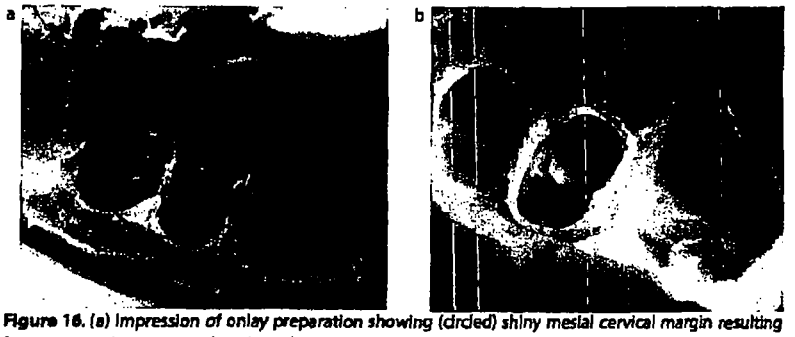

Figure 16. *(a) Impression of onlay preparation showing (circled) shiny mesial cervical margin resulting from poor moisture control, and no clear edge to the margin.* **(b)** *A further attempt made using a two-cord technique has achieved a dry field, and the margins are easily identified.*

been used. They represent poor blending of the two viscosities and do not occur on the interproximal areas as the materials are enclosed and there is a greater build-up of pressure here. Heat from the prepared tooth causes the wash in this area to start to react first and become more elastic, reducing its ability to homogenize with the putty. All addition-cured silicones should be placed as quickly as possible before the polymerization starts; chilling them, especially the wash material, gives the operator some extra time. Teardrop defects may be seen at the back of the last tooth, particularly on tall teeth and at edentulous areas as the putty escapes posteriorly. The tray needs to be closed off with self-cure acrylic or greenstick additions. In a two-stage technique, the wash material will fill up any such putty defects.

Vertical drags

Commonly seen extending from below undercuts when one-stage putty impressions are taken (Figure 15). This is again owing to the poor flow characteristic of putties preventing them adapting well to irregular contours. Where marked undercuts present on prepared teeth, use a two-stage, or a heavy-light combination. The sensitivity of the polymerization reaction to temperature of the vinyl polysiloxanes can also contribute to drags. If partial setting occurs, the material's ability to flow will be reduced. Refrigerating these materials and ensuring their rapid placement once mixed should prevent this problem. Allowing additional time before removing the impression, beyond the manufacturer's recommendations, will ensure that complete cure has occurred.

Margin defects

Voids are the result of air or moisture inclusions. Hand-mixing is more likely to trap air within the mix than using the more current auto-mix guns. When injecting wash materials, ensure that the tip remains within the expressed material and pushes it ahead while moving around the preparation margin. If grooves or boxes have been included in the resistance form, fill the base of these first and move the syringe tip up to the occlusal surface. The appearance of rounded polished margins in the impression indicates a wet surface (Figure 16). Small teardrop defects can occur as small amounts of fluid within the gingival crevice are driven around the crevice by impression material, and then across the margin as the tooth is completely encircled. Thorough but gentle use of the air syringe should avoid this, but also consider using a two cord technique. Unclear margins may be due to poor preparation, or inadequate gingival displacement. Where margins are at or below the gingival crest, some form of gingival displacement is essential and needs to provide sufficient separation of the gingivae from the tooth for the technician to identify the preparation's limits.

Conclusions

Obtaining impressions of sufficient detail and accuracy for the construction of indirect restorations is dependent on the interplay of several factors. Modern materials are more user-friendly than their predecessors but can still produce poor results if not manipulated correctly. The increased choice of viscosities now available brings with it the need to understand how best to use them. Inappropriate use of trays, poor moisture control, and inadequate retraction methods will negate the potential of the best impression material. Dentists should have an appreciation of all these factors, and understand how each influences their results. More critical examination (with magnification) of impressions, and especially the resulting casts before they are trimmed, may reveal defects which can be corrected in the future, if the clinician can recognize how each has been caused. The apparently small details of technique are important and can mean the difference between impressions which visually appear adequate and ones which are truly accurate. Going to these lengths will result in restorations which fit more accurately and require less adjustment. Not only will chairside time be saved, but patients will feel more confident, your technician will be happier to make your restorations and, most importantly, your job satisfaction will increase.

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Cochrane Synopses

M Esposito, P Coulthard, P Thomsen, HV Worthington. Interventions for *replacing missing teeth: different types of* dental implants. *The Cochrane Database of Systematic Reviews* 2005, Issue 1. Art. No.: CD003815. DOI: 10.1002/14651858. CD003815.pub2.

'There is limited evidence showing that implants with relatively smooth surfaces are less prone to loose bone due to chronic infection (perimplantitis) than implants with rougher surfaces. However, there is no evidence showing that any particular type of dental implant has superior long-term success.

Missing teeth can sometimes be replaced with dental implants into the jaw, as bone can grow around the implant. A crown, bridge or denture can then be attached to the implant. Many modifications have been developed to try to improve the long-term success rates of implants, and different types have been heavily marketed. More than 1300 types of dental implants are now available, in different materials, shapes, sizes, lengths and with different surface characteristics or coatings. However, the review found there is not enough evidence from trials to demonstrate superiority of any particular type of implant or implant system.'

JM Zakrzewska, H Forssell, AM Glenny. Interventions for the treatment of burning mouth syndrome. *The Cochrane Database of Systematic Reviews* 2005, Issue 1. Art. No.: CD002779. DOI: 10.1002/14651858. CD002779.pub2.

'There is insufficient evidence to show the effect of painkillers, hormones or antidepressants for 'burning mouth syndrome' but there is some evidence that learning to cope with the disorder, anticonvulsants and alpha-lipoic acid may help.

A burning sensation on the lips, tongue or within the mouth is called 'burning mouth syndrome' when the cause is unknown and it is not a symptom of another disease. Other symptoms include dryness and altered taste and it is common in people with anxiety, depression and personality disorders. Women after menopause are at highest risk of this syndrome. Painkillers, hormone therapies, antidepressants have all been tried as possible cures. This review did not find enough evidence to show their effects. Treatments designed to help people cope with the discomfort and the use of alpha-lipoic acid may be beneficial. More research is needed.'

JV Keenan, AG Farman, Z Fedorowicz, JT Newton. Antibiotic use for irreversible pulpitis. *The Cochrane Database of Systematic Reviews* 2005, Issue 2. Art. No.: CD004969. DOI: 10.1002/14651858. CD004969.pub2.

'Antibiotics do not appear to significantly reduce toothache caused by irreversible pulpitis.

Irreversible pulpitis, where the dental pulp (nerve) has been damaged beyond repair is characterised by intense pain and considered to be one of the most frequent reasons that patients attend for emergency dental care. This review, which included 1 trial (40 participants), found that there is a small amount of evidence to suggest that the administration of penicillin does not significantly reduce the pain perception, the percussion perception or the quantity of pain medication required by patients with irreversible pulpitis.'

An Innovative Tissue-Retraction Material

CE 3

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Private Practice
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Abstract: *One of the most challenging problems of fixed prosthodontics is tissue control. Gingival retraction before a final impression can be very frustrating and time consuming. Many different techniques have been developed over the years to accommodate the clinician's struggle to obtain tissue control and achieve an ideal impression. This article discusses several of those techniques and how the new, innovative product Expa-syl™ can be incorporated into these techniques. Expa-syl™ is an injectable retraction and hemostatic agent that can cause little trauma to the tissue as well as save the dentist time and money. The author elaborates on the multiple uses of Expa-syl™ and the correct techniques for making this material a successful tool in any dental office.*

Four gingival retraction techniques are described in this article: rotary curettage, electrosurgery, retraction cord, and a new injectable retraction material.[1]

Rotary Curettage Method

The first technique, rotary curettage, has two main advantages: it is easy to perform and it requires no special equipment. It is also the least expensive of the four techniques presented here. Although rotary curettage is one of the easiest techniques, it has numerous disadvantages. The bleeding it can cause can be difficult to control, which can make the final impression difficult to obtain. The amount of tissue that can be removed is limited, and there is also a great deal of patient discomfort.

Electrosurgery Method

The second technique for tissue control is electrosurgery.[2] The main advantage to electrosurgery is that posthemorrhage is well controlled provided the tissue is not inflamed. However, there are multiple disadvantages with electrosurgery. The first is the unpredictable way in which the tissue will heal. In an anterior tooth there would be considerable concern about the possibility of recession. Second, if the clinician is not careful, and too much heat is generated, there could be a considerable amount of collateral damage to the surrounding tissue. Third, caution must be used in patients with pacemakers as well as patients undergoing radiation therapy.

Retraction Cord Method

Retraction cords are the most common method for retracting tissue.[3] There are two main techniques: the single cord and the double cord. The choice of cord depends on the amount of tissue that needs to be retracted. There are three advantages to the cord technique. First, it is the most universal technique used today. Second, there is a variety of cords that can be used to achieve different results and different degrees of retraction. Third, retraction cord is very inexpensive. However, in some instances, cord can provide a challenge for the clini-

Learning Objectives

After reading this article, the reader should be able to:

- discuss different types of gingival retraction methods.
- compare different types of hemostatic agents.
- discuss predictable techniques for the use of Expa-syl™.

CE 3

Figure 1A—Gingival irritation after post-and-core buildup.

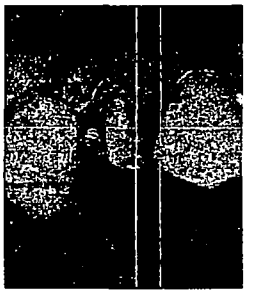

Figure 1B—Expa-syl™ needle placed to the long axis of the tooth.

Figure 1C—Injecting the Expa-syl™.

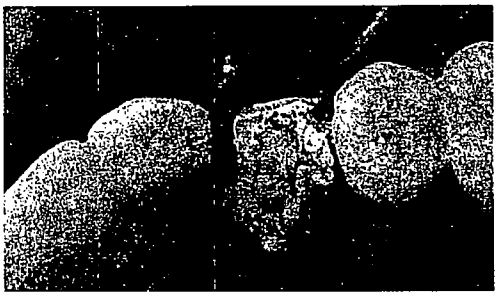

Figure 1D—Expa-syl™ placed around the entire tooth.

Figure 1E—Rinsing Expa-syl™ with air and water.

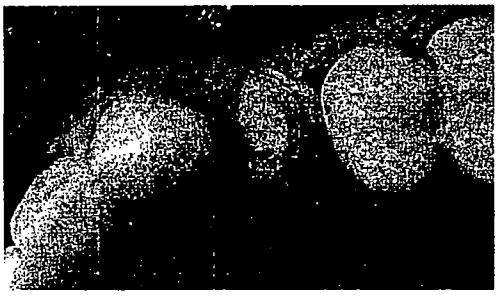

Figure 1F—Dry field is ready for impression.

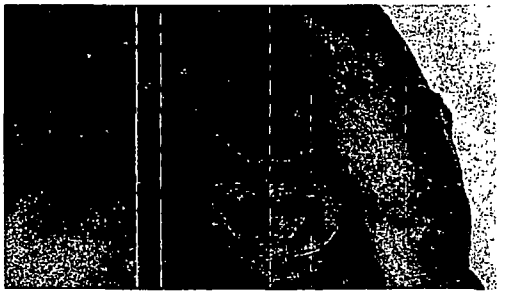

Figure 1G—Final polyvinyl impression exhibiting accurate marginal replication.

cian. Positioning the cord in a shallow sulcus can be quite difficult and runs the risk of creating a lesion in the epithelial attachment. There is also a risk of bleeding upon removal of the cord. The double-cord technique presents some of the same challenges as the single-cord technique. Additionally, anesthesia will most likely have to be used and chairtime is increased dramatically.[3]

There is also a variety of hemostatic agents that can be used in conjunction with retraction cord. Aluminum chloride provides hemostasis by constricting the blood vessels in the gingival tissues. It is the least reactive agent with polyvinyl impressions.[4] Ferric sulfate provides hemostasis by cauterizing the tissue. The downside is that ferric sulfate turns the tissue black and may inhibit the setting of the impression material.[5] Aluminum sulfate controls bleeding by constricting the blood vessels, but patients complain about the bitter taste. While epinephrine is also a popular agent used with retraction cord to control bleeding, its vasoconstrictive properties can lead to problems with some patients because it can increase the heart rate. The patient's health history is critical when deciding whether to use epinephrine for hemostasis.

Injectable Retraction Method

A fourth technique for gingival retraction and hemostasis recently became available—

CE 3

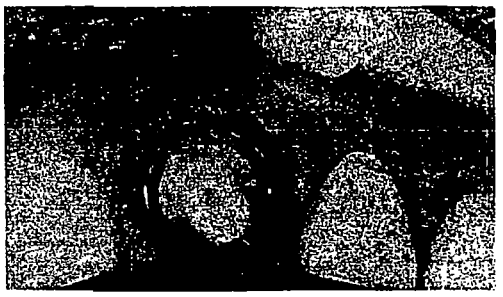

Figure 2A—Gingival irritation after the crown is removed.

Figure 2B—Injecting Expa-syl™ around the tooth.

Figure 2C—Injecting Expa-syl™ around the tooth.

Figure 2D—Dry sulcus is ready for impression.

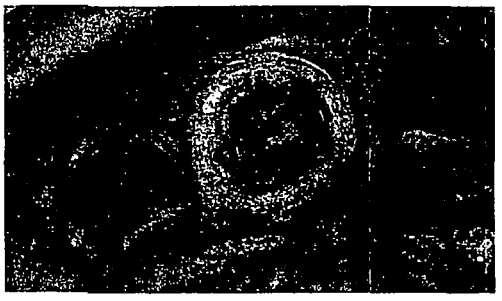

Figure 2E—Polyvinyl impression with clear margins.

Expa-syl™[3]—a new, innovative material from the Kerr® Corporation. The aim of the Expa-syl™ system is to detach the marginal gingiva without injuring the epithelial attachment. With Expa-syl™, exposure of the sulcus no longer causes bleeding or oozing. The system consists of an injectable material that contains a hemostatic agent, a specially designed gun, and tips. This injectable material is prepackaged in a carpule. Expa-syl™ consists of a highly viscous organic binder, kaolin, which is essentially clay. A small amount of aluminum chloride is mixed with the kaolin to act as a hemostatic agent. Because of its consistency, Expa-syl™ can displace tissue and, because of the aluminum chloride, will act as a hemostatic agent. Unlike cord, Expa-syl™ does not have to be placed around the entire tooth in every situation; it is used only where needed.

There are many advantages to this system, such as convenience and reduced chair-time. Because the delivery of Expa-syl™ is gentle to the tissue, the risk of damage to the epithelial attachment, gingival recession, and bone resorption is greatly reduced. Expa-syl™ is a viscous paste that can be injected directly into the sulcus. It not only opens the sulcus, but also leaves the field dry, ready for an impression or cementation. Expa-syl™ creates and maintains space in the sulcus, although there is no change in the material once it is applied—there is no chemical reaction, material expansion, or trauma to the tissue. The aluminum chloride controls the bleeding and, along with the kaolin, keeps the working field dry.

The physical properties of Expa-syl™ are remarkable. Expa-syl™ exhibits a yield stress higher than the force exerted on the tooth by the gingiva. Therefore, it is able to keep the gingival sulcus open. The forces exhibited by Expa-syl™ are still nearly 20 times less than that of a single cord and almost 50 times less than the double-cord technique.[6] When

[3] Kerr® Corporation, Orange, CA 92867; 800-537-7123

CE 3

Figure 3A—Gingival seepage before cementation.

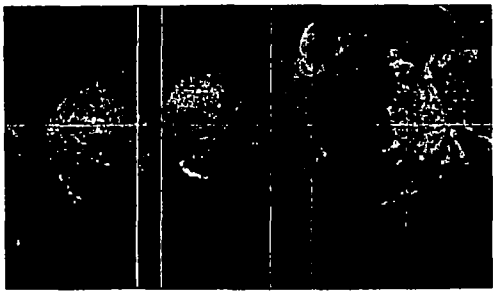

Figure 3B—Expa-syl™ placed to control gingival seepage.

Figure 3C—After rinsing Expa-syl™ away, the tooth is ready for cementation.

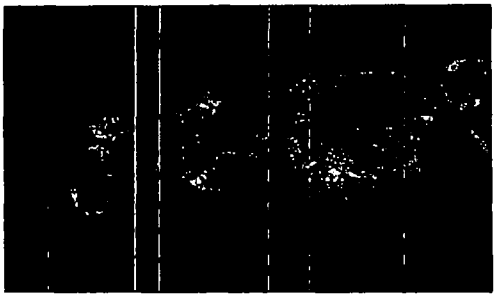

Figure 3D—The ceramic crown is successfully cemented in place.

Expa-syl™ absorbs moisture, the yield stress drops dramatically. It is very important to keep the Expa-syl™ as dry as possible, especially from saliva.[6]

Case 1

A 52-year-old man presented with tooth No. 4 broken off at the gingival. A post-and-core was placed (Figure 1A). The gingival tissue was irritated and inflamed. It is best for the field to be dry before placing Expa-syl™; however, in this situation it was very difficult to do so. The tip on the Expa-syl™ was placed at a 90-degree angle to the long axis of the tooth (Figures 1B and 1C). If possible, it is best to use the tip to mechanically displace the tissue as the material is injected. Because there was bleeding around the entire tooth, Expa-syl™ was placed accordingly (Figure 1D). The aluminum chloride in Expa-syl™ was sufficient to stop the bleeding and dry the field for the final impression. After only 2 minutes, a heavy blast of air and water was used to flush out the Expa-syl™ (Figure 1E). Even with the heavy pressure of the air and water, there was no seepage of blood or any other gingival fluids (Figure 1F). The tissue remained sufficiently retracted to make a polyvinyl impression (Figure 1G).

Case 2

A 29-year-old woman wanted to enhance the esthetics of tooth No. 9. She had an existing porcelain-fused-to-metal crown in which the margins were subgingival. After the crown was removed, there was a considerable amount of gingival hemorrhaging (Figure 2A). Expa-syl™ was placed for 2 minutes (Figures 2B and 2C). After rinsing thoroughly, the field was dry enough to make a polyvinyl impression using materials such as Take One®[a] or Aquasil™[b] (Figures 2D and 2E). In this instance it would have been very difficult to pack cord and not cause excess trauma to the tissue.

Case 3

Expa-syl™ is also an excellent material to use during cementation. Often, provisionals can lead to gingival irritation. The clinician can control the placement of Expa-syl™ to exactly where it is needed, and once it is rinsed off, the tooth is ready for cementation whether it is conventionally cemented or the restoration is bonded in place. In this situation, after the provisional was removed, Expa-syl™ was used to dry any gingival seepage (Figures 3A and 3B). The restoration could now be bonded

[6] DENTSPLY®/Caulk®, Milford, DE 19963; 800-LD-CAULK

in place (Figures 3C and 3D).

Expa-syl™ also can be used for Class V restorations that require gingival retraction. The techniques used in such cases are the same as described earlier.

Conclusion

Expa-syl™ offers many advantages to the patient as well as to the clinician. Expa-syl™ represents certainty of obtaining access to the true anatomical cervical margin. When Expa-syl™ is removed, the clinician can obtain a clean clinical site that is ideal for a perfect impression. It is quick and easy for the dentist, saving valuable chairtime. The procedure is painless for the patient, and anesthesia is no longer required because there is no damage to the sulcus. Expa-syl™ can change the way clinicians manage tissue in a variety of restorative procedures, providing a win-win situation for both the clinician and the patient.

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Chapter 5.

Hemostatics, Astringents and Gingival Retraction Cords

Kenneth H. Burrell, D.D.S., S.M.; Michael Glick, D.M.D.

Hemostatics

An understanding of hemostasis, identification of patients with excessive bleeding tendencies, and interventions to stop abnormal bleeding is essential to the provision of safe and appropriate dental care.

Hemostasis can be divided arbitrarily into four phases: a vascular phase and a platelet phase, also referred to as "primary hemostasis"; and a coagulation phase and a fibrinolytic phase, also referred to as "secondary hemostasis."

Defects in any phase of normal hemostasis have characteristic signs and symptoms. Most commonly, dental health care providers will be faced with patients who have defects of the platelet and coagulation phases.

People with quantitative or qualitative platelet disorders usually have superficial signs such as petechiae and ecchymosis on the mucosa and skin. Furthermore, patients may report spontaneous gingival bleeding, epistaxis, prolonged postextraction bleeding or prolonged bleeding after minor trauma. Spontaneous clinical hemorrhage is usually present when the platelet count drops below 15,000-20,000/mm^3. (For normal laboratory values, see Appendix H.)

The clinical value of a bleeding time for dental procedures has been challenged. However, significant prolonged bleeding times beyond 15-20 min may suggest significant hemorrhage after dental surgery.

Causes of defects of primary hemostasis include congenital as well as acquired disorders. The most common inherited bleeding disorder in the United States is von Willebrand's disease. This disorder is characterized by various degrees of deficiency of the von Willebrand factor, which is needed primarily for platelet adhesion. In severe cases of von Willebrand's disease, spontaneous bleeding may occur. However, mild cases may be associated with prolonged bleeding only after major trauma. Common acquired dysfunctions of primary hemostasis include idiopathic thrombocytopenia purpura, liver disease and drug-induced platelet disorders. Also, both acute and chronic leukemia are associated with thrombocytopenia. Some medications are used intentionally to decrease platelet functions, such as aspirin-containing medications and ticlopidine, in patients with disorders such as coronary artery disease.

Disorders of secondary hemostasis include hemophilia, vitamin K deficiency and liver disease. Hemophilia is usually classified according to the specific factor deficiency, such as hemophilia A for factor VIII deficiency and hemophilia B for factor IX deficiency. Patients with hemophilia lack the ability to form fibrin and have bleeding episodes particularly within stress-bearing joints (deep-seated

bleeding). This eventually can cause destruction of these joints.

General dentistry can be performed in patients with > 50% factor activity, but 100% activity is recommended for surgical procedures. In a 60-kg patient with hemophilia A, a 100% plasma level equals 6,000 units of factor VIII.

Vitamin K deficiency causes decreased activation and production of factors II, VII, IX and X, resulting in a defective coagulation cascade and consequent decreased fibrin production. Virtually all coagulation factors are produced in the liver, and vitamin K is stored in the liver. Thus, liver disease may result in increased bleeding tendencies. Medications such as warfarin, an anticoagulant that impairs the action of vitamin K, is used to prevent thrombosis in patients with such disorders as atrial fibrillation, deep venous thrombosis, ischemic cardiovascular disease and stroke.

A thorough medical history, examination and laboratory evaluation will identify most patients who have increased bleeding tendencies. Included in the patient assessment should be questions addressing whether the patient has relatives with bleeding problems, has experienced prolonged bleeding after trauma, or takes medications or has diseases associated with increased bleeding tendencies. Examination should focus on signs of bruising, jaundice, hyperplastic gingival tissue, spontaneous gingival bleeding and hemarthrosis. Screening tests for impaired hemostasis include platelet count and bleeding time for primary hemostasis, as well as prothrombin time, international normalization ratio, activated partial thromboplastin time and thrombin time for secondary hemostasis. (See Appendix H for normal values.)

Dental treatment of patients with impaired hemostasis includes the use of both local and systemic measures. The use of the appropriate technique or agent depends on the patient's underlying condition and specific hemostatic impairment.

Accepted Indications

If blood flow is profuse, mechanical aids such as a compress, hemostatic forceps, a modeling compound splint or hemostatic ligatures can be used. Mechanical obliteration with cryosurgery, electrocauterization and laser also can be used. Although these thermal methods are effective, they may be associated with impaired healing. A third kind of mechanically aided hemostasis is the use of chemical glues, such as n-butyl cyanoacrylate and bone wax. These compounds have a mechanical effect without directly affecting the coagulation process.

For slow blood flow and oozing, a combination of hemostatics can be used. The three kinds of hemostatics to be noted here are absorbable hemostatic agents, agents that modify blood coagulation and vasoconstrictors. Vasoconstrictors act by constricting or closing blood vessels. They are used to a limited extent to control capillary bleeding. Vasoconstrictors are described in detail in Chapter 1 (Tables 1.3, 1.6). See Table 5.1 for a comparison of various hemostatics useful in dentistry.

Absorbable Gelatin Sponge

The absorbable gelatin sponge consists of a tough, porous matrix prepared from purified pork skin gelatin, granules and water that is indicated as a hemostatic device for control of capillary, venous or arteriolar bleeding when pressure, ligature or other conventional procedures are either ineffective or impractical. It can be used in extraction sites and is absorbed in 4-6 w.

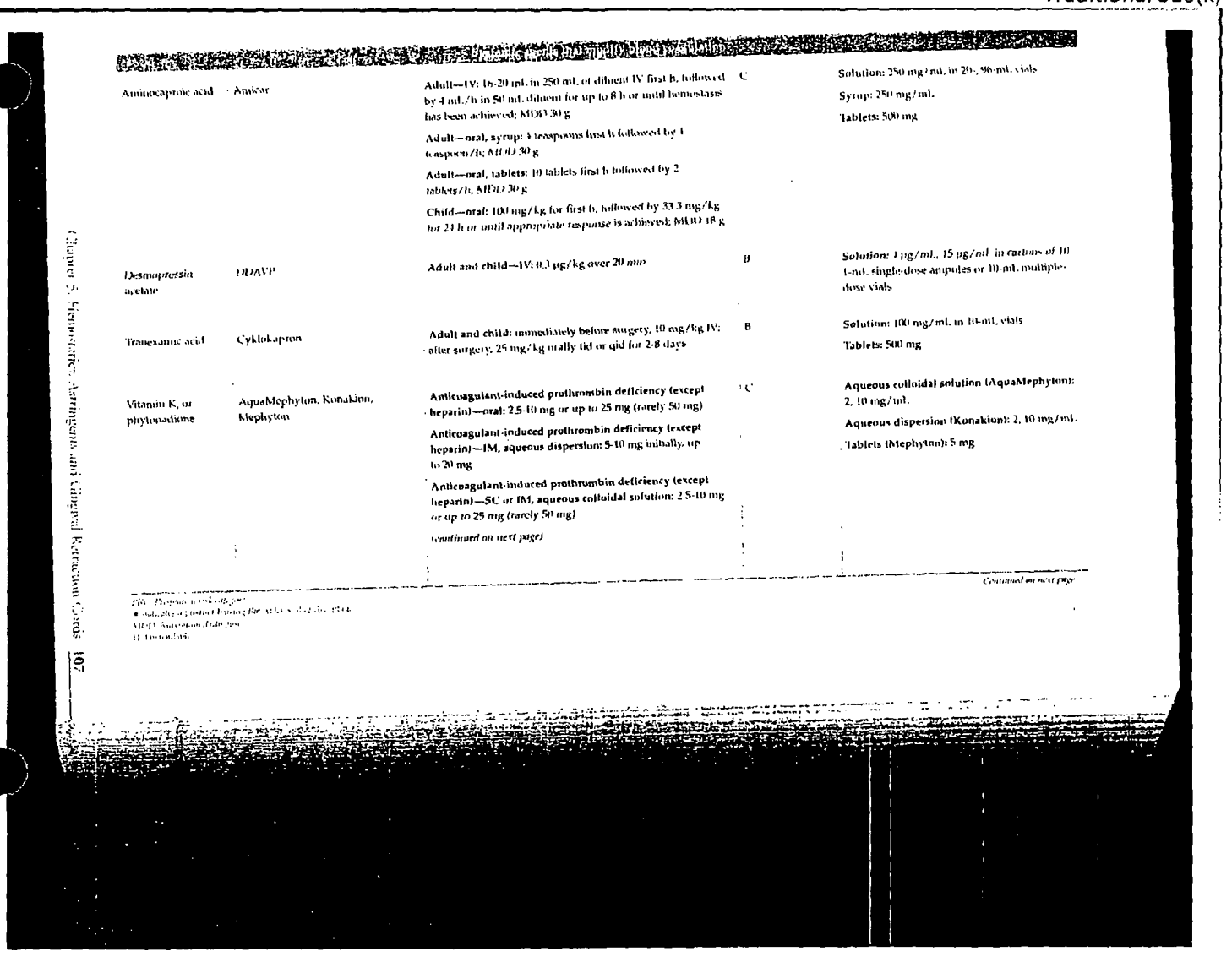
Oxidized Cellulose

Oxidized cellulose is a chemically modified form of surgical gauze or cotton that is used to control moderate bleeding by forming an artificial clot when suturing or ligation is impractical and ineffective. Because it is friable, oxidized cellulose is difficult to place and retain in extraction sockets, but can be used as a sutured implant or temporary pack-

Table 5.1

Hemostatics: Dosage and Prescribing Information

Generic name	Brand name(s)	Dosage	PRC	Form
		Topical that locally coagulates		
Absorbable gelatin sponge	*Gelfoam*	*Absorbable gelatin sponge may be cut; may be applied to* bleeding surfaces to cover area	U	**Dental packing blocks:** 20 × 20 × 7 mm **Powder:** 1 g
Oxidized cellulose	Oxycel	Hemostatic effect is greater when material is applied dry as opposed to moistened with water or saline	U	**Pad:** 3 × 3 in **Pledget:** 2 × 1 × 1 in **Strip:** 18 × 2, 3 × ½, 36 × ½ in
Oxidized regenerated cellulose	Surgicel Absorbable Hemostat ®, Surgicel Nu-Knit Absorbable Hemostat	Can be laid over extraction socket for control of bleeding; minimal amounts of the material should be placed on bleeding site; may be held firmly against tissue	U	**Surgicel sheets:** 2 × 14, 4 × 8, 2 × 3, ½ × 2 in **Surgicel Nu-Knit sheets:** 1 × 1, 3 × 4, 6 × 9 in
Microfibrillar collagen hemostat	Avitene, Collacote ®, Collaplug, Collatape ®, Instat MCH	Is applied topically and adheres firmly to bleeding surfaces	U	**Avitene Flour:** ½-, 1-, 5-g syringes **Avitene Sheets:** 35 × 35, 70 × 35, 70 × 70 mm **Collacote, Collaplug, Collatape:** 1 × 3, ¾ × 1½, ⅛ × ¾ in **Instat MCH:** Coherent fibers packaged in 0.5- and 1.0-g containers
Collagen hemostat	Instat	Should be applied directly to bleeding surface with pressure; is more effective when applied dry, or may be moistened with sterile saline or thrombin solution; may be left in place as necessary; is absorbed 8-10 w after placement	U	**Pads:** 1 × 2, 3 × 4 in



Aminocaproic acid	Amicar	Adult—IV: 16-20 mL in 250 mL of diluent IV first h, followed by 4 mL/h in 50 mL diluent for up to 8 h or until hemostasis has been achieved; MDD 30 g Adult—oral, syrup: 4 teaspoons first h followed by 4 teaspoon/h; MDD 30 g Adult—oral, tablets: 10 tablets first h followed by 2 tablets/h; MDD 30 g Child—oral: 100 mg/kg for first h, followed by 33.3 mg/kg for 24 h or until appropriate response is achieved; MDD 18 g	C	Solution: 250 mg/mL in 20-, 96-mL vials Syrup: 250 mg/mL Tablets: 500 mg
Desmopressin acetate	*DDAVP*	Adult and child—IV: 0.3 μg/kg over 20 min	B	*Solution: 1 μg/mL, 15 μg/mL in cartons of 10 1-mL single-dose ampules or 10-mL multiple-dose vials*
Tranexamic acid	Cyklokapron	Adult and child: immediately before surgery, 10 mg/kg IV; after surgery, 25 mg/kg orally tid or qid for 2-8 days	B	Solution: 100 mg/mL in 10-mL vials Tablets: 500 mg
Vitamin K, or phytonadione	AquaMephyton, Konakion, Mephyton	Anticoagulant-induced prothrombin deficiency (except heparin)—oral: 2.5-10 mg or up to 25 mg (rarely 50 mg) Anticoagulant-induced prothrombin deficiency (except heparin)—IM, aqueous dispersion: 5-10 mg initially, up to 20 mg Anticoagulant-induced prothrombin deficiency (except heparin)—SC or IM, aqueous colloidal solution: 2.5-10 mg or up to 25 mg (rarely 50 mg) *(continued on next page)*	C	Aqueous colloidal solution (AquaMephyton): 2, 10 mg/mL Aqueous dispersion (Konakion): 2, 10 mg/mL Tablets (Mephyton): 5 mg

Continued on next page

Table 5.1 (cont.)

Hemostatics: Dosage and Prescribing Information

Generic name	Brand name(s)	Dosage	PRG	Form
Vitamin K_1 or phytonadione (cont.)		**Hypoprothrombinemia owing to other causes and factors limiting absorption or synthesis—SC or IM, aqueous colloidal solution:** 2.5-25 mg or more (rarely up to 50 mg) **Hypoprothrombinemia owing to other causes and factors limiting absorption or synthesis—IM, aqueous dispersion:** 2-20 mg **Hypoprothrombinemia owing to other causes and factors limiting absorption or synthesis—oral:** 0.5-25 mg or more (rarely up to 50 mg)		
Vitamin K_3 or menadione	generic	2-10 mg/day, 4-7 days before surgery	U	**Powder**
Vitamin K_3 or menadiol sodium diphosphate	Synkayvite	**Injection:** 5-10 mg q day, 4-7 days **Oral:** 5 mg q day, 4-7 days	U	**Injection:** 5, 10, 37.5 mg/ml. **Tablets:** 5 mg
Thrombin	Thrombin-JMI, Thrombinar, Thrombogen, Thrombostat	**For profuse bleeding—solution:** 1,000-2,000 units/ml **For bleeding from skin or mucosa—solution:** 100 units/ml.	C	**Powder:** 1,000, 5,000, 10,000, 20,000 units; 50,000 units (Thrombinar only) **Powder with isotonic saline diluent:** 5,000-, 10,000- and 20,000-unit containers with 5-, 10-, and 20-ml, of isotonic saline **Thrombostat:** Also contains 0.02 mg/ml. phenerol as a preservative

ing. The cotton or gauze can be removed before dissolution is complete by irrigation with saline or a mildly alkaline solution.

Absorption of oxidized cellulose ordinarily occurs between the second and seventh day after implantation of material, but complete absorption of large amounts of blood-soaked material may take six weeks or longer.

Oxidized Regenerated Cellulose

Oxidized regenerated cellulose is prepared from alpha-cellulose by reaction with alkali to form viscose, which is then spun into filaments and oxidized. This process results in greater chemical purity and uniformity of physical structure than oxidized cellulose. It is a sterile, absorbable, knitted fabric that is strong enough to be sutured or cut. It has less tendency to stick to instruments and gloves and is less friable than oxidized cellulose.

Oxidized regenerated cellulose is used to control capillary, venous and small arterial hemorrhage when ligature, pressure, or other conventional methods of control are impractical or ineffective. The product can be used as a surface dressing because it does not retard epithelialization. It is bactericidal against numerous gram-negative and gram-positive microorganisms, both aerobic and anaerobic.

It can be placed over extraction sites.

Microfibrillar Collagen Hemostat

Microfibrillar collagen hemostat is a hemostatically active agent prepared from bovine deep flexor tendon (Achilles tendon) as a water-soluble, partial-acid salt of natural collagen. It reduces bleeding from surgical sites such as those involving cancellous bone and gingival graft donor sites. It should not be left in infected or contaminated spaces because it may prolong or promote infection and delay healing.

Collagen Hemostat

Collagen hemostat is absorbable and composed of purified and lyophilized bovine dermal collagen. Used as an adjunct to hemostasis, collagen absorbable hemostat can be sutured into place. It reduces bleeding when ligation and other conventional methods are ineffective or impractical. Excess material should be removed before the wound is closed.

Aminocaproic Acid

Aminocaproic acid, or ε-aminocaproic acid, is used in patients with excessive bleeding due to underlying conditions such as systemic hyperfibrinolysis and coagulopathies stemming from promyelocytic leukemia. This medication is seldom used for elective oral surgery procedures, but rather during emergency situations in combination with transfusion of fresh frozen blood and fibrinogen.

Desmopressin Acetate

Desmopressin acetate is used primarily to reduce spontaneous bleeding in patients with von Willebrand's disease and in patients with moderate-to-mild hemophilia A (factor VIII levels above 5%). It also is used prophylactically during procedures to reduce the incidence of bleeding, as well as after procedures to achieve better hemostasis in these patient populations.

Tranexamic Acid

Tranexamic acid is used primarily to reduce the amount of factor replacement necessary after dental extractions in hemophiliac patients. It is indicated for only 2-8 days during and after the dental procedure. It also is used for other patient populations with impaired secondary hemostasis, including patients who are receiving anticoagulation therapy.

Vitamin K

Vitamin K therapy is required when hypoprothrombinemia results from inadequately available vitamins K_1 and K_2. This occurs when there is decreased synthesis by intestinal bacteria, inadequate absorption from the intestinal tract or increased requirement by the liver for normal synthesis of prothrombin.

Vitamin K, in its various forms, is an essential component of blood coagulation. Vitamins K_1, K_2 or menadione (vitamin K_3) are required for the production of the functional

forms of six coagulation proteins: prothrombin, factors VII, IX and X and proteins C and S.

Phytonadione (vitamin K_1)

Phytonadione—known as vitamin K_1—is used for

- anticoagulant–induced prothrombin deficiency;
- prophylaxis and therapy of hemorrhagic disease of the newborn;
- hypoprothrombinemia resulting from oral antibacterial therapy;
- hypoprothrombinemia secondary to factors limiting absorption or synthesis of vitamin K such as obstructive jaundice, biliary fistula, sprue, ulcerative colitis, celiac disease, intestinal resection, cystic fibrosis of the pancreas and regional enteritis;
- other drug-induced hypoprothrombinemia such as that which results from salicylate use.

Menadione (vitamin K_3)

Menadione is a synthetic form of vitamin K, which is sometimes referred to as vitamin K_3.

Menadiol sodium diphosphate (vitamin K_4)

Menadiol sodium diphosphate is effective as a hemostatic agent only when bleeding results from prothrombin deficiency.

Thrombin

Thrombin is useful as a topical local hemostatic agent when blood is oozing from accessible capillaries or venules. In certain kinds of hemorrhage, it can be used to wet pledgets of absorbable gelatin sponge and placed on bleeding tissue or in extraction sockets with or without sutures. It is particularly useful whenever blood is flowing from accessible capillaries and small venules.

General Dosing Information

Table 5.1 lists the general dosing information for specific hemostatics.

Dosage Adjustments

The actual dose for each patient must be individualized according to factors such as his or her size, age and physical status. Reduced doses of vitamin K may be indicated for patients who are taking anticoagulants as opposed to those who have malabsorption problems. The other hemostatic agents should be used as needed.

Special Dental Considerations

Cross-Sensitivity

Patients may experience delayed healing using the gelatin, cellulose and collagen hemostatics. This is more often observed when the surgical site is infected.

Patient Monitoring: Aspects to Watch

Patients receiving vitamin K, especially parenterally, may experience allergic reactions such as rash, urticaria and anaphylaxis.

Adverse Effects and Precautions

The incidence of adverse reactions to hemostatic agents is relatively low. Many reactions are temporary. Idiosyncratic and allergic reactions account for a small minority of adverse responses. See Table 5.2.

Pharmacology

Absorbable Gelatin Sponge

The absorbable gelatin sponge promotes the disruption of platelets and acts as a framework for fibrin, probably because of its physical effect rather than the result of its alteration of the blood clotting mechanism. It can be placed in dry form or may be moistened with sterile saline or thrombin solution and used in extraction sites.

Oxidized Cellulose

Oxidized cellulose is a chemically modified form of surgical gauze or cotton. Its hemostatic action depends on the formation of an artificial clot by cellulosic acid, which has a marked affinity for hemoglobin.

Oxidized Regenerated Cellulose

Oxidized regenerated cellulose probably serves as a hemostatic by providing a physi-

Table 5.2

Hemostatics: Adverse Effects, Precautions and Contraindications

Agent	Adverse effects	Precautions/contraindications
	Absorbable hemostatic agents	
Oxidized cellulose	May lead to a foreign-body reaction	Extremely friable and difficult to place Should not be used at fracture sites because it interferes with bone regeneration Should not be used as a surface dressing except for the immediate control of hemorrhage, as cellulosic acid inhibits epithelialization Should not be used in combination with thrombin because the hemostatic action of either alone is greater than that of the combination
Oxidized *regenerated* cellulose	NS	Placement in extraction sites may delay healing; it should not be placed in fracture sites because it may interfere with callus formation and may cause cyst formation Encapsulation of fluid and foreign bodies possible
Collagen hemostat	Incidence of pain has been reported to increase when this material is placed in extraction sockets Allergic reactions can occur in patients with known sensitivity to bovine material	Should not be used in mucous membrane closure because it may interfere with healing due to mechanical interposition Should not be left in infected or contaminated space because of possible delay in healing and increased likelihood of abscess formation Should not be used in patients with a known sensitivity to bovine material Should not be overpacked because collagen absorbable hemostat absorbs water and can expand to impinge on neighboring structures Should not be used in cases where point of hemorrhage is submerged, because collagen must be in direct contact with bleeding site to achieve desired effect
Microfibrillar collagen hemostat	May potentiate abscess formation, hematoma and wound dehiscence	Is not intended to treat systemic coagulation disorders Placement in extraction sites has been reported to increase pain Should not be left in infected or contaminated spaces because of possible adhesion formation, allergic reaction, foreign body reaction Interferes with wound margins
Absorbable gelatin sponge	May form a nidus for infection or abscess formation	Should not be overpacked in extraction sites or surgical defects because it may expand to impinge on neighboring structures

Continued on next page

Table 5.2 (cont.)

Hemostatics: Adverse Effects, Precautions and Contraindications

Agent	Adverse effects	Precautions/contraindications
Aminocaproic acid	Headache, dizziness, convulsions, weakness, psychosis, dysrhythmias, orthostatic hypotension, thrombosis, renal failure, ejaculatory failure, tinnitis, nasal congestion, rash	Use with caution in patients with mild-to-moderate renal failure, hepatic disease, thrombosis, cardiac disease or hypertension, as well as in lactating women *Contraindicated in patients with abnormal bleeding, postpartum bleeding, new burns, nephrogenic diabetes insipidus*
Desmopressin acetate	Headache, drowsiness, lethargy, flushing, increased blood pressure, nausea, heartburn, vulval pain	See note above
Tranexamic acid	Giddiness, nausea, vomiting, diarrhea, blurred vision; hypotension with IV dose	Dose should be reduced for patients with renal impairment *Contraindicated in patients with acquired defective color vision and subarachnoid hemorrhage*
Vitamin K, or phytonadione	Parenteral administration can cause transient "flushing sensations" and "peculiar sensations" of taste; also (rarely) dizziness, rapid and weak pulse, profuse sweating, brief hypotension, dyspnea and cyanosis; allergic sensitivity, including an anaphylactoid reaction, has been reported	Patient undergoing prothrombin reduction therapy should not receive vitamin K preparations except under a physician's supervision Determine if patient is taking anticoagulants, as the drug can decrease effect of anticoagulant Contraindicated in patients with known sensitivity to the drug
Vitamin K_3 or menadione	Adverse reactions are similar to those produced by phytonadione, but incidence is low	Requires normal flow of bile or administration of bile salts Patient undergoing prothrombin reduction therapy should not receive vitamin K preparations except under physician supervision
Vitamin K_4 or menadiol sodium diphosphate	See note above	Before administering drug, determine if patient is receiving anticoagulant therapy; a patient undergoing prothrombin reduction therapy should not receive vitamin K preparations except under physician supervision If patient is taking anticoagulants, this agent may decrease their effectiveness
Thrombin	Allergic reactions can occur in patients with known sensitivity to bovine material	Thrombin must not be injected into blood vessels because it might cause serious or even fatal embolism from extensive intravascular thrombosis; instead, should be applied to surface of bleeding tissue as solution or powder

cal effect rather than altering the normal physiological clotting mechanism.

Microfibrillar Collagen Hemostat

This hemostatic agent is used topically to trigger the adhesiveness of platelets and stimulate the release phenomenon to produce aggregation of platelets leading to their disintegration and to release coagulation factors that, together with plasma factors, enable fibrin to form. The physical structure of microfibrillar collagen hemostat adds strength to the clot.

Collagen Hemostat

When collagen comes into contact with blood, platelets aggregate and release coagulation factors, which together with plasma factors, cause the formation of fibrin and a clot.

Aminocaproic Acid

Aminocaproic acid is an antifibrinolytic agent that slows or stops fibrinolysis by inhibiting the action of plasminogen. Consequently, it delays the breakdown of the hemostatic plug. This medication is administered both intravenously and orally in the form of tablets and syrup. Concurrent use of other hemostatic agents in patients with significant bleeding tendencies is recommended.

Desmopressin Acetate

Desamino-*D*-arginine vasopressin is a synthetic analogue of the natural pituitary hormone 1-8-D-arginine vasopressin. This medication increases plasma levels of von Willebrand factor-VIII complex and factor VIII levels. It is administered 30 min before the dental appointment. It facilitates outpatient care for patients with hemophilia, but should always be used in conjunction with other hemostatic agents.

Tranexamic Acid

Tranexamic acid is an antithrombolytic hemostatic agent that acts by decreasing conversion of plasminogen to plasmin. At much higher doses, it acts as a noncompetitive inhibitor of plasmin. It is indicated for prophylaxis and treatment of patients with hemophilia, to prevent or reduce hemorrhage during and after tooth extraction. Unlabeled uses include topical use as a mouthwash, along with systemic therapy to reduce bleeding after oral surgery. It is contraindicated for use in patients receiving anticoagulant therapy. This medication is administered both intravenously and orally.

Vitamin K

Two forms of naturally occurring vitamin K have been isolated and prepared synthetically. The naturally occurring forms are designated vitamins K_1 and K_2. Vitamin K_1 is present in most vegetables, particularly in their green leaves. Vitamin K_2 is produced by intestinal bacteria. Menadione has vitamin K activity and is derived from a breakdown of the vitamin K molecule by intestinal bacteria and is sometimes referred to as vitamin K_3. Menadiol sodium diphosphate, or vitamin K_4, is a water-soluble derivative that is converted to menadione in the liver.

Hypoprothrombinemia may result from inadequately available vitamins K_1 and K_2 because of decreased synthesis by intestinal bacteria, inadequate absorption from the intestinal tract or increased requirement by the liver for normal synthesis of prothrombin. Liver dysfunction may also decrease the production of prothrombin, but the hypoprothrombinemia from hepatic cell injury may not respond to the administration of vitamin K as many coagulation proteins are produced in hepatocytes.

Insufficient vitamin K in ingested foods becomes significant only when the synthesis of the vitamin by intestinal bacteria is markedly reduced by the oral administration of antibacterial agents. Biliary obstructions or intestinal disorders may result in an inadequate rate of absorption of vitamin K.

Phytonadione (vitamin K_1)

Vitamin K_1 is required for the production of the functional forms of six coagulation proteins: prothrombin, factors VII, IX and X and proteins C and S.

Menadione (vitamin K_3)
Although it is readily absorbed from the intestine, menadione must be converted to vitamin K_2 by the liver. Therefore, it requires a normal flow of bile into the intestine or the concomitant administration of bile salts.

Menadiol sodium diphosphate (vitamin K_4)
Vitamin K_4, because of its water solubility, is absorbed from the intestinal tract even in the absence of bile salts.

Thrombin

Thrombin is a sterile protein substance that is an essential component of blood coagulation. It combines with fibrinogen to form fibrin.

Patient Advice

- Let the patient know that a hemostatic has been used, what kind of hemostatic it is and why it was used.
- Advise the patient to let you know if bleeding continues from the surgical site.

Astringents

Astringents cause contraction of tissues. They accomplish this by constricting small blood vessels, extracting water from tissue or precipitating protein.

Accepted Indications

Dentists can apply astringents to gingival tissues before taking impressions or placing Class V or root-surface restorations. They can be used alone or in combination with retraction cords. Aluminum and iron salts are the compounds used as astringents in dentistry.

Aluminum Chloride

Aluminum chloride causes contraction or shrinking of tissue, making it useful in retracting gingival tissue. It also reduces secretions and minor hemorrhage.

Aluminum Potassium Sulfate

Aluminum potassium sulfate, or alum, is not widely used even though it is relatively innocuous, because its tissue retraction and hemostatic properties are limited.

Aluminum Sulfate

Aluminum sulfate, as with other aluminum salts, serves as an effective astringent for gingival retraction and hemostatic action.

Ferric Sulfate

Ferric sulfate is an effective and safe astringent and hemostatic for use in gingival retraction. It also can be used in vital pulpotomies.

General Dosing Information

Table 5.3 lists the general dosing and administration information for specific astringents.

Adverse Effects

The incidence of adverse reactions to astringents is relatively low. Most reactions (presented in Table 5.4) are temporary. The adverse effects listed in Table 5.4 apply to all major types of astringents.

Pharmacology

The ability of any astringent to contract or shrink mucous membrane or skin tissue is related to its mode of action involving protein precipitation and water absorption.

Gingival Retraction Cords

Gingival retraction cords can be used alone or in combination with astringents or vasoconstrictors. They are usually made of cotton and are woven in various ways to suit the practitioner's preference. They are also available in a variety of diameters to accommodate the variation in gingival sulcus width and depth.

These cords can be impregnated with astringents or vasoconstrictors either by the manufacturer or at chairside. Aluminum chloride, aluminum sulfate and ferric sulfate

Table 5.3

Astringents: Dosage and Prescribing Information

Generic name	Brand name(s)	Adult dosage	Content/form
Aluminum chloride	Gingi-Aid, Hemodent ★, Hemodettes, Hemogin-L, Rastringent, Styptin, Ultradent	Apply product directly to tissues using a cotton pledget or apply to gingival retraction cords	**Gel:** 20% (Hemodettes) **Solution:** 20% (Hemodent, Styptin), 25% (Gingi-Aid, Rastringent, Ultradent) **Ointment:** 25% (Hemogin-L) **Retraction cords:** Average concentration of 0.915, 3.5 mg/in
Aluminum potassium sulfate	generic	Any concentration, including 100% powder, can be used	**Powder:** 100% Various concentrations, all available and prepared by chemical supply houses
Aluminum sulfate	Gel-Cord	Apply product directly to tissues using a cotton pledget or apply to gingival retraction cords	**Gel:** In unit-dose cartridge **Impregnated retraction cord:** Average concentration of 0.48, 0.85, 1.45 mg/in **Topical solution:** 25%
Ferric sulfate	Astringedent ★, Hemodent-FS, Stasis, ViscoStat	Apply product directly to tissues using a cotton pledget or apply to gingival retraction cords	**Solution:** 13.3% (Astringedent), 13.5 (Hemodent-FS), 20% (ViscoStat—for use in infuser kit), 21% (Stasis)

★ indicates a product bearing the ADA Seal of Acceptance.

are used as the astringents, while racemic epinephrine is used as the vasoconstrictor.

Although epinephrine cord is used by a majority of practitioners rather than an astringent cord for gingival retraction and hemostasis, epinephrine cord is contraindicated in patients with a history of cardiovascular diseases, diabetes and hyperthyroidism and in those taking monoamine oxidase inhibitors, rauwolfias and ganglionic blocking agents.

Some practitioners and educators believe that epinephrine-containing retraction cord and solutions should not be used in dentistry. However, plasma epinephrine concentration increased significantly only after 60 min in a study of healthy subjects without a history of high blood pressure. In spite of the elevated plasma epinephrine levels, the subjects' heart rates, mean arterial pressures and pulse pressure products were not significantly different when the same subjects were exposed to a potassium aluminum sulfate (alum) impregnated cord. The gingival tissues of the subjects were intact, however. Therefore, the patient's medical history, oral health, type of procedure to be done, amount and length of retraction, and exposure of the vascular bed should be considered before deciding to use epinephrine-containing retraction cords. Table 5.5 provides gingival retraction cord information; Table 5.6 shows the adverse effects, precautions and contraindications of a variety of commercially available retraction cords.

Accepted Indications

Gingival retraction cord is used for all kinds of gingival retraction before taking impressions or placing restorations.

Table 5.4

Astringents: Adverse Effects

Agent	Adverse effects
Aluminum chloride	Concentrated solutions of aluminum chloride are acidic and may have an irritating and even caustic effect on tissues
Aluminum potassium sulfate	May have an irritating effect
Aluminum sulfate	May have an irritating and even caustic effect
Ferric sulfate	Compound may cause tissue irritation to a greater degree than aluminum compounds

Table 5.5

Gingival Retraction Cords: Usage Information*

Generic name	Brand name(s)	Content/form
Retraction cord, plain	Gingi-Plain, Gingi-Plain Z-Twist, Hemodent, Retrax, Sil-Trax Plain, Ultrapak	**Gingi-Plain Firm Cord:** #1 (thin); #2 (medium); #3 (thick) **Gingi-Plain Z-Twist Braided Cord:** #00 (very thin); #1 (thin); #2 (medium); #3 (thick) **Hemodent:** #9 (medium thin), #3 (medium heavy) **Retrax Twisted Cord:** #7 (thin); #8 (small); #9 (medium); #10 (large) **Sil-Trax Plain Braided Cord:** #7 (thin); #8 (small); #9 (medium); #10 (large) **Ultrapak:** Ultrapak #000 (ultra thin); #00 (very thin); #0 (thin); #1 (medium); #2 (thick); #3 (ultra thick)
Retraction cord with aluminum chloride	Hemodent +, Retreat	**Hemodent:** #9 (medium thin); #3 (medium heavy), 0.915 mg/in **Retreat:** #1 (thin); #2 (medium); #3 (thick)

* [illegible]

Continued on next page

Table 5.5 (cont.)
Gingival Retraction Cords: Usage Information*

Generic name	Brand name(s)	Content/form
Retraction cord with aluminum sulfate	Gingi-Aid Z-Twist, Pascord, R-Cord, Sil-Trax AS	**Gingi-Aid Z-Twist Braided Cord:** #00 (very thin); #1 (thin); #2 (medium); #3 (thick); 0.5 mg/in **Pascord Twisted Cord:** #7 (thin), 0.48 mg/in; #8 (small), 0.48 mg/in; #9 (medium), 0.85 mg/in; #10 (large), 1.45 mg/in **R-Cord:** Braided cord with or without epinephrine **Sil-Trax AS Braided Cord:** #7 (thin), 0.48 mg/in; #8 (small), 0.48 mg/in; #9 (medium), 0.85 mg/in; #10 (large), 1.45 mg/in
Retraction cord with potassium aluminum sulfate	GingiBraid, GingiKnit, Gingi-Tract, Sulpak, Sultan Ultra, UniBraid	**GingiBraid:** 0 (fine); 1 (small); 2 (medium); 3 (large); also available plain **GingiKnit:** 000 (very fine); 00 (fine); 0 (small); 1 (medium); 2 (large); 3 (extra large) **Gingi-Tract:** Thin, medium, thick **Sulpak:** Braided cord in thin, medium, large **Sultan:** Braided cord in thin, medium, large; available with either aluminum potassium sulfate or racemic epinephrine **UniBraid:** 0 (fine); 1 (small); 2 (medium); 3 (large); also available plain
Retraction cord with epinephrine	Gingi-Pak	#1 (thin); #2 (medium); #3 (thick); 0.5 mg/in
Retraction cord with racemic epinephrine	R-Cord, Racord, Sil-Trax EPI, Sultan	**Racord Twisted Cord:** #7 (thin), 0.50 mg/in.; #8 (small), 0.50 mg/in.; #9 (medium), 0.85 mg/in.; #10 (large), 1.15 mg/in **Sil-Trax EPI Braided Cord:** #7 (thin), 0.50 mg/in; #8 (small), 0.50 mg/in; #9 (medium), 0.85 mg/in; #10 (large), 1.15 mg/in **Sultan:** 0.108-0.48 mg/in
Retraction cord with zinc chloride	Sultan	0.06-0.218 mg/in

Table 5.6

Gingival Retraction Cords: Adverse Effects, Precautions and Contraindications

Type of cord	Adverse effects	Precautions/contraindications
Retraction cord, plain	NS	NS
Retraction cord with aluminum chloride	May cause irritation or tissue destruction	Contraindicated in those with a history of allergy
Retraction cord with aluminum sulfate	See note above	NS
Retraction cord with potassium aluminum sulfate	See note above	NS
Retraction cord with epinephrine	See note above	Patient's medical history and oral health, type of procedure to be done, amount and length of retraction, and exposure of the vascular bed should be considered before epinephrine-containing retraction cords are used Contraindicated in patients with a history of cardiovascular diseases, diabetes, hyperthyroidism, hypertension or arteriosclerosis and in patients taking tricyclic antidepressants, monoamine oxidase inhibitors, rauwolfias, or ganglionic blocking agents
Retraction cord with racemic epinephrine	See note above	See note above

NS, None of significance to dentistry

General Dosing Information

Dosage Adjustments

The actual maximum dose for each patient must be individualized depending on factors such as oral health and sensitivity.

Adverse Effects and Precautions

The incidence of adverse reactions to gingival retraction cords is relatively low. Most reactions are temporary, but gingival tissue destruction may permanently alter gingival architecture, especially after vigorous cord placement.

Pharmacology

Gingival retraction cords work mechanically to widen the gingival sulcus. With the addition of astringents or vasoconstrictors, the gingival tissue is retracted further. The astringents act by constricting blood vessels, extracting water from tissue or precipitating proteins.

Suggested Readings

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TISSUE MANAGEMENT NEEDS FOR ADHESIVE DENTISTRY NOW AND IN THE FUTURE

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HISTORY AND METHODOLOGIES

Dental Impressions

Reproducing a tooth preparation for the purpose of generating a stone replica became a standardized procedure as early as 1937, when Sears[18] introduced reversible hydrocolloid for fixed prosthodontics. The single greatest challenge to accurate reproduction of subgingival surfaces, including the finished margins of the tooth preparation, has been and continues to be in obtaining (1) predictable hemostasis, (2) sulcular fluid control, and (3) adequate displacement of overlying gingival tissue. Clinical unpredictability has been demonstrated for years when attempting to overcome the above-mentioned challenges. In addition, many of the hemostatics in use have significant limitations or possess the potential of causing mild to serious systemic or local adverse reactions.[2, 10, 11, 17, 20, 25]

Electrosurgery has been used in dentistry for more than 60 years,[13, 24] even though the principles of the technique as well as improved equipment were not available until the late 1960s.[17] Electrosurgery has been touted as an effective method of preimpression tissue management. One of the most obvious limitations in using this method of tissue management is the incalculable prognosis of the gingival contours on healing. Careful consideration for esthetics, whereby it is imperative to hide the margin of the restoration, exposes the shortcomings

Dr. Fischer is the founder and CEO of Ultradent Products, Inc., and acknowledges financial interest in the products discussed.

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Figure 1. Placement of hemostatic solution using infusion device and scrubbing action.

of electrosurgery as well as its unpredictable nature as a method of hemostasis on placement of impression material.

In 1981, the author introduced a new concept for hemostasis known as the *infusion technique.*[7] This process used the Dento-Infusor device (Ultradent Products, Inc., South Jordan, UT), a unique tip attached to a syringe. The device was designed to facilitate placement of the coagulating hemostatic into the cut capillary openings (Figs. 1 and 2). The purpose was to produce coagulum plugs

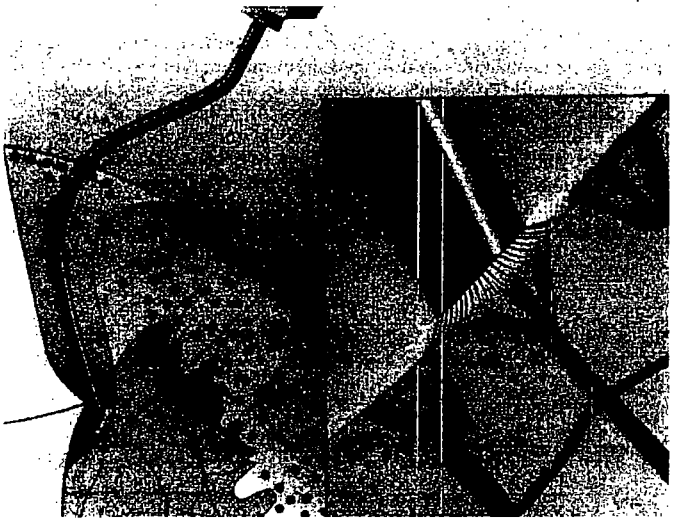

Figure 2. Scrubbing action produces coagulum plugs in the open capillaries.

within each capillary orifice below the cut tissue only, thereby preventing their dislodgment during cleaning and impression material placement. These coagulum plugs are best achieved by using a scrubbing action during application, which also prevents coagulum residue from competing with impression material for reproduction of the sulcus, preparation (especially the margin), and tooth surface just apical to the margin. Several articles have addressed this technique of hemostatic placement.[4, 7–9, 12, 21] Later, a unique knitted cord was introduced to simplify further the total technique and to offer greater flexibility.[5, 8, 9, 15]

Direct Restorative Dentistry

Although directly placed restorations constitute approximately 85% of all restorations placed, clinicians have failed to view tissue management as an integral segment of these procedures. Since its introduction in the early 1800s,[19] amalgam has maintained its status as the most widely used material for directly placed restorations. One of the greatest advantages to using amalgam is that it is more forgiving than other restorative materials. Despite the need for good hemostatic control before placement, many amalgam fillings are placed in the presence of blood or saliva (or both) and almost miraculously manage to survive. Because of the silver corrosion of amalgam, which tends to seal the spaces caused by inadequate tissue management among other things, an *E* to *D* grade restoration manages to upgrade itself to a *D* or *C* grade. This phenomenon is certainly difficult to brag about. Logic should dictate that the tissue management requirements and techniques for impression making should be extrapolated for use with any directly placed restoration including amalgam.

CURRENT AND FUTURE NEEDS

As important as hemostasis and other tissue control have been for proper impression making, never before have their needs been felt more than they are today for adhesive dentistry. Bondable restorations, whether directly or indirectly placed, demand as contaminant-free a field as possible. In 1955, Buonocore[1] established that acid etching of teeth made the teeth more receptive to bondable materials. In 1983, the author was developing a phosphoric acid etchant formula (Ultra-Etch, Ultradent Products, Inc., South Jordan, UT) to improve the delivery and control of this process. Initially, it was thought that only the enamel should be etched, whereas etching of the dentin should be avoided (Fig. 3). The literature now reports that etching of enamel and dentin (where dentin has been exposed) provides better bond strengths, provided that state-of-the-art dentin bonding technologies are used after etching. Acid etchants should have colorants in them to allow visualization of the etchant placement and, more importantly, to ensure isolation to the desired application site. Contact of phosphoric or other strong acids with cut tissues that have been treated for hemostasis can reinitiate bleeding. Contact with the tongue or other tissues can produce additional adverse reactions. Contrary to its green appearance in Figure 3, the colorant used in this R & D etchant is a sky blue dye commonly used in many personal care products and referenced by the Food, Drug and Cosmetic (FD&C) Act as *Blue Number 1*. When the pH is low, however, *Blue Number 1* becomes green. This is consistent with many organic dyes—as pH changes, color also changes. Hence, Blue Number 1 is blue unless the pH is low (acidic), then it becomes green. This is one of the methods using various dyes to determine

Figure 3. In 1983, only enamel was being etched. Note the green color of the etchant except at the gingival margin where it is blue because the sulcular fluid has neutralized the pH.

Figure 5. Etchant has not changed colors from its original blue.

Figure 6. Note profound discoloration of right central incisor (#8).

Figure 7. This type of discoloration migrates inward starting at the gingival margin.

Figure 10. Two months post-operative.

Figure 3.

Figure 5.

Figure 6.

Figure 7.

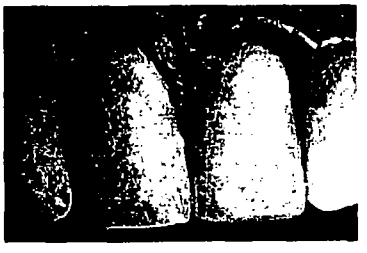

Figure 10.

pH changes of chemical solutions. Even though the preparation's margin was supragingival and no bleeding occurred, sulcular fluid migrated into the etchant, thereby neutralizing it (note blue-colored etchant at gingival margin), thus potentially contaminating the tooth surface with sulcular fluid protein. Although a rubber dam can be effective in such cases, a viable alternative is a displacement/barrier cord soaked in an astringent, then packed into the sulcus. If the tissues are healthy, the astringent can be diluted with water. Astringent hemostatics, such as alum, aluminum chloride, and ferric sulfate (Fig. 4), effectively seal epithelium (in this case, sulcular epithelium) against fluid flow. This sealing capability is inherent with all astringents. After cord placement, the preparation, cord, and surrounding tissues must be thoroughly washed. Any residual astringent can potentially contaminate the tooth surface to be bonded, thereby causing adverse effects on the bond strengths, and threaten the integrity of the bond and the restoration. The etchant in Figure 5 does not change colors. Now, adhesive chemistries, including primers and bonding resins, can also be placed with a high level of confidence.

Figure 6 shows five class V restorations in the anterior teeth. The bonded restorations were placed 6 weeks before the photograph. Note the right central incisor (#8) with its profound discoloration (Figs. 6 and 7). This type of discoloration migrates inward starting at the gingival margin; this is also visualized with the resin-bonded porcelain veneer. All five composites shown were placed

Figure 4. Barrier-cord soaked in ferric sulfate, placed in sulcus.

Figure 8. The composite roof is easily separated from the non-bonded surface.

subgingivally, and all five had barriers placed with cords soaked in ferric sulfate.[23] All hemostatics can be potential contaminants to the bonding procedure. Because all hemostatics are hydrophilic, their presence on the primer layer, bonding resin layer, or between layers of composite immediately contaminates and prevents intimate adaptation of succeeding hydrophobic or semihydrophilic resins. Just as important, the chemistries themselves of the hemostatics can also be potential contaminants. The composite roof is easily separated from the nonbonded surface (Fig. 8). It is clear that the dark color was from microleakage rather than discoloration of the composite itself. Soon after placement of the *nonbonded* restoration, blood pigments containing iron or possibly ferric sulfate migrated between the composite and the tooth surface. These pigments turn dark, similar to what occurs when blood accumulates under the skin when a person gets a bruise. In cases such as these, further darkening may occur if hydrogen sulfide from anaerobic bacteria reacts with the iron in the blood to produce ferric sulfide. Whether these additional problems occur or not, a discolored leaking restoration is unacceptable. The good news regarding this case and cases similar to it is that because of the translucency of the composite resin, the microleakage was easily identified. This is not possible with metallic or other opacious restorative materials. The preparation is redefined and cleaned. Once the hemostatic-laden barrier-cord (UltraPak, Ultradent Products, Inc., South Jordan, UT) is placed,[23] it is imperative that all of the residual hemostatic/astringent from the exposed cord, preparation, and adjacent soft tissue be washed thoroughly with firm water and air spray (Fig. 9). The preparation is then etched and washed (including exposed adjacent cord), and excess water is blown from the cord to prevent *wicking* water onto succeeding resin layers. Although the tooth surface should be slightly wet for optimal dentin adhesion, excess water can and should be removed from the cord; if necessary, the tooth surface can be rehydrated carefully with a damp cotton pellet. After the primer is applied, further assurance of complete water removal from the cord is accomplished with a firm air blast to the exposed cord followed by reapplication of primer to the preparation. In the case of a one-component bonding system, the primer/bonding resin should be reapplied. Note the final result 2 months postoperatively (Fig. 10).

Figure 9. All residual hemostatic/astringent from the exposed cord, preparation, and adjacent soft tissue must be washed thoroughly with firm water and air spray.

Tissue management is also essential for proper bonding of anterior indirect restorations. Figure 11 demonstrates both barrier to sulcular fluid flow and displacement for controlled bonding of a porcelain veneer. Without an adequate barrier and thorough cleaning of potential contaminants from the tooth surface before bonding veneers, microleakage can occur in one to multiple units.[6] This problem can be particularly frustrating not only because of the multiple appointments, but also because of the additional laboratory work and expense. Some clinicians and manufacturers have claimed that the ferric sulfate hemostatic

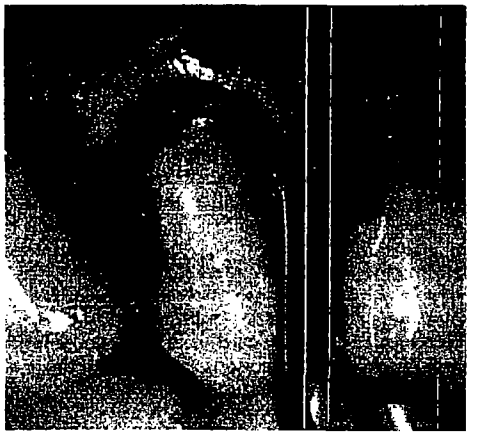

Figure 11. Cord serving as both barrier to sulcular flow as well as displacement for controlled bonding of a porcelain veneer.

discolors composite or luting resin, causing the unacceptable discolorations. Several tests by the author have shown that this is not the case. The cause is contamination with resultant microleakage. Potential contaminants include all hemostatics, blood, sulcular fluid, and saliva. These contaminants result in a nonbonded, nonsealed restoration with secondary blood infiltration (microleakage).

The wants and needs of society have changed. Improving the quality of life seems to be the primary motivating factor. Exciting new technologies in adhesives as well as improved physical properties of esthetic restorative materials have made the direct and indirect posterior esthetic restoration a reality. One of the greatest tools in dentistry, especially for the posterior bonded restoration, is the rubber dam. When the preparation must extend subgingivally or the interproximal tissues have been chronically irritated by an old and possibly poorly fitting amalgam restoration, the soft tissues may bleed past the rubber dam and significantly challenge the bonding procedure. At other times, conditions may occur that preclude use of the rubber dam.

A key thing to remember whenever performing a bonded procedure: never start the procedure in the presence of blood whether a rubber dam is being used or not. Figure 12 shows a class II preparation in which the proximal recurrent decay extends beyond the old amalgam and subgingivally down the root. Before placing the rubber dam and before addressing decay toward the pulp, the clinician should establish position of and refine the gingival margin in the proximal box. To prevent tearing of the rubber dam during instrumentation, the clinician should establish and refine sufficient solid gingival floor width before placing the rubber dam to preclude the need to instrument the margin after the rubber dam is placed (approximately 1 mm in from the margin is usually adequate). With the Dento Infusor and syringe loaded with Viscostat[23] (use Astringedent X[1] if inflamed tissues or if systemic conditions such as anticoagulant therapy mandate a stronger hemostatic), the clinician rubs the bleeding tissues firmly until profound hemostasis is achieved. The site is washed with a

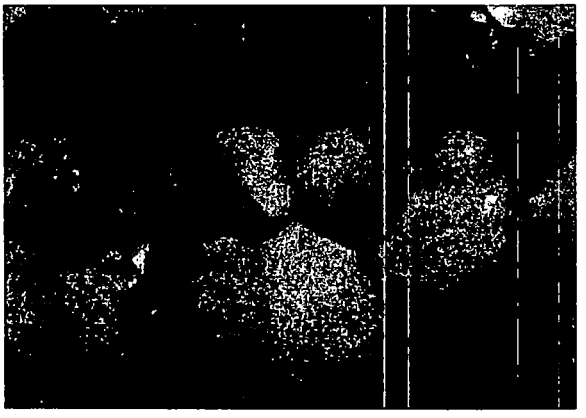

Figure 12. Class II preparation in which proximal recurrent decay extends beyond the old amalgam and subgingivally down the root. Gingival margins and adequate hemorrhage control must first be established.

firm air/water spray both to clean and to check for complete hemostasis. If any bleeding is observed, the process is repeated. After washing, the clinician inspects to make sure that hemostasis is afforded with no apparent coagulum being present on the surface of the tissues, sealing of blood vessels has occurred within the cut capillaries, and extraneous coagulum has been wiped or scrubbed from the surfaces of the cut tissue. The rubber dam is now placed, and any remaining caries is removed. The preparation is refined complete with toileting of the preparation. In this case, an added benefit to rubber dam placement before deep caries removal was that the deeper decay acted as a protective barrier to the fragile pulpal tissues on exposure until after a sound barrier of sealed tissues plus rubber dam was in place (Fig. 13). This situation leads to superior and more predictable pulp capping techniques[18] in addition to more predictable subgingival adhesive dentistry.

With current techniques for tissue management, including hemostasis, there is seldom if ever the need to be bonding in a compromised environment. Humans are living biologic entities with all the unexpected variables one would expect. These variables become quite evident when performing dental procedures. For predictable near-gingival or subgingival bonding, clinicians should understand the *whys* of adhesive dentistry and should feel comfortable as to the course of action to follow for some of the unexpected *what ifs*. For example: (1) What if after hemostasis and on etching of the preparation or shortly thereafter, a little blood oozes up onto the preparation? What should be done? For all systems using a phosphoric etchant, the clinician should first stop the bleeding using the ferric sulfate with infusor or cord,[25] then thoroughly and firmly wash all residual hemostatic away. The clinician should re-etch to ensure all ferric sulfate or other astringent is removed from the preparation, including the dentin decalcification zone. The clinician then washes and continues. (2) What if after etching during or shortly after primer application, a little blood oozes onto the surface? Again, the bleeding is controlled as mentioned previously, then the clinician thoroughly and firmly washes the preparation. The clinician dries and

Figure 13. Deeper decay acts as a protective barrier to the fragile pulpal tissues upon exposure until after a sound barrier of sealed tissues plus rubber dam is in place.

reapplies the primer. There is no need to re-etch before reapplying primer. The same would be true for bonding resin.

The basic logic is to control the bleeding, wash, dry, and reapply the previous material used in the previous step. For saliva contamination, the clinician should wash with a firm air/water spray, dry, and reapply the component used in the previous step. The above-mentioned procedure has been proven to be successful with laboratory testing when using the Perma Quick bonding system.[22] For all bonding systems using phosphoric acid etchants, the results are predictable should ferric sulfate make its way to the etched surface before primer or resin placement. Phosphoric acid readily breaks down and removes ferric sulfate. The clinician should follow with thorough washing. Testing has not been done with other bonding systems to substantiate that primers or bonding resins need only to be reapplied after hemostatic contact and washing. Manufacturers are encouraged to test their systems under similar protocols to determine the correct steps to take when contamination occurs during bonding procedure, and to verify that resulting bond strengths are not compromised.

CONCLUSION

The demands of new technologies and modern societies can be challenging to dentists. Posterior bonded restorations that extend near or under the gingiva can be some of the most challenging. There are solutions. Even though they may take more time to address appropriately, the successful and esthetic result is exciting for both the patient and the clinician. In short, many dentists state, "it makes dentistry fun again." Most importantly, quality bonded restorations possessing both a quality bonding system and a material condusive for strong bonding, such as state-of-the-art composites, have the ability to strengthen teeth significantly and even facilitate treatments to more socioeconomic groups in more esthetic ways than ever before possible. Predictable quality tissue management is the primary fulcrum to successful placement for all bonded restorations with near-gingival or subgingival extensions.

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Tissue Management, Gingival Retraction and Hemostasis

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2011-07-01

The oral cavity is a difficult area to treat in restorative dentistry because of the constraints of the lips, tongue, cheeks, challenges for access to visualize and manipulate instruments, as well as, the position of the teeth that are being treated relative to the gingival tissues, which if improperly managed, bleed. While for operative dentistry and single tooth restorations, the use of the dental dam provides control of the field and access to tooth preparation and restoration, there are many times in restorative dentistry that use of the dental dam is precluded. When caries or non-carious cervical lesions are at or below the free margin of the gingiva other tissue management techniques with gingival retraction must be used. (Fig. 1). For fixed prosthodontics, crown or inlay/onlay margins are at or below the free margin of the gingiva and access to them for both preparation, impressioning, and cementation is impossible without additional techniques to displace the gingival tissues and control gingival hemorrhage and sulcular fluids. (Fig. 2).

One of the most challenging aspects of crown and bridge is management of the gingival tissues when making an impression. Tissue management includes placing the gingival tissues away from the preparation margins so they can be impressed combined with providing for hemostasis when the gingival tissues are susceptible to bleeding.1,2 The rationale for tissue management is a critical aspect of impression making whether the impression is made with a conventional impression material or by a digital impression technique so that all tooth preparation margins are captured in the impression to assure an excellent marginal fit of a laboratory fabricated restoration.1,3

Methods And Materials
For Soft Tissue Management,

Displacement-Retraction
Aand Hemorrhage Control

Mechanical methods

Among the first techniques developed and available to clinicians for displacement of gingival tissues, especially for crown and bridge impressions, were mechanical displacement. Mechanical displacement refers to physically moving the gingival tissues aside from the tooth/tooth preparation margins to allow for visualization and access for treatment.1,2,4,5 In many cases, the materials used for gingival retraction can be used by themselves or in combination with other materials and techniques.

Among the most popular methods of gingival displacement is the use of gingival retraction cord.1,2,4,5,6-8 Gingival retraction cords can be woven, braided or twisted in a variety of configurations to provide for different diameters and thicknesses.

The choice of gingival retraction cord has proven itself to be one of personal preference by the clinician. Keep in mind that different cord types offer a variety of properties that to some make them more desirable. Also many manufacturers have a range of options of non-impregnated and chemically impregnated cords. Of importance, when handling gingival retraction cord one should use latex-free gloves. Indirect latex contamination can have an inhibitory effect on the setting of vinyl polysiloxane impressions materials. This is especially critical in the gingival sulcus, where a minimal amount of light body is placed as an incomplete cure may result in gingival tears of the impression materials.(9)

Clinician preference to braided cords relates to their tight and consistent weave, e.g, First String Retraction Cord, (Clinical Research Dental) and GingiBraid (Dux Dental). Braided cords for many clinicians are easier to place in the gingival sulcus with packing-placement instruments, both serrated and smooth, non-serrated, because they are solid and can be pushed to place. Knitted cords have increased in popularity. Knitted cords when saturated with astringents and when placed in the gingival sulcus expand creating a physical effect of enlarging the sulcus for access for impressions or to displace the gingival tissues when placing direct restorative materials. Also the unique knitted weave (UltraPak, Ultradent) (Fig. 3). minimizes unraveling and fraying after cutting and during cord placement. Knitted cords offer an ease in their placement and they expand when wet opening up the sulcus greater than the original diameter of the cord.1,2 The knitting and yarn selection allows for a greater range of knitted cotton cord diameters/sizes. In the authors' experience, when using knitted cord, a smooth, non-serrated placement instrument allows for precise placement without pulling the cord out of a gingival sulcus. Also, the range of sizes/diameters allow for placement in both the easy to access gingival sulcus and the tighter, healthier gingival sulcus. (Fig. 4)

When describing mechanical displacement of gingival tissues with gingival retraction cords, one would be remiss if there was no mention of retraction cord placement, packing instruments. Key to placement of cord with instruments is that the end of the cord packer be thin enough to be placed in the gingival sulcus without damaging the gingival tissue and potentially causing bleeding, the angle of the instrument allow for orientation so that cord placement can be accomplished around all surfaces of the tooth. Most commonly, the clinician will use double-ended instruments. Recently a novel double-ended instrument with multiple orientations of a dual-packing blade (TN010 Double Cord Packer, Garrison Dental Solutions) has been introduced so that the instrument does not need to be twirled to get the end orientation needed. (Fig. 5). A good friend, Dr. Bob Margeas designed this instrument because when using magnification, he found that this design maintains the instrument in the field of view while packing cord around the tooth.

Mechanicochemical methods

A variety of chemical solutions and gels have been recommended for use with gingival retraction cords because of the properties as drugs to act as an astringent or hemostatic agent.1,2,4 In most cases these drugs are both astringent, causing contraction-retraction of the gingival tissues, and hemostasis, constricting blood flow through coagulation. When these reagents are placed on a retraction cord they cause a transient ischemia shrinking the gingival tissue and blood vessel coagulation. Common astringent-hemostatic agents include ferric sulfate, aluminum chloride, and racemic epinephrine, aluminum potassium sulfate, aluminum sulfate, and zinc phenolsulfonate/racemic epinephrine. Gingival retraction cords are available unimpregnated or impregnated with astringent-hemostatic agents. Chemically impregnated cords offer greater sulcus displacement with the combined physical and chemical effect.1 Also, cord diameter, astringent-hemostatic agent, and cord type have a direct effect on the physical properties of the cord.10 In some cases both solutions and gel formulations are recommended for direct placement into the gingival sulcus with specialized tips (Tissue Goo, Clinical Research Dental, Astringedent, Ultradent; ViscoStat, Ultradent; Racecord, Septodont) to achieve an excellent hemostatic effect with some ischemic effect before cord placement.

A 20-25% aluminum chloride and 15.5-20% ferric sulfate are among the most popularly used chemical reagents. When used for durations within the gingival sulcus of less than 10 minutes, they cause minimal tissue damage.1,2,11 Ferric sulfate has been shown to interfere with surface detail of impression materials, as well as, it can discolour dentin by precipitating ferric sulfide in an anaerobic environment.12 It has been suggested that both ferric sulfate and aluminum chloride can have a negative effect on adhesion.12,13 When using these materials, before cementing the final restoration with a composite resin cement, both etch and rinse and self-etch, one should thoroughly clean the dentin surface with a pumice-water paste to create a dentin smear layer. There has been concern with the use of an 8% racemic epinephrine impregnated cord.4,14-18 It has been reported that epinephrine impregnated cords should be used with care. It has been reported that an 8% racemic epinephrine cord can cause elevation in blood pressure and tachycardia, especially if the gingival tissue is bleeding due to laceration.15 In fact it has been demonstrated that no clinical benefit in gingival retraction could be recognized between an epinephrine containing cord and other cords.16.

Of special note, the solutions that are used as astringents and for hemostasis, are acidic (pH range of 0.7-2.0). There has been evidence demonstrating that the use of these products remove the smear layer.18,19 There has been some concern that if the root surfaces beyond the crown preparation margins, as well as, the dentin of tooth preparations are exposed to these solutions that there may be an increase in postoperative sensitivity. If as a clinician you have this problem, it is recommended that after making the impression and before cementation of the provisional restoration, the preparations be treated with a desensitizing agent, e.g., G5 Desensitizer, (Clinical Research Dental) or Gluma (Heraeus-Kulzer).

Cordless retraction

In most cases, gingival retraction cord is the most effective method for retracting tissue to the depth of the sulcus. Unfortunately, many times on the day of the tooth preparation, gingival bleeding is difficult to control or when packing a cord into the sulcus, the tissues start to bleed making impression difficult or impossible. For this reason a new class of gingival retraction materials have been introduced. These cordless retraction materials, e.g, Expasyl (Kerr); Racegel (Septodont) Traxodent (Premier); GingiTrac (Centrix) provide for excellent hemostasis and some gingival retraction.20-23 Some of the materials incorporate the use of a compression cap GingiTrac (Centrix) to enhance the retraction effects of the material. (Fig. 6) Using these cordless retraction techniques provide for a non-traumatic, non-invasive tissue management and hemostasis in the gingival sulcus for fixed prosthodontic impressions. These materials and techniques can be used by

themselves or in combination with the use of gingival retraction cord, electrosurgery or laser tissue sculpting when bleeding is difficult to control.

Clinical Technique For Predictable Gingival Retraction and Hemostasis With Gingival Retraction Cord

When deciding which technique to use with gingival retraction cord, it is important to evaluate the health of the gingiva and the depth of the gingival sulcus. When there is minimal sulcus depth, the clinician is limited in many cases to placing only a single cord. When possible, recommendations for improved gingival retraction with cord include use of a double cord technique where a thin cord is placed flush in the sulcus, followed by a wider diameter cord. Both braided and knitted cords can be used with this technique. It is advisable to use a chemical astringent-hemostatic agent in combination with the gingival retraction cord. These two authors prefer high viscosity hemostatic gel that can be placed in the sulcus to both help with hemostasis and act as a lubricant for atraumatic placement of the gingival retraction cord and can be placed on the cord itself.

For this case a 25% aluminum sulfate hemostatic gel (Tissue Goo, Clinical Research Dental) was used to impregnate and lubricate a knitted cord (Fig. 7). Using an atraumatic cord placement technique, a thin diameter knitted cord (UltraPak, Ultradent) is placed to the base of the gingival sulcus without overlap (Fig. 8) and cut with a small tipped suture scissors (Micropoint Scissors, Clinical Research Dental) to be flush within the sulcus. (Fig. 9) This cord will be maintained during the impression to control any bleeding from the base of the sulcus. A second wider diameter UltraPak cord was then placed on top of the first cord to achieve tissue displacement. (Fig. 10) Immediately before making the impression and before the wider diameter cord's removal, the cord should be wetted with water so as not to grab and tear the gingival tissues when the cord is removed which can create bleeding. The wider diameter cord was then removed leaving excellent tissue displacement and hemorrhage control for the impression. Once the cord is removed the retraction is maintained for only 30 seconds.1 Before making the impression, it is important there are no contaminants on the tooth preparation surface. By using a 10% EDTA cavity cleanser (Detail, Clinical Research Dental) one can be assured that the tooth surface is free of hemostatic agent contaminants and any associated debris. The EDTA leaves the dentin tubules plugged and decreases the surface tension of the dentin facilitating flow of light body impression material resulting better adapatation of the impression material to the preparation and in better surface detail of the impression. **Clinical tip: If bleeding is persistent when the first cord is removed continue with the impression making certain to syringe the impression material within the sulcus. Even with the expectation that the impression will be unsuccessful this impression will maintain the retraction while allowing for hemostasis. Remove the first impression and DO NOT look at it. Immediately make a second impression. The sulcus will still be open and will not be bleeding.**

Conclusion

There are a variety of techniques and materials that allow the clinician to manage the gingival tissues during restoration and when making an impression. These include gingival retraction cords, chemical reagents, electrosurgery, laser tissue sculpting, copper tube impressions, hydraulic impressions, and non-invasive, atraumatic displacement/hemostatic materials. In most cases gingival retraction cord is the most effective method for retracting tissue to the depth of the sulcus. The other methods have their advantages and indications. In any case, the control of the soft tissue for exposing the margins of the tooth preparation for

restoration and impressioning is critical. It would be worthwhile for the clinician to understand all the choices available.**OH**

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Oral Health welcomes this original article.

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24 efficacy issues

Nonsurgical Gingival Displacement in Restorative Dentistry

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Compendium of Continuing Education in Dentistry

Abstract

Gingival displacement is critical for obtaining accurate impressions for the fabrication of fixed restorations, especially when the finish line is at or just within the gingival sulcus. Displacement of the gingival tissue is also important when dealing with the restoration of cervical lesions due to their proximity to the periodontal tissue. The methods of gingival tissue displacement can be broadly classified as nonsurgical and surgical techniques, with nonsurgical being the more commonly practiced method. Dentists must alter their armamentarium and gingival displacement techniques to meet specific demands and obtain predictable results. Hence, the purpose of this article is to describe the different means by which nonsurgical gingival displacement can be achieved effectively under a variety of clinical situations.

Harmony between a restoration and the periodontium that surrounds the teeth is crucial to the success of a restorative procedure. Key to achieving such a relationship is an accurately made impression for indirect restorations or a properly placed direct restoration into the prepared cavity.[1] Displacement of the gingival tissue is essential for obtaining accurate impressions for the fabrication of fixed restorations, particularly when the finish line is at, or just within, the gingival sulcus. This is also true when dealing with the restoration of cervical lesions due to their proximity to the periodontal tissue.

Gingival displacement is defined as the deflection of marginal gingiva away from the tooth. This is performed to create sufficient lateral and vertical space between the preparation finish line and the gingival tissue to allow the injection of adequate bulk of the impression material into the expanded crevice. Impression along the subgingival margin is critical to the marginal fit and emergence profile of the prosthesis.[2] A bulk of the impression material is required to obtain maximum accuracy and to improve the tear strength of the impression material so it can be removed from the mouth intact with no tearing. The critical sulcular width in this regard seems to be approximately 0.2 mm at the level of the finish line. Control of moisture in the sulcus, particularly when a

hydrophobic impression material is used, is also necessary because moisture can cause an incomplete impression of the critical finish line.[3] The displacement of the gingiva is also required during the preparation of the tooth cervically and even while placing and finishing the restoration located cervically. This is done to avoid trauma to the periodontal tissue.

The techniques of gingival tissue displacement can be broadly classified as nonsurgical and surgical methods (Table 1). Since surgical methods are usually effective in skilled hands, these techniques are used only by a minority of clinicians in their profession, and even then they are used only as adjuncts to mechanical or mechano-chemical means of gingival displacement. Therefore, the purpose of this article is to describe the different means by which nonsurgical gingival displacement can be achieved effectively under a variety of clinical situations (Table 2).

Retraction Crown/Sleeve

Temporary crown filled with thermoplastic stopping material or bulky temporary cement: In order to displace the gingiva a temporary crown can be adapted to the finish line of the tooth and lined with an excess of temporary stopping material. The crown is then placed on the prepared tooth, and any excess stopping material protruding into the gingival crevice is rounded and smoothened with a hot instrument. In a different method, a custom temporary restoration is placed in which the gingival ends are blunted and covered with bulky temporary cements such as zinc oxide eugenol or non-eugenol-containing periodontal pack. The temporary crown thus fabricated is left in place until the next appointment, at which time the final impression is made.

These methods are no longer practiced since a temporary crown filled with thermoplastic stopping material or temporary cement can cause prolonged or lasting recession if left in place for more than 12 hours. The resulting uncovered neck of the tooth may be sensitive and susceptible to caries. Also, impressions cannot be made the same day as the tooth preparation.[4,5]

Anatomic compression caps: Anatomically formed compression caps with semicircle spaces on two opposite sides can be easily placed on adjacent teeth. After placement of the adjusted anatomic cap, the patient bites on it and maintains pressure. The cap stops bleeding naturally by compression, opens the sulcus wide, and ensures a dry, clean area with well-defined gingival margin.

Modified Impression Techniques for Gingival Retraction

Copper band impression technique: A copper band can serve as a means of carrying the impression material as well as a mechanism for displacing the gingiva to ensure that the gingival finish line is captured in the impression. One end of the tube is festooned, or trimmed, to follow the contours of the free gingival margin. The tube with the impression material is mechanically carried to the finish line of the preparation and displaces the gingiva to produce an adequate impression. This technique can be used with impression compound and elastomeric impression. If utilized with an elastomeric material, the copper band must be filled with acrylic, fitted to the preparation, and subsequently relieved and vented. An adhesive must also be applied prior to taking the impression. Without the acrylic reinforcement, the band might get distorted during removal. Copper bands are especially useful when multiple preparations are recorded in an elastomeric impression and a localized impression defect has occurred.

The use of a copper band could negate the need to remake an entire full-arch impression just to capture one or two preparations.[6] On the basis of wound healing and gingival recession, the metal band with impression material is shown to be better than either surgery or retraction cord. Disadvantages of this technique include the amount of time required to fit and adapt the band, the difficulty in removing the modeling compound-filled band from undercuts, and the trauma to tissue caused by the band itself.[4]

Temporary acrylic coping: In another technique, a temporary acrylic resin coping is constructed. The inside of this coping is relieved by approximately 1 mm, and a tray adhesive is applied. The temporary coping is then filled with elastomeric impression material and reseated. The tissue is displaced mechanically when the impression

material is mechanically forced into the sulcus. A complete arch impression is subsequently made over the coping, and the coping becomes an integral part of the complete arch impression.[4] This is a cumbersome technique that is not very popular.

Matrix impression system: A technique called the matrix impression system (MIS) has been described by Livaditis.[7] The MIS is done in three steps: 1) a suitable elastomeric semi-rigid material is used initially to form the matrix; 2) a high-viscosity elastomeric impression material that will preferably bond to the matrix-forming material and which is required to make an impression of the preparations in the matrix is used to facilitate displacement of the gingival tissue and effectively flush debris out of the sulcus; and 3) a stock tray with a medium-viscosity elastomeric impression material is used to pick up the matrix impression and the remaining arch not covered by the matrix.[7]

Modified custom tray technique: In another method, a custom tray is modified by intraoral relining with autopolymerizing resin that is polymerized at 100°C for 5 minutes. Relined areas are refined by trimming excess resin with burs of a known diameter to create a 2-mm clearance for the elastomeric impression material. For areas with subgingival finish lines, only 0.5 mm of resin is removed to direct the elastomer into the gingival sulcus. The procedure is said to be time-saving because it reduces the need for a retraction cord and minimizes inaccuracies that would necessitate another impression.[8]

Mechanical Retractor

Gingival protector: A gingival protector can be used to displace soft tissue to protect gingiva from rotary instruments during tooth preparation and finishing (Figure 1). A unit is available that features a crescent-shaped tip on an adjustable ball-joint attached to a metal handle. The tip can be rotated to an angle that precisely matches the tooth's facial surface, thereby achieving gingival fit. Such protectors can be used for veneer preparations, finishing porcelain or resin veneer margins, cervical (facial) subgingival caries, and removal and checking marginal fit of crowns. Autoclavable metal protector tips prevent cross-contamination.

Matrices and wedges: Wooden wedges can be placed interproximally to mechanically depress the gingiva, thus providing retraction. Matrices with gingival extension can also displace the gingival tissue when placing interproximal restorations.

Rubber dam: Heavy, extra heavy and special heavy gauges of rubber dam with proper interseptal dimensions can be used when a limited number of teeth in one quadrant are being restored and in situations where the preparations do not extend very far subgingivally. The use of rubber dam is valuable during the preparation of a tooth cervically and also when placing, finishing, and polishing cervical restorations on the buccal/lingual aspect. Inversion of the rubber dam will also aid in gingival displacement. For extra retraction a Ferrier 212 clamp (cervical clamp) can be used (Figure 2 , Figure 3 and Figure 4). Use of the rubber dam helps not only in preparing the tooth but also when making the impression. Impressions can be taken with modified trays with the rubber dam on if the bows and wings of the clamp are blocked out.

This procedure, however, is very tedious, and complete arch impressions are not compatible with the technique.[4] The sulfide compounds utilized in the manufacturing of latex can inhibit the polymerization of polyvinyl siloxane (PVS) impression material. Hence, rubber dam should be avoided when this material is used.[6]

Retraction Cords

Plain retraction cords can be gently forced into the gingival sulcus to displace the gingiva laterally from the tooth. Cords can be fabricated from cotton yarn or purchased commercially in a variety of forms. Retraction cords are supplied as twisted/braided/knitted cord. Desirable qualities of a cord are that it is:[9] dark in color, to maximize contrast with the tissues, tooth, and cord; absorbent, to allow the uptake of the liquid medicaments; and available in different diameters to accommodate the varying morphologies of the gingival sulcus. Unfortunately, their effectiveness is limited because the use of pressure alone often will not control sulcular hemorrhage. Pre-

impregnating and/or soaking a cord with a hemostatic can control the sulcular hemorrhage and improve its tissue retraction qualities. The chemicals used along with retraction cords (gingival displacement medicaments) can be broadly classified into vasoconstrictors and astringents.[10]

Vasoconstrictors

Epinephrine: The vasoconstrictor used is typically epinephrine in the racemic form. Endogenous epinephrine is the l-form, whereas the racemic form contains equal amounts of d- and l-form. The overall activity of the racemic epinephrine is about one-half of that of endogenous epinephrine. The epinephrine is used in the concentration of 0.1% and 8%. There is some debate regarding the use of epinephrine for gingival retraction. The local use of epinephrine as a gingival displacement medicament can be absorbed into the systemic circulation and, consequently, affect the cardiovascular system.[10] Epinephrine-impregnated retraction cords contain 0.2 mg to 1 mg of racemic epinephrine per inch of cord depending on the diameter and the brand. One inch of the retraction cord with 0.2 mg of racemic epinephrine is capable of exposing the patient to the maximum dose of 0.2 mg (200 µg) for a healthy adult and nearly five times the recommended amount of 0.04 mg (40 µg) for a cardiac patient.[11] The amount absorbed depends on its concentration in the cord, length of cord used, amount of vascular bed exposed, and duration of the cord application.[10] The possible cumulative effect of epinephrine from cord combined with epinephrine from other sources (epinephrine administered in the local anesthetic and endogenous epinephrine that may be secreted by the patient in reaction to stress associated with dental procedures) must also be considered.[11]

For patients with cardiovascular disease, hypertension, diabetes, hyperthyroidism, or known hypersensitivity to epinephrine, a cord impregnated with some other agent must be substituted. Epinephrine should also not be used on patients taking monoamine oxidase or tricyclic antidepressants, rauwolfia compounds, ganglionic blockers, or cocaine. Patients without the aforementioned contraindications can also exhibit "epinephrine syndrome" (tachycardia, rapid respiration, elevated blood pressure, anxiety, and postoperative depression). Clinicians should avoid using epinephrine for gingival displacement because of the significant number of contraindications for its use.

Sympathomimetic amine: Several sympathomimetic amines capable of producing local vasoconstriction with minimal systemic side effects are available as nonprescription nasal and ophthalmic decongestants. These include tetrahydrozoline HCl, 0.05%; oxymetazoline, 0.05%; and phenylephrine HCl, 0.25%. Retraction cord can be dipped in these prescriptions to assist in hemostasis.[12] Newer hemostatic agents such as the tetrahydrozolines and oxymetazolines have a more acceptable pH and are thought to be kinder to the tooth structure and soft tissues than the conventional solutions.[13]

Astringents

Astringents act primarily by precipitation of protein and inhibiting transcapillary movement of plasma proteins. They have relatively low cell permeability and act generally as irritants in moderate concentrations and as caustics in higher concentrations. The astringents used in gingival displacement are as follows:

Aluminum sulfate compounds (aluminum potassium sulfate [Alum] and aluminum sulfate): Alum in 100% concentration has been shown to be only slightly less effective in shrinking the gingival tissues than epinephrine, and it shows good tissue response.[14] Alum is safer and has fewer systemic effects than epinephrine and, therefore, has been recommended for use in place of epinephrine. Cords saturated with 100% alum can be safely left in the sulcus for as long as 20 minutes without any adverse effect.[4]

Aluminum sulfate, which differs from alum, has been suggested as a gingival retraction material. The available data indicate that the material is effective and biologically acceptable.[15] A practical concern is that, like most sulfates, aluminum sulfate compounds can inhibit/retard the setting reaction of additional reaction impression materials.[16]

Aluminum chloride: Aluminum chloride is one of the most commonly used astringents.[17] The actions of aluminum chloride result from its ability to precipitate protein, constrict blood vessels, and extract fluid from tissues.[18] It is used in the concentration of 5% to 25%. Studies have shown that solutions stronger than 10% can cause local tissue destruction. A 10-minute application is usually sufficient.[4] Aluminum chloride is the least irritating of the medicaments used for impregnating retraction cords, but it is shown to disturb the setting of PVS impression materials.[19] The inhibitory effect can be greatly reduced by thoroughly rinsing the preparation with water after the treated cord is removed.

Ferric sulfate: Ferric sulfate provides good hemostasis on exposed connective tissue. This astringent is provided in solution form only, generally in the concentration of 13% to 20%. Solutions of ferric sulfate above 15% are very acidic and can cause significant tissue irritation and postoperative root sensitivity. The recommended packing time for cord dipped in ferric sulfate solution is 1 to 3 minutes. When tissues are hemorrhaging, the solution should be rubbed into the bleeding areas with an applicator (dento-infusor) or a soaked cotton pellet. Ferric sulfate can modify the accuracy of surface detail reproduction during impressions because it disturbs the setting reaction of polyvinyl siloxanes. Therefore, all traces of medicament should be carefully removed from the tissues before the impressions are recorded.[19] Due to its iron content, ferric sulfate stains gingival tissues a yellow -brown to black color for several days after being used as a retraction agent.[20] The esthetics of the anterior all-ceramic crowns may also be compromised due to the use of ferric sulfate since it has shown to produce internalized discoloration of the tooth structure.[21]

The acidity of the commonly used gingival displacement medicaments are high, with pH ranging from 1 to 3.[13,22,23] This could result in the removal of the smear layer and can negatively affect the bonding mechanism of the self-etch dentin bonding systems.[24] The removal of smear layer could also cause the opening up of the dentinal tubules cervically and cause dentinal hypersensitivity.[23]

Many different instruments are available for placing cord in the gingival sulcus. Some are purpose-designed packing devices with smooth, nonserrated circular heads that can be used to place and compress twisted cord with a sliding motion. Other devices have serrated circular heads for use with braided cords. The thin edges of these serrated circular heads sink into the braided cord, and the fine serrations keep it from slipping off and cutting the gingival attachment.[20] The instrument design used is a matter of the dentist's individual preference.

Techniques for Retraction Cord Placement

Two procedures for placing the retraction cord are the single-cord and double-cord techniques. The technique used is based on the clinical situation.[3]

The single-cord technique is indicated when making impressions of one to three prepared teeth with healthy gingival tissues, especially when the prepared margins are at or above the tissue. In this technique, a single cord is placed in the sulcus and removed before the impression is taken. This provides displacement about the width of the cord. In a deep sulcus, however, the tissue can collapse over the top of the cord, restricting access of the impression material to the retracted sulcus. This often causes the impression material to tear on removal. Even when tearing does not occur, impression material near the most critical margins will be extremely thin and easy to deform. Though commonly practiced, this technique is often unsatisfactory.

The double-cord technique can be used with single or multiple preparations. It is especially useful for making impressions when tissue health is compromised and the procedure absolutely cannot be delayed. The double-cord technique, which some clinicians use routinely for all impressions, employs two cords, one placed above the other. A thin cord such as silk suture or #000 retraction cord is first packed under the preparation margin to control gingival seepage and hemorrhage. This cord is typically left in place for the impression. The second, larger cord is impregnated with hemostatic agent and placed above the first cord for a minimum of 4 minutes and removed before the impression is taken, Figure 5, Figure 6, Figure 7, Figure 8 and Figure 9). The principal advantage of this technique is that the first cord remains in place within the sulcus, thus reducing the tendency of

the gingival cuff to recoil and displace partially set impression material. This approach not only helps to control gingival hemorrhage and exudates but also overcomes the problem of the sulcus impression tearing because of inadequate bulk.[25] Another advantage of the double-cord technique is that the first cord acts as a sulcus liner, preventing tearing of the epithelium and subsequent bleeding. The main disadvantage of this technique, however, is that failure to remove the first cord can cause gingival inflammation. Also, if the deeper cord is left in place the impression material may stick to it and cause the impression to tear upon removal.

Use of retraction cord, which can be laborious and time-consuming, must be done carefully as gingival bleeding may occur. It can also be uncomfortable for patients in the absence of anesthesia, and when inappropriately manipulated it can lead to direct injury and gingival recession.[26] Clinicians should be cautious when using retraction cords around implants since the junctional epithelium that surrounds an implant is not as adherent, is more permeable, and has a lower regenerative capacity than the junctional epithelium around teeth.[20] The artifacts caused by retraction cord fibers that may remain in the sulcus can also affect the accuracy of optical impressions used for CAD/CAM prostheses.[27] To overcome these problems, new products and techniques have been introduced into the market.

Retraction Strip

New retraction strips have been proposed for use in dentistry to displace gingival tissue prior to impression-making without damaging the tissue. The synthetic retraction material is chemically extracted from a biocompatible polymer (hydroxylate polyvinyl acetate) that creates net-like strips without debris or fragments. The material, which can be easily shaped and adapted into the sulcus without local anesthesia, is highly effective for absorption of intraoral fluids such as blood, saliva, and crevicular fluid.[28] Once inserted around the tooth, the sponge-like strips expand with absorption of fluids and exert pressure on gingival tissues to cause displacement.[3] Though time-consuming, this technique has shown to be suitable for the displacement of gingival tissue and to provide a readable impression that is gentle to the periodontium.[29]

Retraction Paste

Use of cordless retraction materials has gradually made impregnated retraction cords less competitive. Available in a paste-like form and supplied with a specialized dispenser, cordless retraction materials displace the gingiva when injected into the sulcus. Because of the passive technique used to place these pastes, they are significantly less traumatic to the tissue than conventional retraction cord.[30] Hence, they are preferred for gingival tissue displacement, especially around cement-retained implant prostheses.[20] These materials are also preferred when taking a digital impression for CAD/CAM prostheses since the artifacts caused by retraction cord fibers can be avoided.[27]

The amount of retraction offered by these pastes is limited, especially with extremely subgingival margins.[20] The high cost of retraction pastes, commercially available with or without hemostatic agents, has also prevented them from becoming a mainstream commodity.

Retraction paste with hemostatic agent: There are a number of retraction paste products available with hemostatic agents. One such product is an injectable viscous paste that depends on the hemostatic properties of aluminum chloride and the hygroscopic expansion of kaolin upon contact with the crevicular fluid to provide mild displacement of the gingiva in about 2 minutes. Retraction paste products contain as much as 15% aluminum chloride, which may be hazardous to the gingival tissue.[26] The viscosity of an injectable matrix may not be enough to provide sufficient displacement for deeper subgingival preparations, and aluminum chloride can inhibit the set of polyether and PVS materials if clinicians do not rinse it away properly before making impressions.[20]

Another product is a cordless gingival displacement system that utilizes the patient's bite pressure via a preformed matrix for single-tooth or a custom-made matrix for multiple teeth preparations. The bite pressure pushes the

hydrophilic silicone retraction paste to gently retract the gingiva with no tissue damage. The retraction paste also contains a mild, natural astringent to control the seepage of fluid.

Retraction paste without hemostatic agent: There are also various retraction paste products available without hemostatic agents. For example, one PVS material used for gingival displacement generates hydrogen to cause expansion of the material against the sulcus walls during setting. The product is syringed around the preparation margins of the abutment teeth and maintained under pressure using a compression cap for 5 minutes before impression taking. The manufacturer has reported such benefits as gentle placement without the need for local anesthetic, good product visibility in the sulcus due to its bright color, ease of removal, and minimal rinsing of residue. However, since there is no hemostatic agent, hemostasis should be achieved in all cases before using this technique. It is also less effective in cases of teeth with subgingival margins.[29]

Another type of product in this category is an injection-type retraction material that contains no aluminum chloride. It has shown to produce satisfactory gingival displacement without the drawbacks of pain and gingival recession.[31]

Conclusion

A healthy coexistence between restorations and their surrounding periodontal structures should be the goal of a diligent dentist. Several techniques have proven to be relatively predictable, safe, and efficacious in the management of the gingival tissue in restorative dentistry. No scientific evidence has established the superiority of one technique over the other. The selection of any one of the various methods of soft-tissue management to control the operative site depends on the clinical situation and the preference of the operator.

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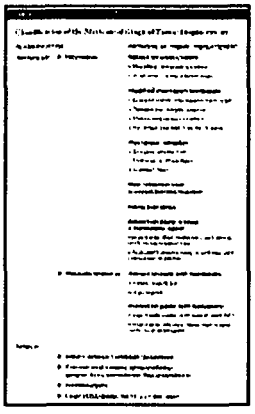

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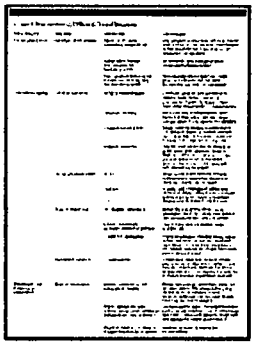

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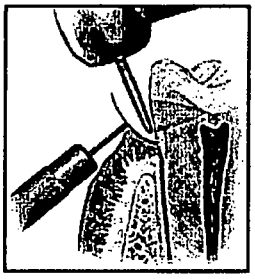

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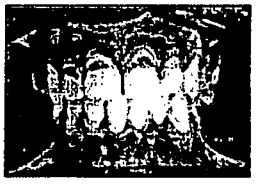

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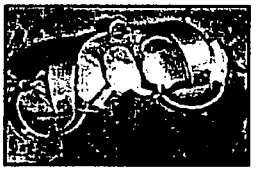

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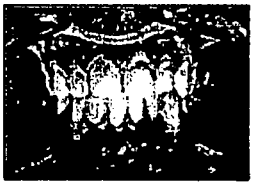

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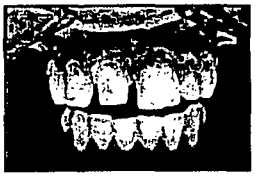

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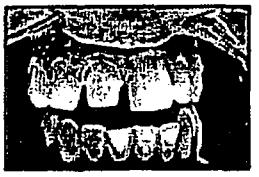

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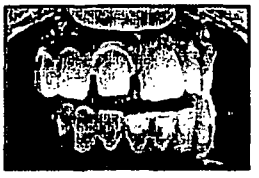

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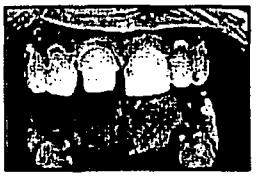

Figure 8

Figure 9

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LEARNING OBJECTIVES:

After reading this article, the reader should be able to:

- enumerate the various methods of gingival tissue displacement
- list the advantages and disadvantages of various nonsurgical gingival displacement methods
- choose the appropriate method of gingival tissue displacement as the clinical situation demands

Appendix B : Stability Report

The stability report for ViscoStat Clear is attached, demonstrating the product can be released with a 42-month room temperature shelf life. Note that "Hemostatic Gel AC Clear" is a synonym for ViscoStat Clear. The former name is used interchangeably during Formulation and Testing phases, while "ViscoStat® Clear" is the final, branded name.

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