K964970

APR -3 1997

SUMMARY OF SAFETY AND EFFECTIVENESS

The Biomet Bone Screw is indicated for ankle fractures, metatarsal fusions and metatarsal osteotomies (Hallux Valgus).

The screws are made of a resorbable copolymer comprised of polylactic acid (PLA) and polyglycolic acid (PGA). In histological animal studies, the bone screw was completely resorbed by 15 months IN VIVO.

The Biomet Bone Screw is made of bioresorbable and biocompatible polymers that have been used in surgical procedures for years. LactoSorb® resorbable copolymer is a synthetic polyester derived from lactic and glycolic acids. Polylactic/polyglycolic acid copolymer degrades and resorbs IN VIVO by hydrolysis to lactic and glycolic acids which are then metabolized by the body. The safety of PLA/PGA material has been well documented since the early 1970's when the FDA first approved the use of resorbable PLA/PGA sutures. The exact same LactoSorb® material has been implanted in humans for over 10 years in a ligating clip. The LactoSorb® material has been found to be biocompatible in both soft tissue and bone tissue.

The effectiveness of the Biomet Bone Screw was determined by mechanical testing. The LactoSorb® screws were found to provide the same healing as a stainless steel screw in an animal model. There was no adverse tissue response to either the metal or LactoSorb® screws.

In summary the Biomet Bone Screw is safe and effective for fixation of cancellous bone. Mechanical testing demonstrated the Biomet Bone Screw to be as effective as the comparative metal and PGA resorbable cancellous screw.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 3 1997

Ms. Mary L. Verstynen
Clinical Research Manager
Biomet, Inc.
P.O. Box 587
Airport Industrial Park
Warsaw, Indiana 46581-0587

Re: K964970
Biomet Bone Screw
Regulatory Class: II
Product Codes: HWC and MAI
Dated: March 17, 1997
Received: March 18, 1997

Dear Ms. Verstynen:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K964970

Device Name: Biomet Bone Screw

Indications For Use:

The Biomet Bone Screw is indicated for ankle fractures, metatarsal fusions and metatarsal osteotomies (Hallux Valgus).

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K964970

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use____

(Optional Format 1-2-96)

510(K) ROUTE SLIP

Kmm

510(k) NUMBER K964970 PANEL OR DIVISION DGRD BRANCH ORDB

TRADE NAME BIOMET BONE SCREW

COMMON NAME SCREW, FIXATION, BONE

PRODUCT CODE HWC SCREW, FIXATION, BONE

APPLICANT BIOMET, INC.
SHORT NAME BIOMET
CONTACT MARY L VERSTYNEN
DIVISION
ADDRESS AIRPORT INDUSTRIAL PARK
P.O. BOX 587
WARSAW, IN 465810587
PHONE NO. (219) 267-6639 FAX NO. (219) 268-2742

MANUFACTURER BIOMET, INC.
UNITED STATES SURGICAL CORP.
GRIFFITH MICRO SCIENCE, INC.
REGISTRATION NO. 1825034

DATE ON SUBMISSION 11-DEC-96 DATE DUE TO 510(K) STAFF 25-FEB-97

DATE RECEIVED IN ODE 12-DEC-96 DATE DECISION DUE 12-MAR-97

DECISION SE DECISION DATE _____

SUPPLEMENTS	SUBMITTED	RECEIVED	DUE POS	DUE	OUT
S001	17-MAR-97	18-MAR-97	01-JUN-97	16-JUN-97	

CORRESPONDENCE	SENT	DUE BACK		
C001	06-MAR-97	05-APR-97	HOLD LETTER	

OTHER SUBMISSIONS	SUBMITTED	RECEIVED	DUE POS	DUE	OUT
ADD-TO-FILE	02-JAN-97	07-JAN-97	08-MAR-97		

Is this 510(k) identified as a Class III device ____YES ____NO
Is this 510(k) the result of additional information ____YES ____NO

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DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service
Food And Drug Administration

Memorandum

From: Reviewer(s) - Name(s) iDem07

Subject: 510(k) Number K964970 /s1

To: The Record - It is my recommendation that the subject 510(k) Notification:

- ☐ Refused to accept.
- ☐ Requires additional information (other than refuse to accept).
- ☐ Accepted for review_____.
- ☒ Is substantially equivalent to marketed devices.
- ☐ NOT substantially equivalent to marketed devices.
- ☐ Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Is this device subject to Postmarket Surveillance?	☐YES	☒NO
Is this device subject to the Tracking Regulation?	☐YES	☐NO
Was clinical data necessary to support the review of this 510(k)?	☐YES	☒NO
Is this a prescription device?	☒YES	☐NO
Was this 510(k) reviewed by a Third Party?	☐YES	☒NO

This 510(k) contains:

Truthful and Accurate Statement ☐Requested ☒ Enclosed
(required for originals received 3-14-95 and after)

☐A 510(k) summary OR ☐A 510(k) statement

☐ The required certification and summary for class III devices

☐ The indication for use form (required for originals received 1-1-96 and after)

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

☐ No Confidentiality ☒ Confidentiality for 90 days ☐ Continued Confidentiality exceeding 90 days

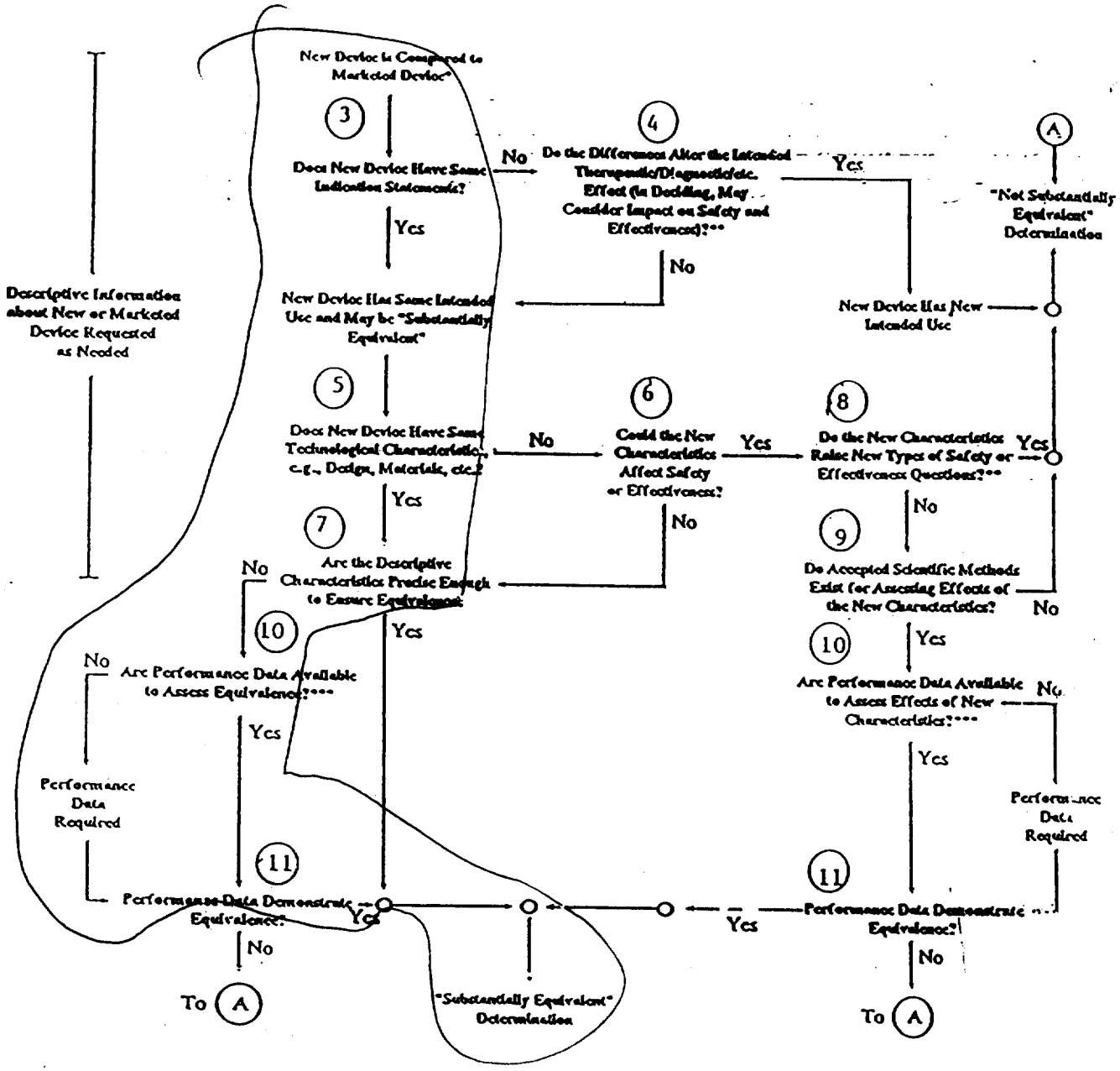
Predicate Product Code with panel and class:	Additional Product Code(s) with panel (optional):
87 II HWC	MAI

Review: Mark N Milhoan ORDB 4/3/97
(Branch Chief) (Branch Code) (Date)

Final Review: _____ 4/3/97
(Division Director) (Date)

Revised:11-20-96

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



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

bsc abs copol pla pga flexi

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

5 1 0 (k) R E V I E W

DATE March 31, 1997
FROM KEN MCDERMOTT
TO File

DOCUMENT # K964970
SPONSOR Biomet
DEVICE NAME Bone Screw

CLASS HWC MAI
DISEASE/USE see next page

REASON FOR APPLICATION New device

DECISION SE The most important factors affecting this decision include the following:

1. The intended use of the above referenced device and predicate absorbable threaded devices are exactly the same. The intended uses are restricted to use in the ankle and metatarsal, as are the predicate absorbable screw devices.

2. The above referenced device is similar in size and design to an absorbable predicate screw (different material, same intended use), and made of the same material as another predicate screw (different size and intended use). There are no predicate absorbable screws with the head snap-off feature and cannulation. These and other minor differences in design were addressed in an animal study and in an in vitro strength retention study.

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510(k) Number (if known): K964970

Device Name: Biomet Bone Screw

Indications For Use:

The Biomet Bone Screw is indicated for ankle fractures, metatarsal fusions and metatarsal osteotomies (Hallux Valgus).

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

_____ _____ _____ _____ _____ _____ _____

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use____ OR Over-The-Counter Use____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

MATERIALS pla/pga 82%/18%
STANDARD # TRADE NAME LactoSorb

INTERFACES ARTICULATIONS none MATING PARTS none
TISSUE FIXATION bone COATINGS none

DESIGN 5 mm diameter, 35-70 mm long untapered screws (12 sizes), partially threaded, cannulated or solid (see Figs. 1-3). When the permanent head contacts the bone surface, the hex head, used to turn the screw, shears off of it.

MANUFACTURE **US Surgical pellets extruded into a rod and machined. Exactly same process and materials as absorbable predicate devices.**

STERILITY EtO
FILE mat\abs\ RECNO 976

COMPARABLE PREDICATE DEVICES

PREDICATE DEVICE I REVIEWED RECENTLY WITH SNAP-OFF FEATURE

DOCUMENT # K962233
SPONSOR Medinov
DEVICE NAME Twist-off Screw

CLASS HWC 2 888.3040 SCREW, FIXATION, BONE
DISEASE/USE Fixing and stabilizing osteotomies of the metatarsals and phalanges of the foot.

REASON FOR APPLICATION New device.
DECISION SE

MATERIALS Ti-6Al-4V STANDARD # ASTM F 136
INTERFACES ARTICULATIONS none MATING PARTS none
TISSUE FIXATION bone COATINGS none

DESIGN Self drilling, self tapping, partially threaded screw attached to a "screw-holder" which fits into a screwdriver. The connection between the screw and screw-holder breaks when the screw head contacts the bone cortex. 4 lengths. 2 mm OD.

PROCESSING Machined and oxidized in air. STERILITY nonsterile
FILE ba\bsc\ RECNO 998

OTHER PREDICATE DEVICES (see Figs. 4, 6)

As required by 21 CFR 807.87 (f), the device under review in this 510k is compared for substantial equivalence to legally marketed predicate devices which were found to be substantially equivalent in a 510k, i.e., K920188 PGA and K925098 PLLA Biofix pins and rods (Fig. 4a

9

and b), K925471 Biofix SRPLLA Threaded Fixation Rod (similarly size screw: 4.5 mm diameter, 25-70 mm long)(see attached memo) and K955729 LactoSorb Trauma Plating System (smaller screws, same material, used with plates in cranial maxillofacial indications) as well as other metal screws (Fig. 6).

The device under review is made of the same absorbable material and is about the same size as are other absorbable threaded devices and has the same geometry, size, partial threading, head snap-off feature during implantation and cannulation as are present in predicate metal screws. However, there are no predicate absorbable screws with the head snap-off feature and cannulation. These and other minor differences in design were addressed in an animal study as discussed below.

Predicate absorbable devices only have indications for use in the ankle and metatarsal. The indications have been modified to include only these.

TECHNOLOGICAL CHARACTERISTICS:

The animal testing included the following:

1 Friedman, R.J.; et al. implanted metal and absorbable bone screws (Tab. 1) in weight bearing dog femoral osteotomy models (Tab. 2, Fig. 7). After 2 months, the torsional strength (Tab. 3) of the whole bone implanted with the SS screws tended to be slightly higher compared to absorbable screws, but the differences were not significant. The hardness of the bone around the SS screws were not significantly higher than around the absorbable screws (Tab. 4).

Histology at 2, 9 and 15-17 months showed good healing without inflammation or osteolysis as occurs in PLA implants. This is because the copolymer resorbs more uniformly so crystallites are not present to cause inflammation. Bony union was 90% and 80% for bones fixed by absorbable and SS screws respectively as determined from fragment displacement measurements. There was complete resorption in 9-15 months. Fragment displacement fixed by both types of screw was low (0.5 mm) compared to other studies (1-2 mm).

This study demonstrated that the screws provided adequate healing in this animal model without inflammation.

10

2 Bianchini, S.; Pietrzak, W.S. aged 5 mm LactoSorb screws and 4.5 mm Biofix PGA screws in 37 C phosphate buffer for up to 2 months. The LactoSorb screws had greater shear and pullout loads (Fig. 5, Tab. 6). Non-soaked LactoSorb screws also had greater torque strengths (Tab. 5). The strength vs time aging study indicated that these screws had adequate strength during the 6 week healing time.

There is no clinical data on this device. A 510(k) indications for use statement, truthful and accuracy statement and summary of safety and effectiveness were submitted as required in the Safe Medical Devices Act.

LABELING

Proposed labels, labeling and advertisements were provided which sufficiently describe the device, its intended use and the directions for use (21 CFR 807.87)

REVIEWED BY: Ken McDermott

ATTACHMENTS:

design drawings
predicate device
Tables and Figures
intended use statement

CONTACT HISTORY:

The following is a chronological listing of all requests for information made by Ken McDermott to the firm regarding this 510k, followed by a summary of the firm's response in their next correspondence (the firm's response is indented below each request):

As per 21 CFR 807.87(h), I advised Ms. Verstynen Ms. Verstynen 2-24-97, 10 am that there is insufficient information to make a determination concerning substantial equivalence. I then requested the following information:

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COMPARABLE PREDICATE DEVICE

COMPARABLE PREDICATE DEVICE

Please determine if there is a absorbable screw with similar threading, cannulation and temporary head twist off.

There is no such predicate device.

INTENDED USE

Please provide specific implantation sites and indications for use. For any changes you make, note that the following should be consistent and resubmitted:

intended use form,
package insert,
510(k) summary of safety and effectiveness

The indications are specific, but there are no predicate absorbable screw devices. The absorbable pin and rod devices only include ankle and metatarsal (Fig. 4).

TESTING

In the report by Friedman, R.J.; et al., please provide the following:

which screws were cannulated;

FDA received an adequate response to this request.

the differences between test samples and marketed devices (include photos/drawings if possible showing the differences in design, dimensions and intended use between the absorbable and SS samples);

FDA received an adequate response to this request.

legible figures;

FDA received an adequate response to this request.

a discussion of the relationship between indentation load and bone strength, viz., how well indentation load correlates to bone strength.

This information was requested but there was no response to this request by the firm.

10

In the report by Bianchini, S.; Pietrzak, W.S., please provide the following:

which screws were cannulated in the shear and pullout tests;

FDA received an adequate response to this request.

As per 21 CFR 807.87(h), I advised Ms. Verstynen Ms. Verstynen 3-4-97, 4 pm that there is insufficient information to make a determination concerning substantial equivalence. I then requested the following information:

COMPARABLE PREDICATE DEVICE
Please provide an absorbable screw with similar design features and intended uses as your device.

FDA received an adequate response to this request.

INTENDED USE
The indications provided are specific, but there are no predicate absorbable screw devices with these indications. The absorbable pin and rod devices only include ankle and metatarsal indications. Please provide specific implantation sites and indications for use for your device that match an appropriate predicate device. For any changes you make, note that the following should be consistent and resubmitted:

intended use form,
package insert,
510(k) summary of safety and effectiveness

FDA received an adequate response to this request.

TESTING
Clinical data may be necessary for those intended uses for which there are no predicate devices.

This does not apply to this device.

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If cannulated, the screws contain a central through-hole of 1.25 mm (0.059 inch) diameter, to permit the bone fragments to be reduced with a 1.1 mm diameter K-wire, with the screw introduced over the K-wire. The instrumentation set is composed of a screwdriver, a tap, and a drill bit. Any standard stainless steel K-wire, up to a diameter of 1.1 mm, may be used with the cannulated screw.

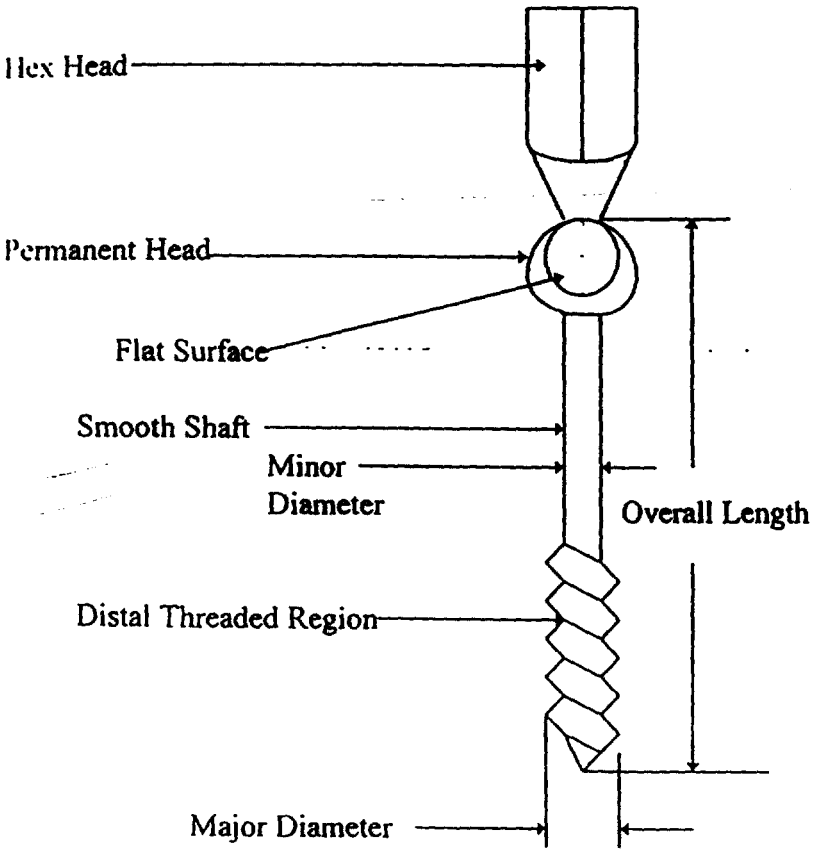

Figure 1. Schematic drawing of the Biomet bone screw.

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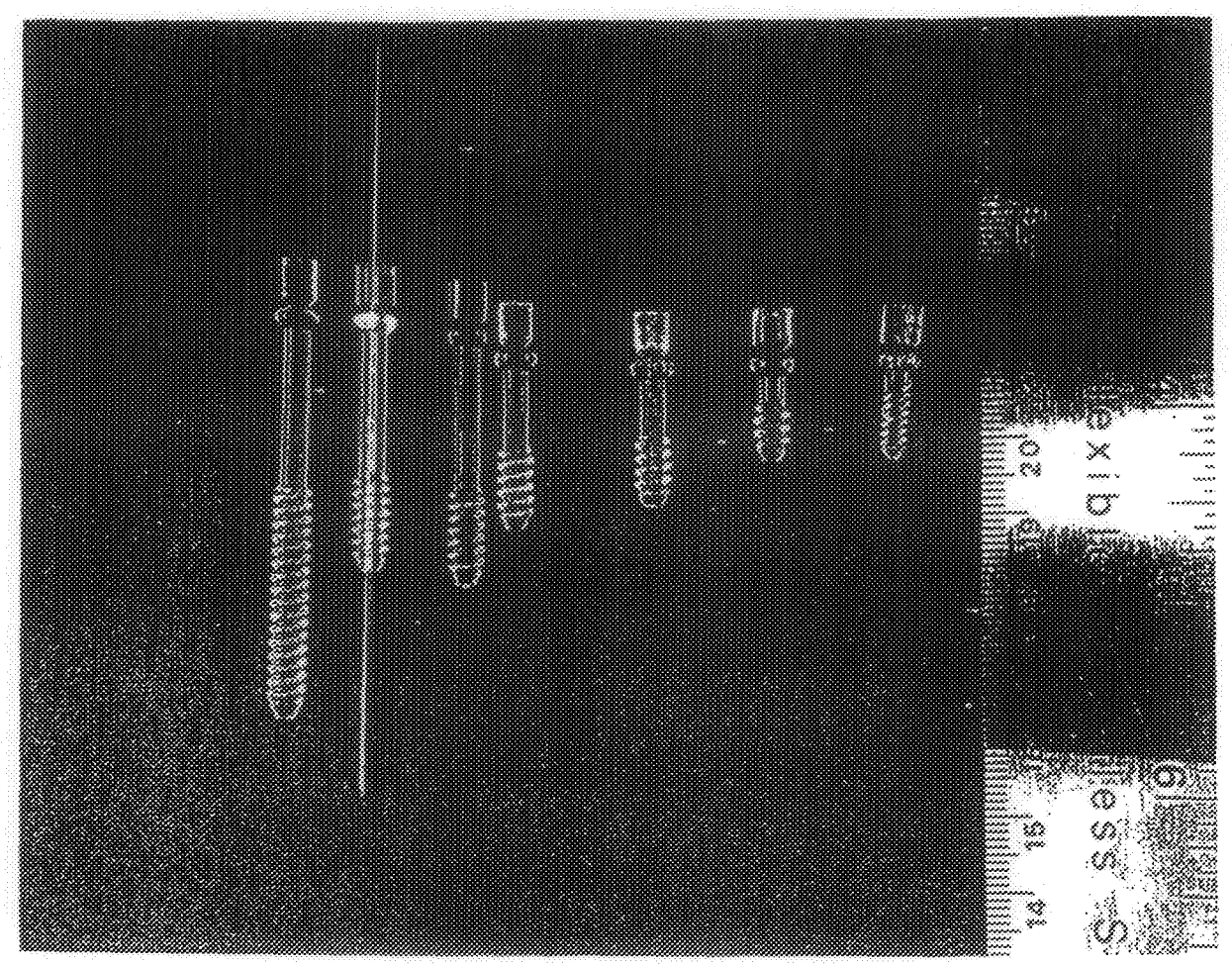

Fig 2

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
1390 Piccard Drive
Rockville MD 20850

JUL 19 1994

Fig 4A

Mr. Jonathan S. Kahan
Bioscience Limited
Representing Hogan and Hartson
Columbia Square
555 Thirteenth Street Northwest
Washington, DC 20004-1109

Re: K925098
BIOFIX Bioabsorbable Self-Reinforced
Poly-L-lactide Fixation Pins
Regulatory Class: II
Product Code: HTY
Dated: June 1, 1994
Received: June 1, 1994

Dear Mr. Kahan:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to 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). You may, therefore, market your device subject to the general controls provisions of the Act and the following limitation: all labeling for this device system, including the package label and labeling included within the package, must prominently state that the Biofix Absorbable SRPLLA Pin is intended only for chevron osteotomies of the first metatarsal bone for hallux valgus.

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.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. In addition, FDA may publish further announcements concerning your device in the Federal Register.

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Fig 4B

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
1390 Piccard Drive
Rockville, MD 20850

MAY 12 1993

Fig 4B

Mr. Sam Son
Director of Corporate
Regulatory Affairs
Kirschner Medical Corporation
9690 Deereco Road
Timonium, Maryland 21093

Re: K920188
BIOFIX® Threaded Bioabsorbable
Fixation Rod
Regulatory Class: II
Dated: February 22, 1993
Received: February 23, 1993

Dear Mr. Son:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to legally marketed devices. This decision is based on your device being found equivalent only to similar devices labeled and intended for the maintenance of alignment of cancellous fractures of the malleolus of the ankle in the presence of appropriate immobilization. The decision was based on your demonstration of the clinical and functional equivalence of your device to metallic bone screw predicate devices. You may, therefore, market the device, subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act). The general controls provisions of the Act include requirements for registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under the Radiation Control for Health and Safety Act of 1968, or other Federal Laws or Regulations.

18

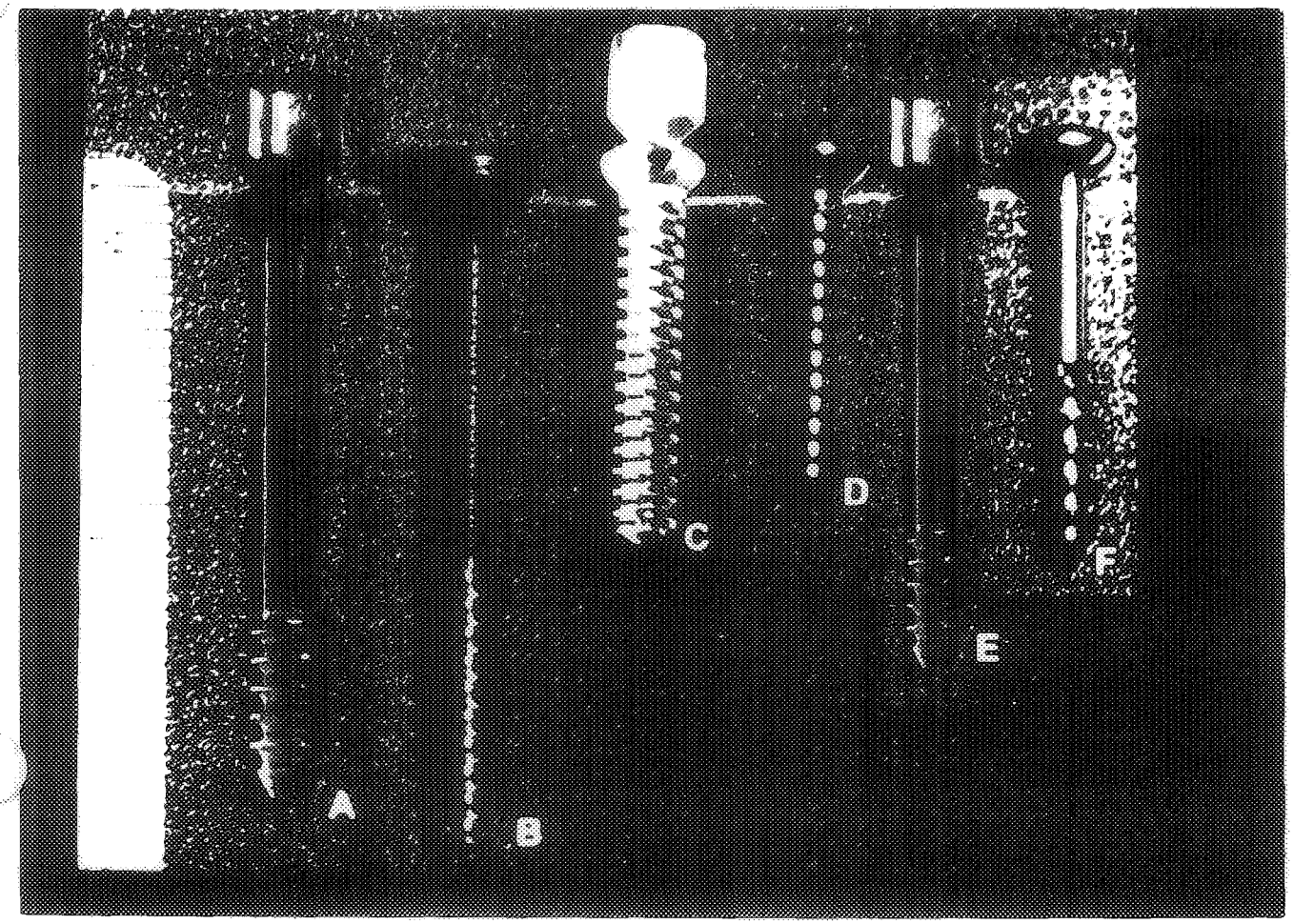

Figure 6

Predicate Screw ... used + ...d

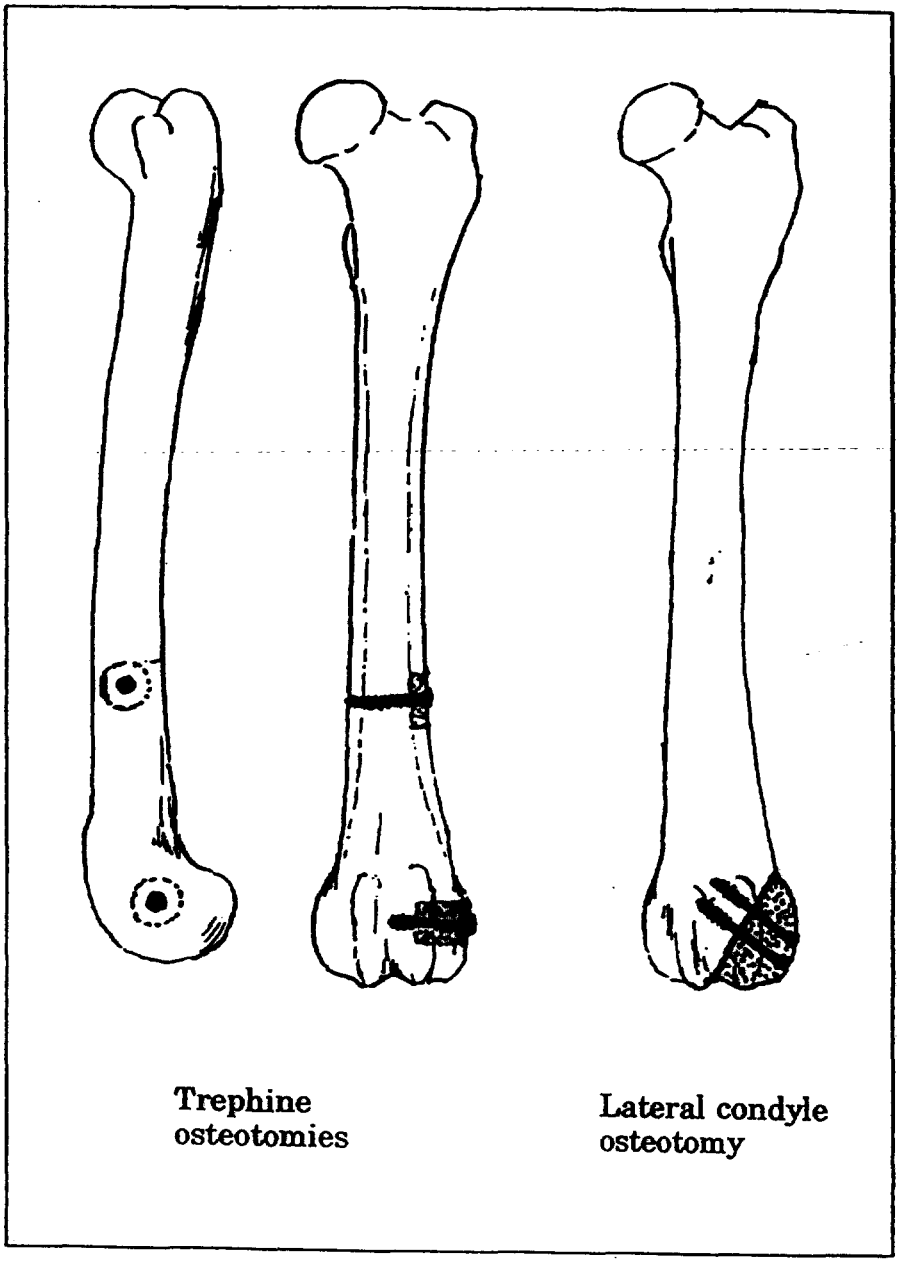

Figure 7

Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation

5 1 0 (k) M E M O R A N D U M

Memorandum

Date: August 2, 1995

Re: K925471
Bioscience, Ltd. c/o Hogan and Hartson
555 13th Street NW
Washington, D.C. 200041-1109
ATTN: Jonathon Kahan
(202) 637-5600

Received: May 26, 1995
Dated: May 26, 1995
Device Name: Biofix Bioabsorbable Self-Reinforced PLLA Threaded Fixation Rod

From: Paula Wilkerson
Chemical Engineer
Orthopedic Devices Branch
General and Restorative Devices Division

To: Record

Recommendation:

Review:

1. Has sponsor provided all administrative requirements?

   Yes

2. Device description: Subject device is a bioabsorbable, fibrous, structurally cut, monofilament suture-like cylindrical bone fixation device composed of self-reinforced PLLA. The device is available in three sizes (see description below in Sizes). Each diameter of this device is sold with an appropriately sized instrumentation set which consists of a screw driver, a countersink tool, and a screw-thread tapping device. The exception to this is the inclusion of an AO tapping device used with the 2.7 mm threaded rod and an AO screwdriver or Leibinger screwdriver used with the 2.00 SR-PLLA threaded rod. Engineering drawings are included.

   Device Name: BIOFIX® Bioabsorbable Self-Reinforced Poly-L-lactide (SR-PLLA) Threaded Fixation Screw

0010

Material: Screwdriver - 400 series SS.
Rod - PLLA with monomer and dimer contents < 0.05% (H-NMR spectroscopy). Trace elements of Cr, Co, Mn, Mo, and Sn determined by flame AAS method as <5ppm. Al, Ni, Si, and Fe contents <20ppm. MW = 30 - 70K. Percent crystallinity = 42-71% (raw materials), and 60-78% (finished product). No solvents used in processing.

Additional physical characteristics:

Density = 1275 - 1280 g/c.
% H_2O absorption = 0.13 - 0.06%.
Expansion of material = 1 - 2%

Surface Characteristics: Threaded polymer.

Range of Sizes:

Diameter Outer/Inner	Length
4.5mm/3.5mm	25 to 70mm in increments of 5mm
3.5mm/2.5mm	10 to 40mm in increments of 4mm
2.5mm/1.85mm	6 to 24mm in increments of 2 to 4mm
2.0mm/1.45mm	6 to 24mm in increments of 2 to 4mm

BioFix SR PLLA LBG Threaded Rods

Diameter, Outer/Inner	Length, Total/Thread
4.5/3.5/3.8 mm	70/23mm
	65/30mm
	60/28mm
	55/26mm
	50/24mm
	45/42mm
	40/20mm
	35/18mm
	30/15mm
	25/12mm

0011

3.5/2.5/2.8 mm	10/5mm
	45/15mm
	40/14mm
	35/14mm
	30/14mm
	28/14mm
	26/12mm
	24/10mm
	22/9mm
	20/8mm
	20/8mm
	18/7mm
	16/6mm
	14/5mm
	12/5mm

Geometry: Subject device is a series of threaded rods with nominal major thread diameters of 2.0mm, 2.7mm, 3.5mm, and 4.5mm, and lengths of 6 to 70mm. The rods are either fully threaded (2.0mm, 2.7mm, 3.5mm, and 4.5mm) or LAG-threaded (3.5mm and 4.5mm).

Method of Fixation: Device is inserted with accompanying instrumentation.

3. Intended Use: Intended for maintenance of alignment of cancellous fractures of the malleolus of the ankle in the presence of appropriate immobilization.

4. Sterilization: Provided sterile

Method: Gamma Irradiation, Cobalt 60, 2.5 Mrad dosage.

Sterilization Validation Method: Bioburden, AAMI.

Sterility Assurance Level: 1×10^{-6}.

Description of Packaging: Double pouch, aluminum then Tyvek.

0012

Is device "pyrogen free"? Yes

Method of determination: LAL

5. Labeling: Labeling is included and appears to be appropriate and complete.

6. Testing:

The sponsor submits testing descriptive information and data in the following areas:

Biocompatibility - Identical material is currently marketed by the sponsor under K925098 and relevant biocompatibility information is referenced to this submission.

Mechanical Properties - Testing done and submitted in the following areas:

1. initial bending strength, shear strength, and torsional strength; and

2. bending and shear strength retention and changes in viscosity-average molecular weight (Mv) under in vitro hydrolytic conditions.

Results:

Diameter, mm	Bending Strength, MPa	Shear Strength, Mpa	Torsional Strength, Mpa	Number of devices tested
2.0	168.3 - 178.8	126.8 - 135.4	45.3 - 47.2	4
2.7	172.8 - 182.7	123.2 - 136.9	45.8 - 50.5	4
3.5	100.7 - 249.4	102.7 - 177.9	20.0 - 70.3	78
4.5	155.7 - 272.4	101.3 - 182.5	22.4 - 58.8	121

FDA Comment

A comparison of this data with that submitted in support of the Linvatec Bioabsorbable Rod, a similar predicate device for the same intended use, shows it to measure favorably.

In Vitro Hydrolytic Testing

Devices tested in this sequence were immersed in phosphate buffer solution (Ph 7.4) at 80° and samples were removed periodically for evaluation. Mechanical testing was conducted to determine bending and shear strengths.

C013

Intrinsic viscosities of the 2.0 mm and 2.7 mm threaded rods were measured in chloroform at 25° with an Ubbelohde capillary viscometer; viscosity-average molecular weight (Mv) was then determined using the Mark-Houwink constants: K=5.45*E-4 and a=0.73.

FDA Comment

The complete results of these tests may be found in the application on pages 13 through 15. A complete replication of these figures in this review is considered by this reviewer to be burdensome and wasteful of time due to their presence in readily available data systems should follow-up be desired at a later time.

Conclusion

The data from these tests indicate that the device will retain mechanical and physical characteristics at an adequate level to for a time period of enough length to assure healing at the intended location.

Other Studies

Additional information on the following applicable literature is submitted by the sponsor:

1. Lavery and Higgins, Mechanical Characteristics of Poly-L-Lactic Acid Absorbable Screws and Stainless Steel Screws in Basilar Osteotomies of the First Metastarsal, University of Texas at San Antonio, 1994.

2. Suuronen, et al., Strength Retention of Self-Reinforced Poly-L-Lactic Screws and Plates: an In Vivo and In Vitro Study, Chapman and Hall, 1992.

Clinical data from 74 patients treated at Helsinki University Hospital is presented and comparative information on alternative treatment modalities is also provided.

7. Sponsor's Information in Support of SE:

The sponsor claims substantial equivalence to the following devices:

1. BIOFIX Bioabsorbable Self-Reinforced Poly-L-Lactic Fixation Pin (K925098);

2. BIOFIX Threaded Bioabsorbable Fixation Rod (K920188);

3. BIOFIX Bioabsorbable Fixation Pin, (K890902); and

4. Johnson & Johnson Orthopedic's Orthosorb Absorbable Pin, (K901456).

A comparison of the subject device with all 4 of thee predicates in made by the sponsor in the following areas: Intended Use, Material, Dimensions, Mechanical Strength Release Criteria, Mechanical Properties and Degradation of Material, and Sterilization.

8. Review of Other 510(k)'s for SE:
Product Name, Company (K#:[DECISION] on [DATE]):

BIOFIX Bioabsorbable Self-Reinforced Poly-L-Lactic Fixation Pin, Bioscience, Ltd., K925098, S.E., July 19, 1994.

9. Summary:

The sponsor has presented material which supports the claim of substantial equivalence to the identified predicate devices. This application is appropriate and complete and this device is found to be substantially equivalent to currently marketed devices is material, design and application.

10. Contact History/Requests for more Information:

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG -7 1995

Mr. Jonathan S. Kahan
Hogan & Hartson
Representing Bioscience, Inc.
Columbia Square
555 Thirteenth Street, Northwest
Washington, DC 20004-1109

Re: K952471
BIOFIX® Bioabsorbable Self-Reinforced
Poly-L-lactide Threaded Fixation Rod
Regulatory Class: II
Product Code: MAI
Dated: May 26, 1995
Received: May 26, 1995

Dear Mr. Kahan:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to 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). 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 practices, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations (CFR), Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practices (GMP) for Medical Devices: General GMP regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

0001

This letter immediately will allow you to begin marketing your device as described in your 510(k) premarket notification. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market, but it does not mean that FDA approves your device. Therefore, you may not promote or in any way represent your device or its labeling as being approved by FDA. If you desire specific advice regarding labeling for your device in accordance with 21 CFR Part 801, promotion, or advertising please contact the Office of Compliance, Promotion and Advertising Policy Staff (HFZ-302) at (301) 594-4639. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,

Kimber C. Richter, M.D.
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

0002

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

March 18, 1997

BIOMET, INC.
AIRPORT INDUSTRIAL PARK
P.O. BOX 587
WARSAW, IN 46581
ATTN: MARY L. VERSTYNEN

510(k) Number: K964970
Product: BIOMET BONE SCREW

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Because of equipment and personnel limitations we cannot accept telefaxed material as part of your official premarket notification submission, unless specifically requested of you by an FDA official.

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

K964970/S1

BIOMET INC®

Corporate
Headquarters

Mailing Address:
P.O. Box 587
Warsaw, IN 46581-0587

Shipping Address:
Airport Industrial Park
Warsaw, IN 46580

(219) 267-6639 Office
(219) 267-8137 FAX

March 17, 1997

Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville, MD 20850

Attention: Ken McDermott

RE: Biomet Bone Screw
K964970

Dear Mr. McDermott:

Enclosed are the following information in duplicate for K964970, the Biomet Bone Screw 510(k).

1. Copies of information faxed to you on March 5, 1997.
2. The Biomet Bone Screw has similar design features as the Biofix SR-PGA screws. The cannulation is the only difference and testing has demonstrated minimal effect on strength.
3. Changes in the intended use form, package insert and 510(k) summary of safety and effectiveness per your fax to me on March 4, 1997.

Sincerely,

Mary L. Verstynen

Mary L. Verstynen
Clinical Research Manager

MLV/clb

SK-7

Fax: 4 pages

Corporate
Headquarters

Mailing Address:
P.O. Box 587
Warsaw, IN 46581-0587

Shipping Address:
Airport Industrial Park
Warsaw, IN 46580

(219) 267-6639 Office
(219) 267-8137 FAX

TO: Ken McDermott

DATE: March 5, 1997

FROM: Mary Verstynen

SUBJECT: Biomet Bone Screw
K964970

COMPARABLE PREDICATE DEVICES

Biofix SR-PGA Screw: K920188 Biofix SR-PLLA Screw: K952471

Please note that in the above 510(k)s the screws were called threaded rods. These rods/screws are partially and fully threaded.

The Biofix screws are not cannulated. As demonstrated in the following Table 3 from the test report "Biomechanical Comparison of 5.0mm Diameter LactoSorb® Screws with 4.5mm Diameter Biofix PGA Screws" the presence of even a 1.00mm diameter cannulation has minimal effect on screw strength.

Table 3. Summary of LactoSorb® Double Shear Testing.

Cannulation Diameter (mm)	Double Shear Peak Load (lb) Ave+/- S.D.	Theoretical Single Shear Peak Load[a]
0	325.6±4.1	162.8
0.84	313.8±4.7	156.9
1.00	309.9±4.1	155.0

Note: [a] Single shear peak load is one-half that of double shear peak load.

INTENDED USE

If indeed the Biofix Screws only include ankle and metatarsal indications, the Biomet Bone Screw package insert etc. will be changed to these indications. According to all the information I have on Biofix rods/screws, the indications are much broader. See the following list of rod indications.

Please inform me if changes in the intended use form, package insert, and summary of safety and effectiveness need to be made.

MLV/clb

Pre-Operative Planning

Obtained from Surgical Technique

Patient selection is very important when using bioabsorbable polymers for fracture fixation. Biofix® SR-PGA® rods are indicated for non-weight bearing cancellous bone fractures, arthrodeses and osteotomies, in the presence of adequate immobilization.

In open procedures, Biofix replaces Kirschner® wire and Steinmann pin fixation. In many instances, metal screw fixation can be replaced with Biofix rods. Biofix rods can be incorporated into tension-band wiring, and more complex fixation, if appropriate precautions are taken.

Indications

Specific uses include:

- Epiphyseal fractures (1.5mm rods only)
- Hand and foot fractures
- Ankle and elbow fractures
- Periarticular and intraarticular fractures
- Osteochondritis dissecans
- Metacarpal and metatarsal fusions
- Phalangeal fusions
- Hallux valgus corrections
- Coracoid process transfers

Biofix has been used in many procedures other than those listed. Research and clinical study are continuously evaluating procedures where Biofix rods can be utilized.

Contraindications

Biofix is contraindicated for use in large cortical shaft fractures and osteotomies. Partial or total weight bearing cannot be recommended prior to clinical union. Patients over 70 years of age, those who have medium to severe osteoporosis, and those who have rheumatoid arthritis should be excluded from Biofix fixation. Biofix should not be used when infection is present at the fracture site. Biofix can augment fixation in complex fractures, but it should not be the primary fixation device. Use of rods larger than 1.5mm in physeal fractures is not recommended.

(See Package Insert for further information.)

Page from Biofix SR-PGA rod Package Insert

sharp because a blunt saw may cause the delamination of the rod. A surgical laser beam can also be applied to cut the rod. Other equipment (such like surgical knives, scissors, saws etc.) are not allowed to cut the Biofix rods which have very strong, hard and tough outer surface.

INDICATIONS

BIOFIX RODS ARE INDICATED FOR INTERNAL FIXATION OF CANCELLOUS BONE FRACTURES AND OSTEOTOMIES.

The primary objective of Biofix rods is to give a patient an initially strong and gradually decreasing internal fixation of cancellous bone fracture or osteotomy against shear loads originating from muscular activity or from external sources. This is, as a rule, achieved with 1—3 Biofix rods which are driven by an applicator (see Figure 1) in predrilled channels through the fracture (or osteotomy) to fix it in lateral plane and prevent it from reopening.

Biofix rods correspond to standard bone drill sizes (1.5 mm, 2.0 mm, 3.2 mm and 4.5 mm). The actual diameters of Biofix rods exceed somewhat (maximally +0.3 mm) those of standard bone drill sizes. This produces locking frictional forces when the rod is tapped into the drilled channel. If a blunt drill is used or the cancellous bone is porous or small fragments are fixed and therefore a strong fixation is not achieved, one or two additional biodegradable fixing sutures (Dexon "S" suture, size 1 or 2) which is (are) knotted over the fracture, can be used to secure the fixation (according to U.S. Patent 4 655 203).

CONTRAINDICATIONS

Biofix is not indicated for internal fixation of fractures or osteotomies in load bearing bones.

Biofix is not suitable for fixation of fractures or osteotomies of cortical bone.

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Biomet, Inc.
Airport Industrial Park
P.O. Box 587
Warsaw, Indiana 46580
USA

WARNINGS AND PRECAUTIONS FOR USE OF THE BIOMET BONE SCREW

ATTENTION OPERATING SURGEON

DESCRIPTION:

The Biomet Bone Screw is a resorbable device used for the fixation of cancellous bone fractures, osteotomies, arthrodeses or bone grafts. The device is made of a resorbable copolymer, a polyester derivative of lactic acid and glycolic acid. Polylactic/polyglycolic acid copolymer degrades and resorbs IN VIVO by hydrolysis to lactic and glycolic acids which are then metabolized by the body. The screws are completely resorbed by 15 months IN VIVO.

WARNINGS:

While these devices are generally successful in the alignment and fixation of bone they do not replace normal healthy body structures. The use of appropriate immobilization and postoperative management is indicated as a part of treatment until healing has occurred.

The surgeon is to be familiar with the implant, instruments, and surgical procedure. In using the device, a judgment must be made as to the holding power of the bone, as a significant degree of osteoporosis will weaken the hold in the bone. In all cases sound orthopedic practice is to be followed and the surgeon must select the type of device appropriate for treatment.

The patient is to be warned that the device can break or loosen as a result of stress, excessive activity or load bearing. The patient is to be made aware of surgical risks and possible adverse effects prior to surgery, and warned that failure to follow postoperative care instructions can cause failure of the implant and the treatment.

INDICATIONS:

The Biomet Bone Screw is indicated for ankle fractures, metatarsal fusions and metatarsal osteotomies (Hallux Valgus).

H/O

CONTRAINDICATIONS:

1. Active infection.
2. Fractures and osteotomies of cortical bone.
3. Patients with mental or neurologic conditions who are unwilling or incapable of following postoperative care instructions.
4. Patient conditions including: blood supply limitations, insufficient quantity or quality of bone, or latent infections.

WARNINGS AND PRECAUTIONS:

1. Patients that engage in stressful physical activities are to be warned that injury at or near the implant site can lead to subsequent failure of the device and/or the treatment.
2. The device can break or be damaged due to excessive activity, and stress caused by full or partial load bearing can cause failure of the device.
3. The Biomet Bone Screw is intended to aid in alignment and bone fixation during the healing process and is not intended to replace normal body structures.
4. Care is to be taken to assure adequate fixation of the bone tissue at the time of surgery. The failure to achieve adequate fixation through improper positioning or placement of the device can contribute to a subsequent undesirable result.
5. DO NOT USE if there is loss of sterility of the device.
6. Discard and DO NOT USE opened or damaged devices, and use only devices that are packaged in unopened, or undamaged containers.
7. **CUTTING OF SCREWS:** The screw can be cut with an oscillating or reciprocating saw. NO OTHER CUTTING METHOD MAY BE USED. After implantation, screws can be cut ONLY at the distal protrusion.

POSSIBLE ADVERSE EFFECTS:

1. Infection can lead to failure of the procedure.
2. Neurovascular injuries can occur due to surgical trauma.
3. Bending, fracture, loosening, rubbing, and migration of the implant may occur as a result of excessive activity, trauma, or load bearing.
4. Delayed or non-union can occur

STERILITY:

Biomet Bone Screws are sterilized by exposure to Ethylene Oxide (ETO) Gas. DO NOT RESTERILIZE.
DO NOT STORE ABOVE 120°F OR 49°C

CAUTION: Federal Law (USA) restricts this device to sale, distribution, or use by or on the order of a physician.

3. Bending, fracture, loosening, rubbing, and migration of the implant may occur as a result of excessive activity, trauma, or load bearing.
4. Delayed or non-union can occur

STERILITY:

Biomet Bone Screws are sterilized by exposure to Ethylene Oxide (ETO) Gas. DO NOT RESTERILIZE.
DO NOT STORE ABOVE 120°F OR 49°C

CAUTION: Federal Law (USA) restricts this device to sale, distribution, or use by or on the order of a physician.

40

SUMMARY OF SAFETY AND EFFECTIVENESS

The Biomet Bone Screw is indicated for ankle fractures, metatarsal fusions and metatarsal osteotomies (Hallux Valgus).

The screws are made of a resorbable copolymer comprised of polylactic acid (PLA) and polyglycolic acid (PGA). In histological animal studies, the bone screw was completely resorbed by 15 months IN VIVO.

The Biomet Bone Screw is made of bioresorbable and biocompatible polymers that have been used in surgical procedures for years. LactoSorb® resorbable copolymer is a synthetic polyester derived from lactic and glycolic acids. Polylactic/polyglycolic acid copolymer degrades and resorbs IN VIVO by hydrolysis to lactic and glycolic acids which are then metabolized by the body. The safety of PLA/PGA material has been well documented since the early 1970's when the FDA first approved the use of resorbable PLA/PGA sutures. The exact same LactoSorb® material has been implanted in humans for over 10 years in a ligating clip. The LactoSorb® material has been found to be biocompatible in both soft tissue and bone tissue.

The effectiveness of the Biomet Bone Screw was determined by mechanical testing. The LactoSorb® screws were found to provide the same healing as a stainless steel screw in an animal model. There was no adverse tissue response to either the metal or LactoSorb® screws.

In summary the Biomet Bone Screw is safe and effective for fixation of cancellous bone. Mechanical testing demonstrated the Biomet Bone Screw to be as effective as the comparative metal and PGA resorbable cancellous screw.

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510(k) Number (if known): K964970

Device Name: Biomet Bone Screw

Indications For Use:

The Biomet Bone Screw is indicated for ankle fractures, metatarsal fusions and metatarsal osteotomies (Hallux Valgus).

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use____ OR Over-The-Counter Use____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

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

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

March 07, 1997

BIOMET, INC.
AIRPORT INDUSTRIAL PARK
P.O. BOX 587
WARSAW, IN 46581
ATTN: MARY L. VERSTYNEN

510(k) Number: K964970
Product: BIOMET BONE SCREW

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. Please remember that all correspondence concerning your submission MUST cite your 510(k) number and be sent in duplicate to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Because of equipment and personnel limitations, we cannot accept telefax material as part of your official premarket notification submission unless specifically requested of you by an FDA official.

If after 30 days the requested information, or a request for an extension of time, is not received, we will discontinue review of your submission and proceed to delete your file from our review system. Pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission.

Please remember that the Safe Medical Devices Act of 1990 states that you may not place this device into commercial distribution until you receive a decision letter from FDA allowing you to do so.

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman
Supervisor Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

48

DEPARTMENT OF HEALTH & HUMAN SERVICES — Public Health Service
Food And Drug Administration

Memorandum

From: Reviewer(s) - Name(s) Mc Dermott

Subject: 510(k) Number K964970

To: The Record - It is my recommendation that the subject 510(k) Notification:

- ☐ Refused to accept.
- ☒ Requires additional information (other than refuse to accept).
- ☐ Accepted for review_____.
- ☐ Is substantially equivalent to marketed devices.
- ☐ NOT substantially equivalent to marketed devices.
- ☐ Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Is this device subject to Postmarket Surveillance?	☐YES	☐NO
Is this device subject to the Tracking Regulation?	☐YES	☐NO
Was clinical data necessary to support the review of this 510(k)?	☐YES	☐NO
Is this a prescription device?	☐YES	☐NO
Was this 510(k) reviewed by a Third Party?	☐YES	☐NO

This 510(k) contains:

Truthful and Accurate Statement ☐Requested ☐ Enclosed
(required for originals received 3-14-95 and after)

☐A 510(k) summary OR ☐A 510(k) statement

☐ The required certification and summary for class III devices

☐ The indication for use form (required for originals received 1-1-96 and after)

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

☐ No Confidentiality ☐ Confidentiality for 90 days ☐ Continued Confidentiality exceeding 90 days

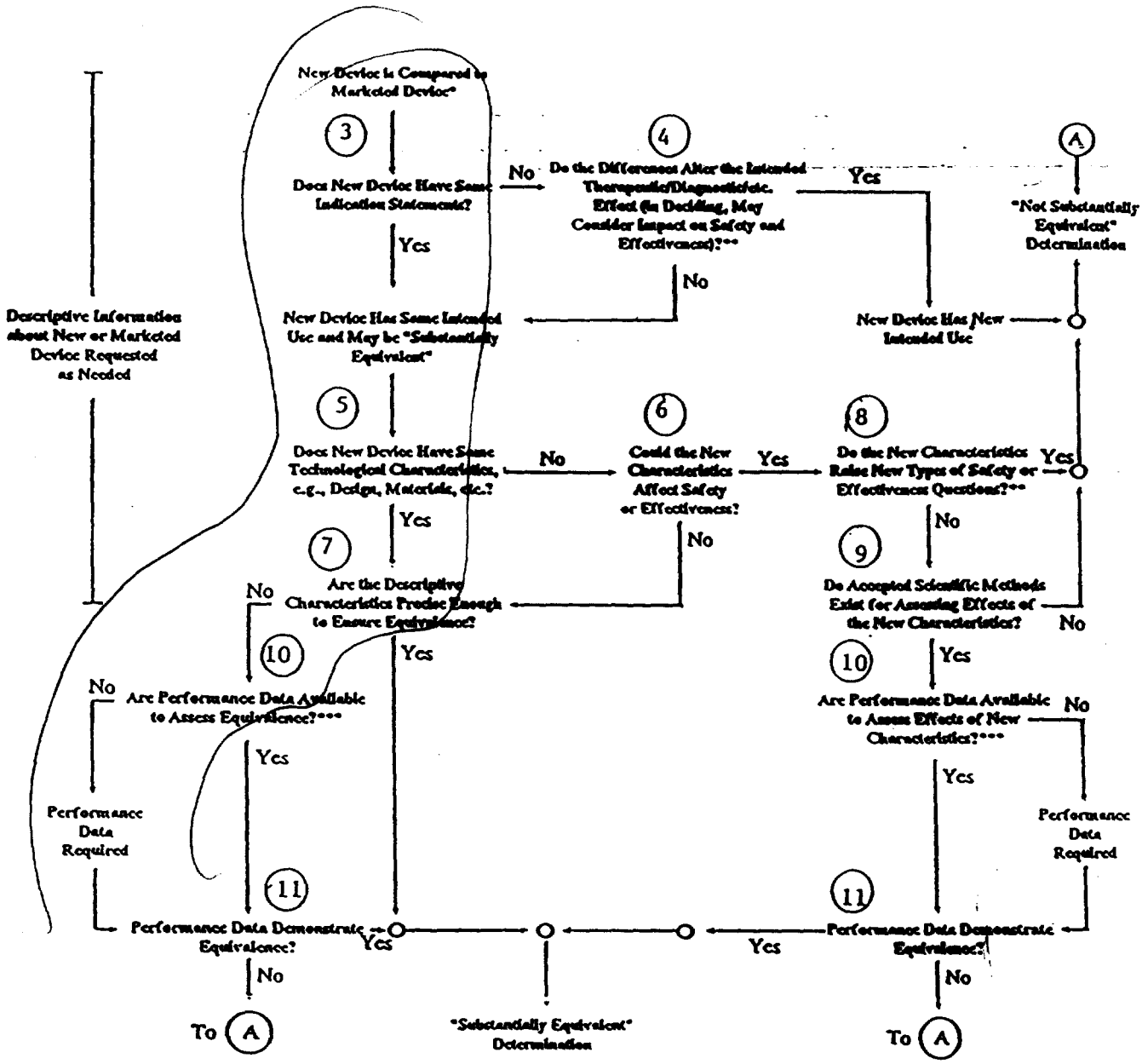
Predicate Product Code with panel and class: Additional Product Code(s) with panel (optional):

Review: Mark N Melkerson ORDB 3/6/97
(Branch Chief) (Branch Code) (Date)

Final Review: for Mark N Melkerson 3/6/97
(Division Director) (Date)

Revised: 11-20-96

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



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

REVISED:3/14/95

THE 510(K) DOCUMENTATION FORMS ARE AVAILABLE ON THE LAN UNDER 510(K) BOILERPLATES TITLED "DOCUMENTATION" AND MUST BE FILLED OUT WITH EVERY FINAL DECISION (SE, NSE, NOT A DEVICE, ETC.).

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

K 964970

Reviewer: Ken McDermott

Division/Branch: PGRD / ORDB

Device Name: Bone Screw

Product To Which Compared (510(K) Number If Known): _____

	YES	NO	
1. Is Product A Device	X		If NO = Stop
2. Is Device Subject To 510(k)?	X		If NO = Stop
3. Same Indication Statement?	X		If YES = Go To 5
4. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If YES = Stop NE
5. Same Technological Characteristics?	X		If YES = Go To 7
6. Could The New Characteristics Affect Safety Or Effectiveness?			If YES = Go To 8
7. Descriptive Characteristics Precise Enough?		X	If NO = Go To 10 If YES = Stop SE
8. New Types Of Safety Or Effectiveness Questions?			If YES = Stop NE
9. Accepted Scientific Methods Exist?			If NO = Stop NE
10. Performance Data Available?		X	If NO = Request Data
11. Data Demonstrate Equivalence?			Final Decision:

Note: In addition to completing the form on the LAN, "yes" responses to questions 4, 6, 8, and 11, and every "no" response requires an explanation.

bsc abs copol pla pga flexi

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

D R A F T
5 1 0 (k) R E V I E W

DATE March 4, 1997
FROM KEN MCDERMOTT
TO File

DOCUMENT # K964970
SPONSOR Biomet
DEVICE NAME Bone Screw

CLASS HWC MAI
DISEASE/USE see last page

REASON FOR APPLICATION New device

DECISION AI The following information is needed:

COMPARABLE PREDICATE DEVICE
The firm provided specific indications that we requested, but there are no predicate absorbable screw devices with these indications. Please provide an absorbable screw with similar design features and intended uses as your device.

INTENDED USE
The predicate absorbable pin and rod devices only include ankle and metatarsal indications. Please provide specific implantation sites and indications for use for your device that match an appropriate predicate device, preferably an absorbable screw. For any changes you make, note that the following should be consistent and resubmitted:

intended use form,
package insert,
510(k) summary of safety and effectiveness

TESTING
The animal testing that was provided together with a legally marketed predicate with the same intended use may be adequate for SE without clinical data. Clinical data may be necessary for those intended uses for which there are no predicate devices.

MATERIALS	pla/pga 82%/18%
STANDARD #	TRADE NAME LactoSorb
INTERFACES	ARTICULATIONS none MATING PARTS none TISSUE FIXATION bone COATINGS none
DESIGN	5 mm diameter, 35-70 mm long untapered screws (12 sizes), partially threaded, cannulated or solid (see Fig. 1-3). When the permanent head contacts the bone surface, the hex head shears off.
MANUFACTURE	**US Surgical pellets Extruded into a rod and machined. Exactly same process as absorbable predicate devices.**
STERILITY	EtO
FILE	mat\abs\ RECNO 976

B

COMPARABLE PREDICATE DEVICES

PREDICATE DEVICE I REVIEWED RECENTLY WITH SNAP-OFF FEATURE

DOCUMENT # K962233
SPONSOR Medinov
DEVICE NAME Twist-off Screw

CLASS HWC 2 888.3040 SCREW, FIXATION, BONE
DISEASE/USE Fixing and stabilizing osteotomies of the metatarsals and phalanges of the foot.

REASON FOR APPLICATION New device.
DECISION SE

MATERIALS Ti-6Al-4V STANDARD # ASTM F 136
INTERFACES ARTICULATIONS none MATING PARTS none
TISSUE FIXATION bone COATINGS none

DESIGN Self drilling, self tapping, partially threaded screw attached to a "screw-holder" which fits into a screwdriver. The connection between the screw and screw-holder breaks when the screw head contacts the bone cortex. 4 lengths. 2 mm OD.

PROCESSING Machined and oxidized in air. STERILITY nonsterile
FILE ba\bsc\ RECNO 998

OTHER PREDICATE DEVICES (see Fig. 4, 6)

As required by 21 CFR 807.87 (f), the device under review in this 510k is compared for substantial equivalence to legally marketed predicate devices which were found to be substantially equivalent in a 510k, i.e., K920188 PGA and K925098 PLLA Biofix pins and rods (Fig. 4) and K955729 LactoSorb Trauma Plating System (smaller screws, same material, used with plates in cranial maxillofacial indications) as well as other metal screws (Fig. 6).

The device under review has the same absorbable material as in other absorbable non-screw devices and the same geometry, size, partial threading, head snap-off during implantation and cannulation as are present in predicate metal screws. However, there are no predicate absorbable screws with the head snap-off feature and cannulation and no absorbable predicate devices for most of the listed indications (other than ankle and metatarsal).

TECHNOLOGICAL CHARACTERISTICS:

The animal testing included the following:

1 Friedman, R.J.; et al. implanted metal and absorbable bone screws (Tab. 1) in weight bearing dog femoral osteotomy models (Tab. 2, Fig. 7). After 2 months, the torsional strength (Tab. 3) of the whole bone implanted with the SS scews tended to be slightly higher compared to absorbable screws, but the differences were not significant. The hardness of the bone around the SS screws were not significantly higher than around the absorbable screws (Tab. 4).

Histology at 2, 9 and 15-17 months showed good healing without inflammation or osteolysis as occurs in PLA implants. This is because the copolymer resorbs more uniformly so crystallites are not present to cause inflammation. Bony union was 90% and 80% for bones fixed by absorbable and SS screws respectively as determined from fragment displacement measurements. There was complete resorption in 9-15 months. Fragment displacement fixed by both types of screw was low (0.5 mm) compared to other studies (1-2 mm).

This study demonstrated that the screws provided adequate healing in this animal model without inflammation.

2 Bianchini, S.; Pietrzak, W.S. aged 5 mm LactoSorb screws and 4.5 mm Biofix PGA screws in 37 C phosphate buffer for up to 2 months. The LactoSorb screws had greater shear and pullout loads (Fig. 5, Tab. 6). Non-soaked LactoSorb screws also had greater torque strengths (Tab. 5). The strength vs time aging study indicated that these screws had adquate strength during the 6 week healing time.

There is no clinical data on this device. A 510(k) indications for use statement, truthful and accuracy statement and summary of safety and effectiveness were submitted as required in the Safe Medical Devices Act.

LABELING

Proposed labels, labeling and advertisements were provided which sufficiently describe the device, its intended use and the directions for use (21 CFR 807.87)

REVIEWED BY: Ken McDermott

Ken McDermott

ATTACHMENTS:

design drawings
predicate device
Tables and Figures
intended use statement

CONTACT HISTORY:

The following is a chronological listing of all requests for information made by Ken McDermott to the firm regarding this 510k, followed by a summary of the firm's response in their next correspondence (the firm's response is indented below each request):

As per 21 CFR 807.87(h), I advised Ms. Verstynen Ms. Verstynen 2-24-97, 10 am that there is insufficient information to make a determination concerning substantial equivalence. I then requested the following information:

COMPARABLE PREDICATE DEVICE

COMPARABLE PREDICATE DEVICE
Please determine if there is a absorbable screw with similar threading, cannulation and temporary head twist off.

There is no such predicate device.

INTENDED USE
Please provide specific implantation sites and indications for use. For any changes you make, note that the following should be consistent and resubmitted:

intended use form,
package insert,
510(k) summary of safety and effectiveness

The indications are specific, but there are no predicate absorbable screw devices. The absorbable pin and rod devices only include ankle and metatarsal (Fig. 4).

TESTING

In the report by Friedman, R.J.; et al., please provide the following:

which screws were cannulated;

FDA received an adequate response to this request.

the differences between test samples and marketed devices (include photos/drawings if possible showing the differences in design, dimensions and intended use between the absorbable and SS samples);

FDA received an adequate response to this request.

legible figures;

FDA received an adequate response to this request.

a discussion of the relationship between indentation load and bone strength, viz., how well indentation load correlates to bone strength.

This information was requested but there was no response to this request by the firm.

In the report by Bianchini, S.; Pietrzak, W.S., please provide the following:

which screws were cannulated in the shear and pullout tests;

FDA received an adequate response to this request.

As per 21 CFR 807.87(h), I advised Ms. Verstynen Ms. Verstynen 3-4-97, 4 pm that there is insufficient information to make a determination concerning substantial equivalence. I then requested the following information:

COMPARABLE PREDICATE DEVICE
Please provide an absorbable screw with similar design features and intended uses as your device.

INTENDED USE
The indications provided are specific, but there are no predicate absorbable screw devices with these indications. The absorbable pin and rod devices only include ankle and metatarsal indications. Please provide specific implantation sites and indications for use for your device that match an appropriate predicate device. For any changes you make, note that the following should be consistent and resubmitted:

intended use form,
package insert,
510(k) summary of safety and effectiveness

TESTING
Clinical data may be necessary for those intended uses for which there are no predicate devices.

If cannulated, the screws contain a central through-hole of 1.25 mm (0.059 inch) diameter, to permit the bone fragments to be reduced with a 1.1 mm diameter K-wire, with the screw introduced over the K-wire. The instrumentation set is composed of a screwdriver, a tap, and a drill bit. Any standard stainless steel K-wire, up to a diameter of 1.1 mm, may be used with the cannulated screw.

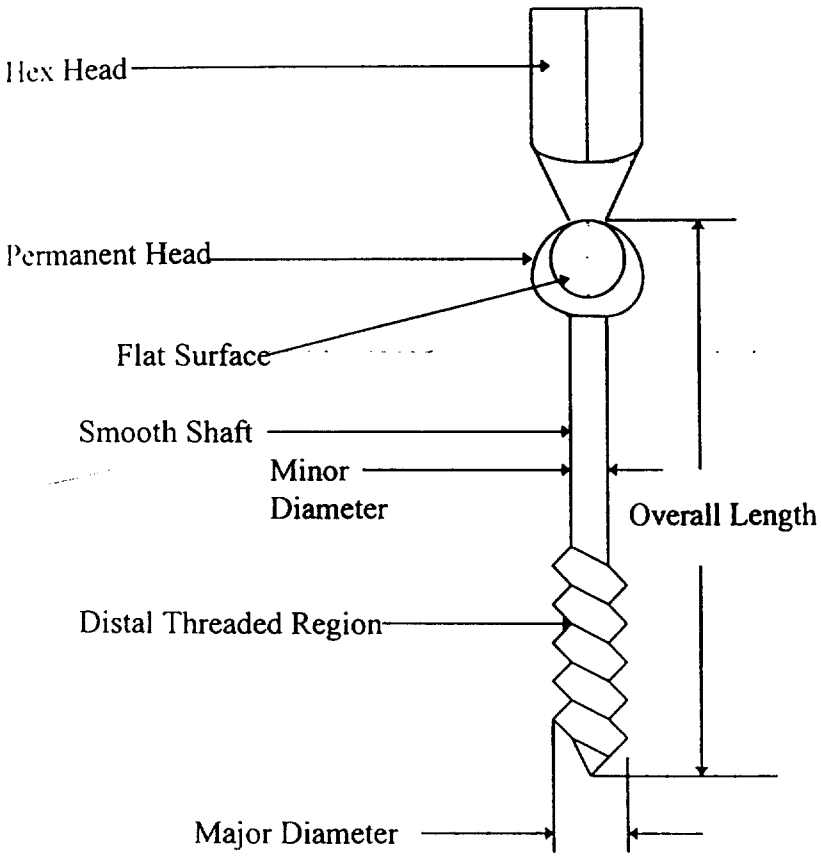


Figure 1. Schematic drawing of the Biomet bone screw.

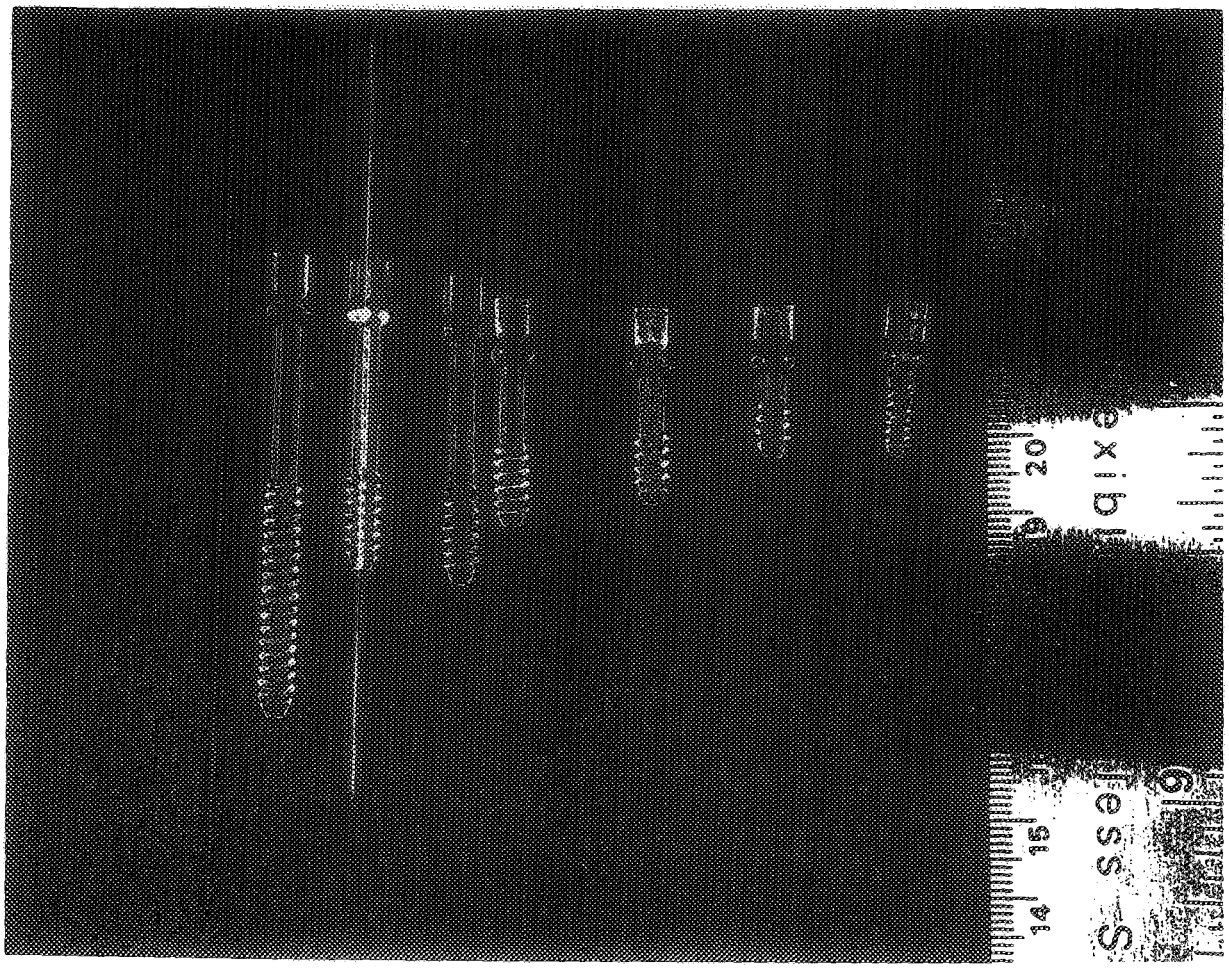


Fig. 2

(b)(4) Schematic Drawing

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
1390 Piccard Drive
Rockville MD 20850

JUL 19 1994

Mr. Jonathan S. Kahan
Bioscience Limited
Representing Hogan and Hartson
Columbia Square
555 Thirteenth Street Northwest
Washington, DC 20004-1109

Re: K925098
BIOFIX Bioabsorbable Self-Reinforced
Poly-L-lactide Fixation Pins
Regulatory Class: II
Product Code: HTY
Dated: June 1, 1994
Received: June 1, 1994

Dear Mr. Kahan:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to 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). You may, therefore, market your device subject to the general controls provisions of the Act and the following limitation: all labeling for this device system, including the package label and labeling included within the package, must prominently state that the Biofix Absorbable SRPLLA Pin is intended only for chevron osteotomies of the first metatarsal bone for hallux valgus.

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.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. In addition, FDA may publish further announcements concerning your device in the Federal Register.

F 1941 3

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
1390 Piccard Drive
Rockville, MD 20850

MAY 12 1993

Mr. Sam Son
Director of Corporate
Regulatory Affairs
Kirschner Medical Corporation
9690 Deereco Road
Timonium, Maryland 21093

Re: K920188
BIOFIX® Threaded Bioabsorbable
Fixation Rod
Regulatory Class: II
Dated: February 22, 1993
Received: February 23, 1993

Dear Mr. Son:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to legally marketed devices. This decision is based on your device being found equivalent only to similar devices labeled and intended for the maintenance of alignment of cancellous fractures of the malleolus of the ankle in the presence of appropriate immobilization. The decision was based on your demonstration of the clinical and functional equivalence of your device to metallic bone screw predicate devices. You may, therefore, market the device, subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act). The general controls provisions of the Act include requirements for registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under the Radiation Control for Health and Safety Act of 1968, or other Federal Laws or Regulations.

03

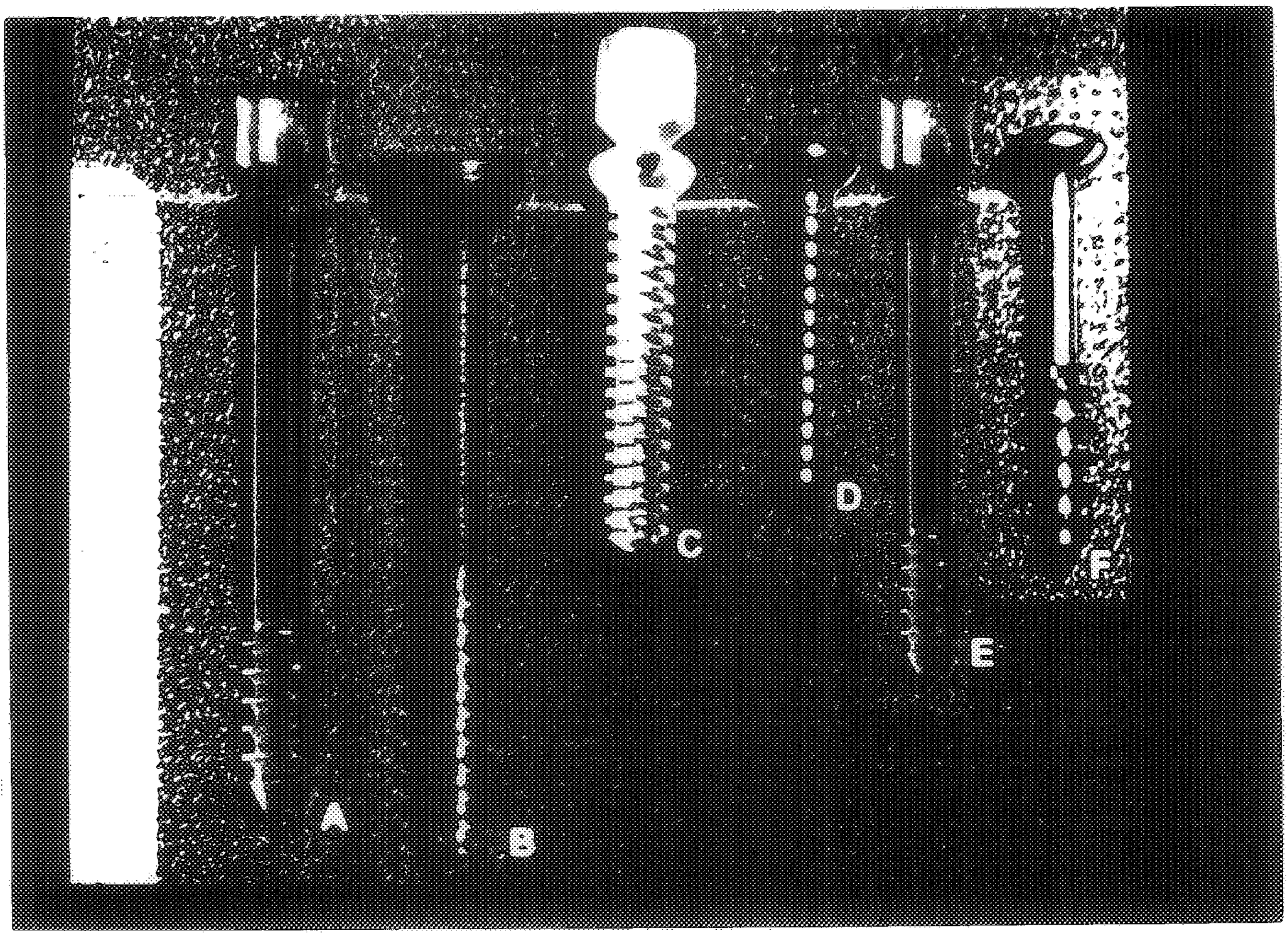


Figure 6

Pred[illegible]

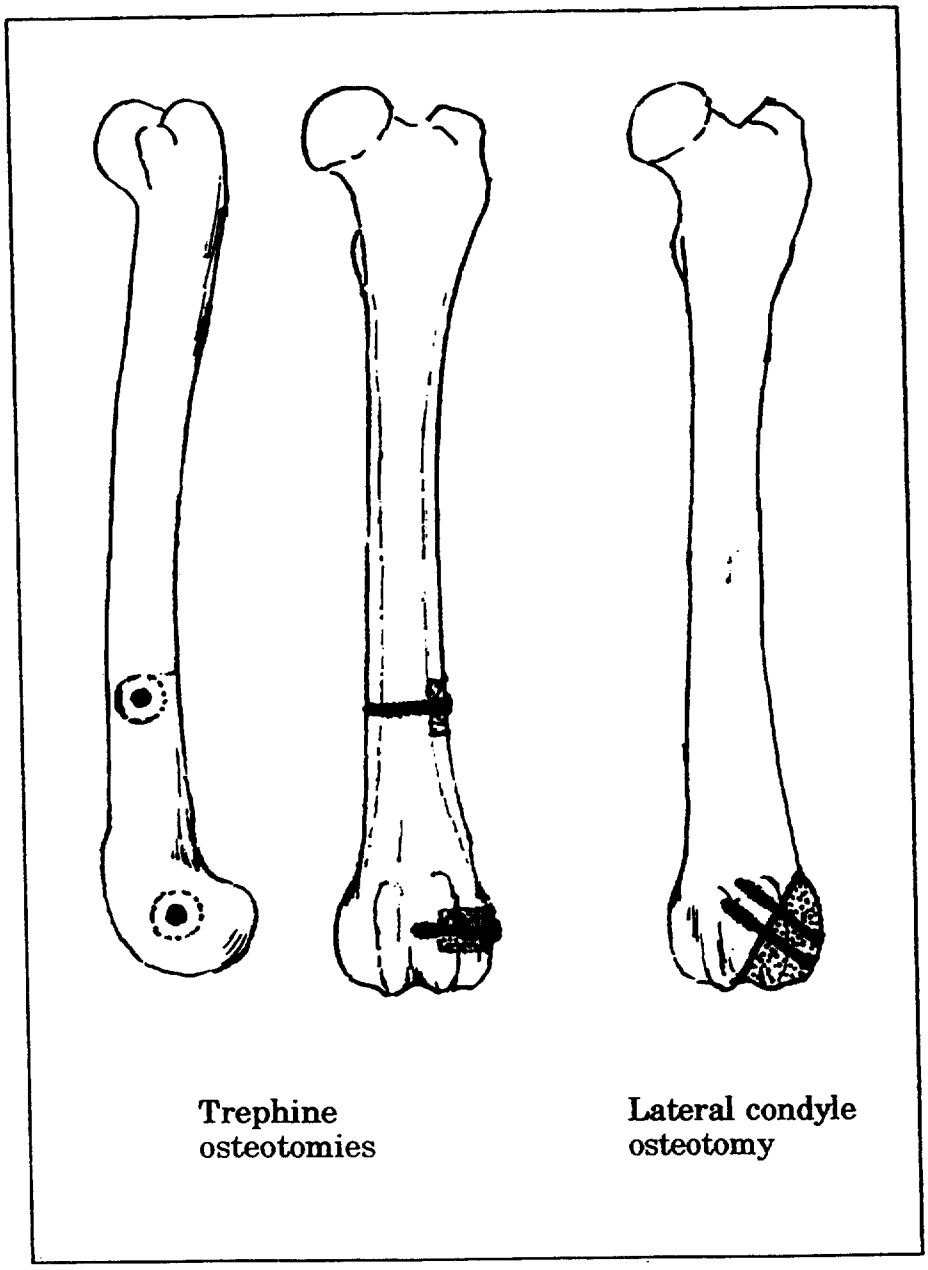


Figure 7

510(k) Number (if known): _____

Device Name: Biomet Bone Screw

Indications For Use:

The Biomet Bone Screw is indicated for fixation of cancellous bone fractures, osteotomies, arthrodeses or bone grafts.

Specific indications include:

1. Ankle fractures
2. Condylar fractures of the femur, tibia, fibula and humerus
3. Acromion/clavicular separation
4. Fractures of the olecranon, patella and talus
5. Fractures of the radial head and neck
6. Osteochondritis dissecans of the knee

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use____ OR Over-The-Counter Use____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

SUMMARY OF SAFETY AND EFFECTIVENESS

The Biomet Bone Screw is indicated for fixation of cancellous bone fractures, osteotomies, arthrodeses, or bone grafts.

Specific indications include:

1. ankle fractures
2. condylar fractures of the femur, tibia, fibula, and humerus
3. acromion/clavicular separation
4. fractures of the olecranon, patella, and talus
5. fractures of the radial read and neck
6. osteochondritis dissecans of the knee

The screws are made of a resorbable copolymer comprised of polylactic acid (PLA) and polyglycolic acid (PGA). In histological animal studies, the bone screw was completely resorbed by 15 months IN VIVO.

The Biomet Bone Screw is made of bioresorbable and biocompatible polymers that have been used in surgical procedures for years. LactoSorb® resorbable copolymer is a synthetic polyester derived from lactic and glycolic acids. Polylactic/polyglycolic acid copolymer degrades and resorbs IN VIVO by hydrolysis to lactic and glycolic acids which are then metabolized by the body. The safety of PLA/PGA material has been well documented since the early 1970's when the FDA first approved the use of resorbable PLA/PGA sutures. The exact same LactoSorb® material has been implanted in humans for over 10 years in a ligating clip. The LactoSorb® material has been found to be biocompatible in both soft tissue and bone tissue.

The effectiveness of the Biomet Bone Screw was determined by mechanical testing. The LactoSorb® screws were found to provide the same healing as a stainless steel screw in an animal model. There was no adverse tissue response to either the metal or LactoSorb® screws.

In summary the Biomet Bone Screw is safe and effective for fixation of cancellous bone. Mechanical testing demonstrated the Biomet Bone Screw to be as effective as the comparative metal and PGA resorbable cancellous screw.

97

DATE March 4, 1997
FROM KEN MCDERMOTT
TO Ms. Verstynen

LIST OF INFORMATION (DEFICIENCIES) NEEDED FOR K964970:

(b)(4)

[redacted]

Corporate
Headquarters

Mailing Address:
P.O. Box 587
Warsaw, IN 46581-0587

Shipping Address:
Airport Industrial Park
Warsaw, IN 46580

(219) 267-6639 Office
(219) 267-8137 FAX

February 28, 1997

Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville, MD 20850

Attention: Ken McDermott

RE: Biomet Bone Screw
K964970

Dear Mr. McDermott:

Enclosed are the following information in duplicate requested for K964970, the Biomet Bone Screw 510(k).

(b) (4)

[redacted]

Sincerely,

Mary L. Verstynen

Mary L. Verstynen
Clinical Research Manager

MLV/clb

510(k) Number (if known):_____

Device Name: Biomet Bone Screw

Indications For Use:

The Biomet Bone Screw is indicated for fixation of cancellous bone fractures, osteotomies, arthrodeses or bone grafts.

Specific indications include:

1. Ankle fractures
2. Condylar fractures of the femur, tibia, fibula and humerus
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4. Fractures of the olecranon, patella and talus
5. Fractures of the radial head and neck
6. Osteochondritis dissecans of the knee

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

_____ _____ _____ _____ _____ _____ _____

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use____ OR Over-The-Counter Use____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Biomet, Inc.
Airport Industrial Park
P.O. Box 587
Warsaw, Indiana 46580
USA

WARNINGS AND PRECAUTIONS FOR USE OF THE BIOMET BONE SCREW

ATTENTION OPERATING SURGEON

DESCRIPTION:

The Biomet Bone Screw is a resorbable device used for the fixation of cancellous bone fractures, osteotomies, arthrodeses or bone grafts. The device is made of a resorbable copolymer, a polyester derivative of lactic acid and glycolic acid. Polylactic/polyglycolic acid copolymer degrades and resorbs IN VIVO by hydrolysis to lactic and glycolic acids which are then metabolized by the body. The screws are completely resorbed by 15 months IN VIVO.

WARNINGS:

While these devices are generally successful in the alignment and fixation of bone they do not replace normal healthy body structures. The use of appropriate immobilization and postoperative management is indicated as a part of treatment until healing has occurred.

The surgeon is to be familiar with the implant, instruments, and surgical procedure. In using the device, a judgment must be made as to the holding power of the bone, as a significant degree of osteoporosis will weaken the hold in the bone. In all cases sound orthopedic practice is to be followed and the surgeon must select the type of device appropriate for treatment.

The patient is to be warned that the device can break or loosen as a result of stress, excessive activity or load bearing. The patient is to be made aware of surgical risks and possible adverse effects prior to surgery, and warned that failure to follow postoperative care instructions can cause failure of the implant and the treatment.

INDICATIONS:

The Biomet Bone Screw is indicated for fixation of cancellous bone fractures, osteotomies, arthrodeses or bone grafts.

76

Specific indications include:

1. ankle fractures
2. condylar fractures of the femur, tibia, fibula, and humerus
3. acromion/clavicular separation
4. fractures of the olecranon, patella, and talus
5. fractures of the radial head and neck
6. osteochondritis dissecans of the knee

CONTRAINDICATIONS:

1. Active infection.
2. Fractures and osteotomies of cortical bone.
3. Patients with mental or neurologic conditions who are unwilling or incapable of following postoperative care instructions.
4. Patient conditions including: blood supply limitations, insufficient quantity or quality of bone, or latent infections.

WARNINGS AND PRECAUTIONS:

1. Patients that engage in stressful physical activities are to be warned that injury at or near the implant site can lead to subsequent failure of the device and/or the treatment.
2. The device can break or be damaged due to excessive activity, and stress caused by full or partial load bearing can cause failure of the device.
3. The Biomet Bone Screw is intended to aid in alignment and bone fixation during the healing process and is not intended to replace normal body structures.
4. Care is to be taken to assure adequate fixation of the bone tissue at the time of surgery. The failure to achieve adequate fixation through improper positioning or placement of the device can contribute to a subsequent undesirable result.
5. DO NOT USE if there is loss of sterility of the device.
6. Discard and DO NOT USE opened or damaged devices, and use only devices that are packaged in unopened, or undamaged containers.
7. **CUTTING OF SCREWS:** The screw can be cut with an oscillating or reciprocating saw. NO OTHER CUTTING METHOD MAY BE USED. After implantation, screws can be cut ONLY at the distal protrusion.

POSSIBLE ADVERSE EFFECTS:

1. Infection can lead to failure of the procedure.
2. Neurovascular injuries can occur due to surgical trauma.

3. Bending, fracture, loosening, rubbing, and migration of the implant may occur as a result of excessive activity, trauma, or load bearing.
4. Delayed or non-union can occur

STERILITY:

Biomet Bone Screws are sterilized by exposure to Ethylene Oxide (ETO) Gas. DO NOT RESTERILIZE.
DO NOT STORE ABOVE 120°F OR 49°C

CAUTION: Federal Law (USA) restricts this device to sale, distribution, or use by or on the order of a physician.

SUMMARY OF SAFETY AND EFFECTIVENESS

The Biomet Bone Screw is indicated for fixation of cancellous bone fractures, osteotomies, arthrodeses, or bone grafts.

Specific indications include:

1. ankle fractures
2. condylar fractures of the femur, tibia, fibula, and humerus
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5. fractures of the radial read and neck
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The screws are made of a resorbable copolymer comprised of polylactic acid (PLA) and polyglycolic acid (PGA). In histological animal studies, the bone screw was completely resorbed by 15 months IN VIVO.

The Biomet Bone Screw is made of bioresorbable and biocompatible polymers that have been used in surgical procedures for years. LactoSorb® resorbable copolymer is a synthetic polyester derived from lactic and glycolic acids. Polylactic/polyglycolic acid copolymer degrades and resorbs IN VIVO by hydrolysis to lactic and glycolic acids which are then metabolized by the body. The safety of PLA/PGA material has been well documented since the early 1970's when the FDA first approved the use of resorbable PLA/PGA sutures. The exact same LactoSorb® material has been implanted in humans for over 10 years in a ligating clip. The LactoSorb® material has been found to be biocompatible in both soft tissue and bone tissue.

The effectiveness of the Biomet Bone Screw was determined by mechanical testing. The LactoSorb® screws were found to provide the same healing as a stainless steel screw in an animal model. There was no adverse tissue response to either the metal or LactoSorb® screws.

In summary the Biomet Bone Screw is safe and effective for fixation of cancellous bone. Mechanical testing demonstrated the Biomet Bone Screw to be as effective as the comparative metal and PGA resorbable cancellous screw.

LEGENDS

Figure 1. Photograph of the screws used in this study.A) 5.0 mm LactoSorb™ cancellous screw. B) 5.0 mm stainless steel cancellous screw. C) 3.5 mm LactoSorb™ cortical screw. D) 3.5 mm stainless steel cortical screw. E) 4.0 mm LactoSorb™ cancellous screw. F) 4.0 mm stainless steel cancellous screw.

Figure 2. Schematic diagrams showing placement of the diaphyseal and metaphyseal trephine osteotomies and lateral femoral condyle osteotomy.

Figure 3. Locations for the indentation testing, including four points on the bone plug surface and seven points on the surrounding metaphyseal bone surface.

Figure 4. The left lateral femoral condyle osteotomy was healed in two months.

Figure 5. A) Two months after the surgery, polymer screw material was seen in the screw track in this cortical trephine osteotomy, with callus around the screw head. B) By seventeen months, the screw track was filled with bone tissue and no evidence of any polymer material remained.

Figure 6. At two months in both the trephine metaphyseal and lateral condyle osteotomy, polymer screw material was clearly seen in the screw tracks (A and D). For the nine month time period, polymer screw material was still seen in the screw tracks but the amount was much less than that at two months (B and E). At fifteen or seventeen months, the screw tracks were still present but no evidence of any polymer material remained. The tracks had filled with fibrous and adipose connective tissue (C and F).

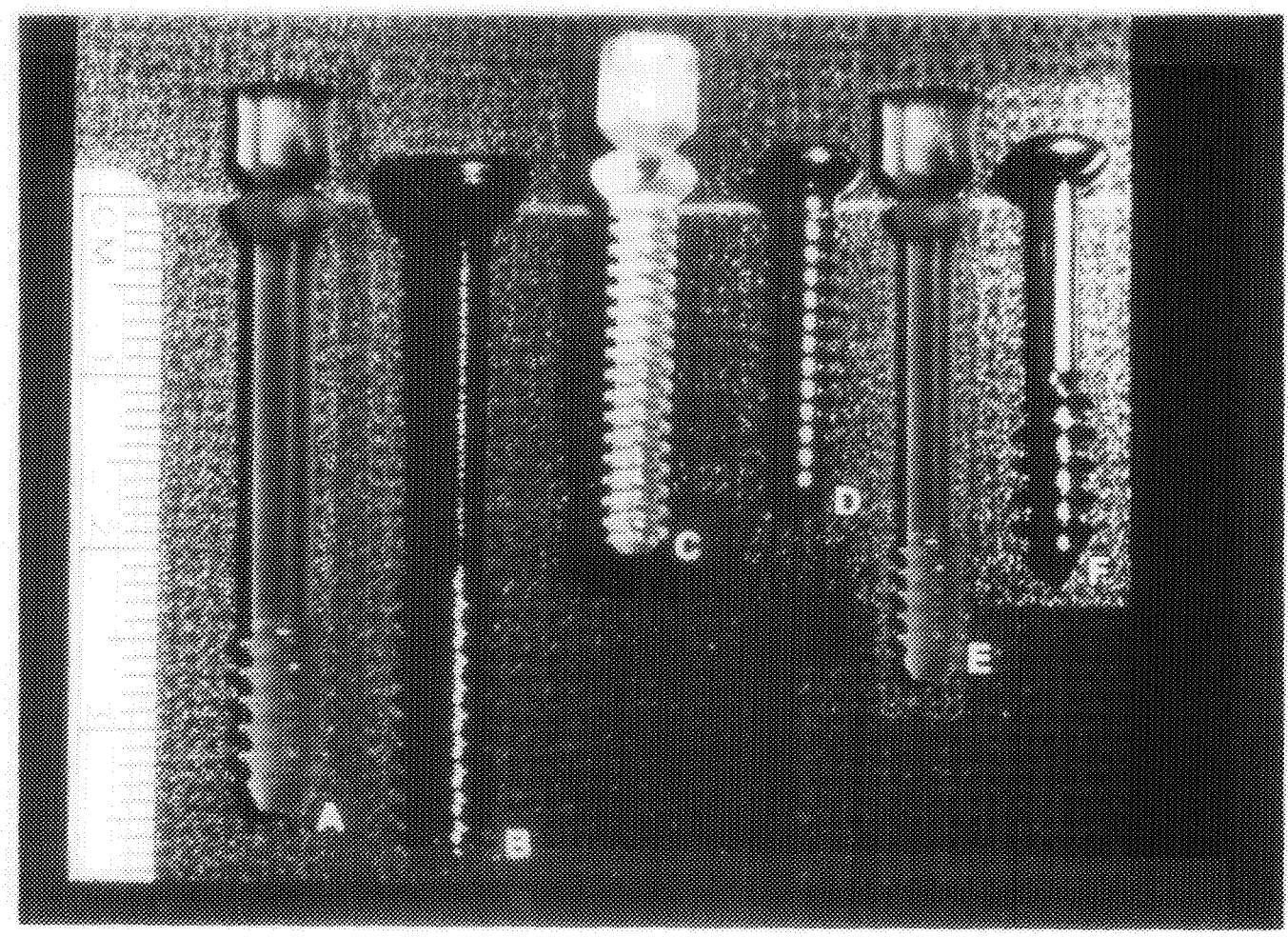


Figure 1

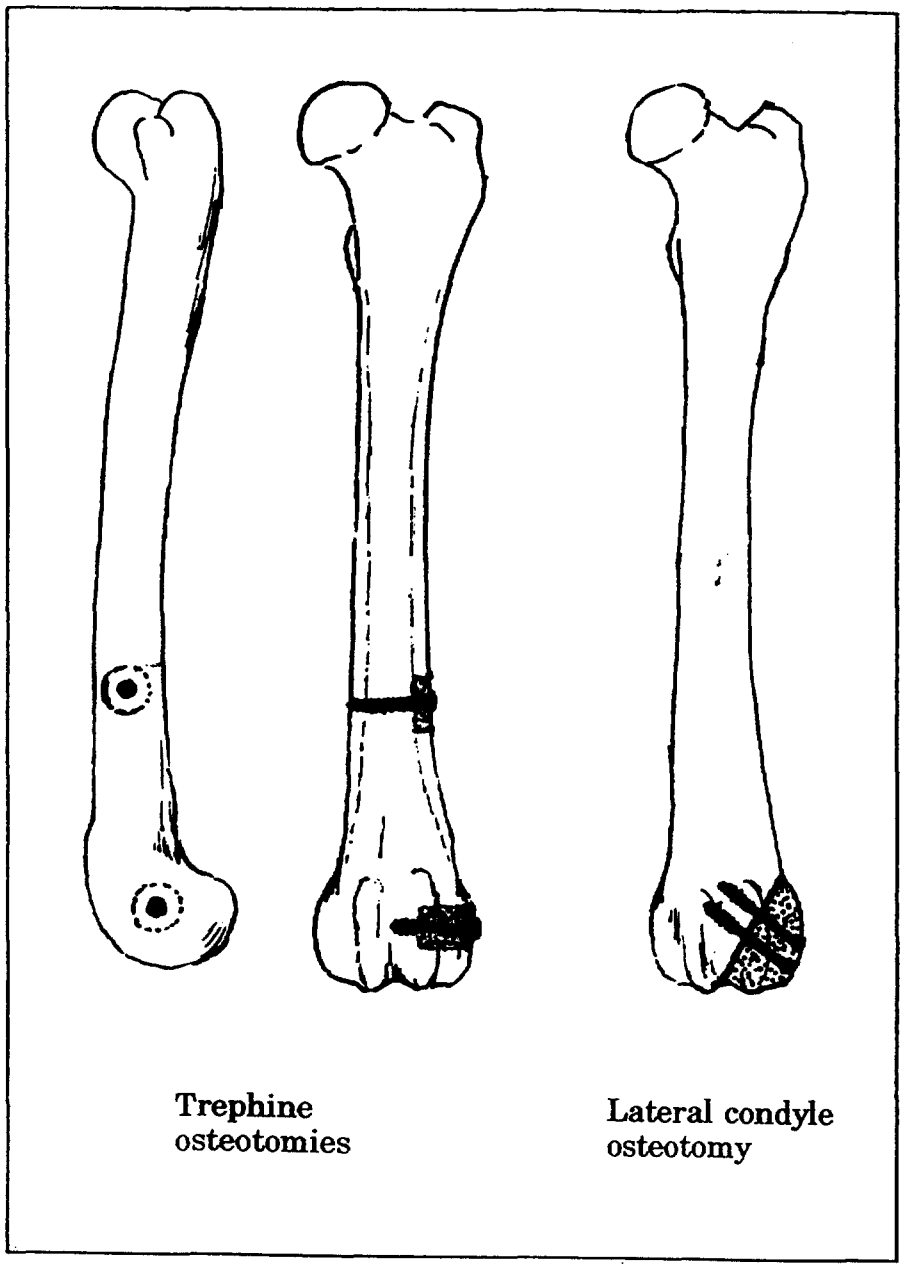


Figure 2

Fig 3

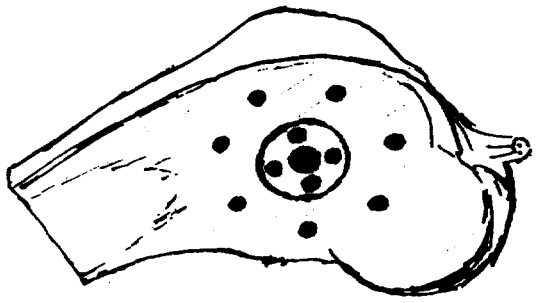


Figure 3

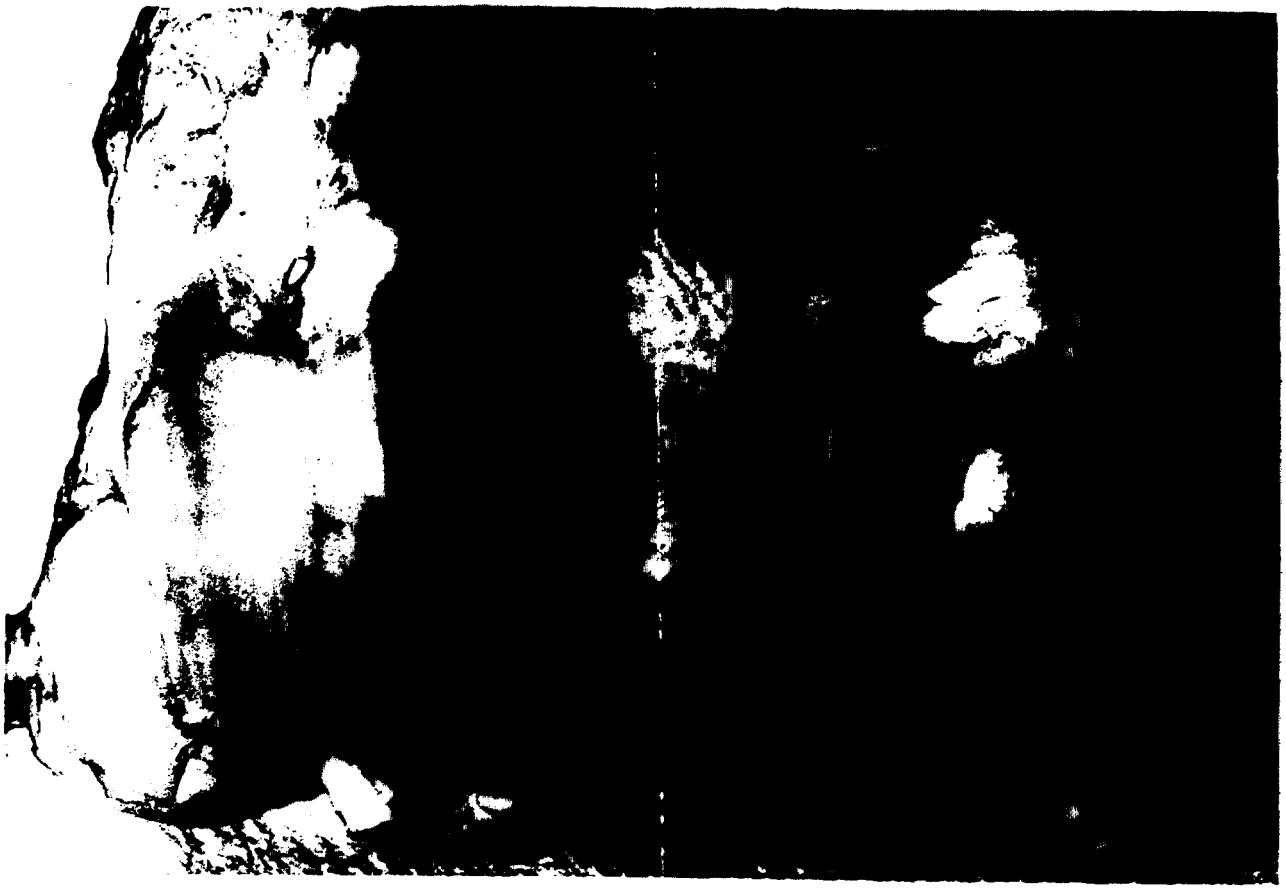
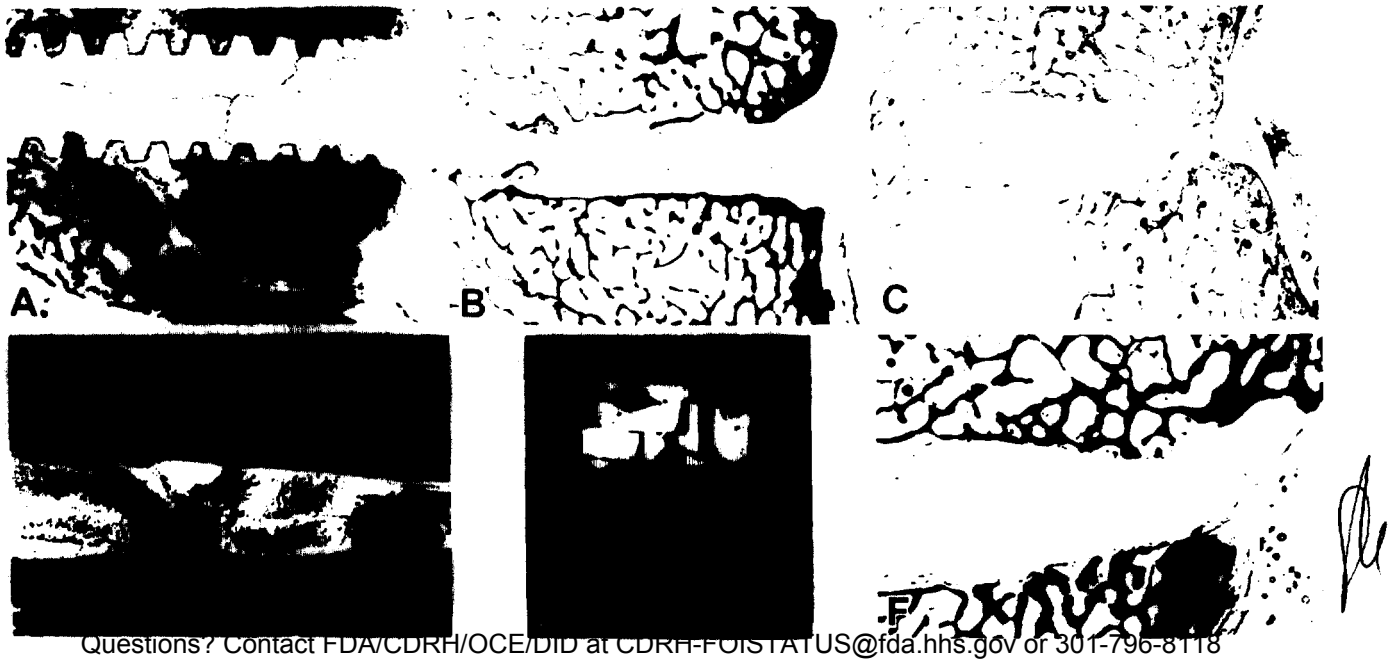


Figure 4

Figure 5

Fig 6

Figure 6



K964970/A1

Corporate
Headquarters

Mailing Address:
P.O. Box 587
Warsaw, IN 46581-0587

Shipping Address:
Airport Industrial Park
Warsaw, IN 46580

(219) 267-6639 Office
(219) 267-8137 FAX

January 2, 1997

Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville, MD 20850

RE: 510(k): K964970
Biomet Bone Screw

Dear Sir or Madam:

Enclosed is the "Truthful and Accurate Statement" sheet which was not included in the K964970 submission. Please attach this sheet to the 510(k).

Sincerely,

Mary L. Verstynen

Mary L. Verstynen
Clinical Research Manager

MLV/clb

SK: 48

PREMARKET NOTIFICATION

TRUTHFUL AND ACCURATE STATEMENT

(As Required by 21 CFR 807.87 (j))

I certify that in my capacity as Director of Resorbable Technology, Biomet, 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.

William S. Pietrzak, Ph.D.

Biomet, Inc. December 11, 1996

Biomet Bone Screw

[Premarket Notification Title]

REVISED:01/22/96

PREMARKET NOTIFICATION (510(K)) CHECKLIST FOR ACCEPTANCE DECISION

K 964970 Device Name Bone screw

Division/Branch ~~ED~~ DGRD/OR

Administrative Reviewer Signature Michael Smith Date 12/26/96

Supervisory Signature _____ Date _____

Did the firm request expedited review? _____Yes X No

Did we grant expedited review? _____Yes X No

Truthful and accurate statement enclosed? X Yes _____No
(If Not Enclosed, Must Be A Refuse To Accept Letter)
Required For Originals Received 3/14/95 And After

Is the Indication for Use Form enclosed? X YES _____No
(Required for Original 510(k)s received 1/1/96 and after -- must be submitted on a separate sheet of paper)

thout reviewing this 510(k), do you believe this device type may be a preamendments lass III device? _____Yes X No (IF YES, NOTIFY POS IMMEDIATELY IF THE OUTSIDE OF THE 510(k) HAS NOT BEEN STAMPED CLASS III SO THAT THE GMP INSPECTION CAN BE SCHEDULED AS SOON AS POSSIBLE). Class III devices can not receive a determination of substantial equivalence until the GMP inspection process has been completed.

Is this a file that was determined to be substantially equivalent by ODE, but placed on hold due to GMP violations and deleted after 12 months on hold? If so, a new ODE review is not required, please forward to POS.

_____Yes X No

_____ Accepted

_____ Refuse To Accept

I. CRITICAL ELEMENTS:	YES PRESENT OMISSION JUSTIFIED	NO INADEQUATE OMITTED
A. Is The Product A Device?	☐	☐
B. Is The Device Exempt From 510(k) By Regulation Or Policy?	☐	☐
C. Is Device Subject To Review By CDRH?	☐	☐
D. (i) Are You Aware That This Device Has Been The Subject Of A Previous NSE Decision?	☐	☐
(ii) If Yes, Does This New 510(k) Address The NSE Issue(s) (E.G., Performance Data)?	☐	☐
E. (i) Are You Aware Of The Submitter Being The Subject Of An Integrity Investigation? If Yes, Consult The ODE Integrity Officer.	☐	☐
(ii) Has The ODE Integrity Officer Given Permission To Proceed With The Review? (Blue Book Memo #I91-2 And Federal Register 90N-0332, September 10, 1991.)	☐	☐
F. Does The Submission Contain The Information Required Under Sections 510(k), 513(f), And 513(i) Of The Federal Food, Drug, and Cosmetic Act (Act) And Subpart E Of Part 807 In Title 21 Of The Code Of Federal Regulations?:	☐	☐
1. Device Trade Or Proprietary Name	☐	☐
2. Device Common Or Usual Name Or Classification Name	☐	☐
3. Establishment Registration Number (Only Applies If Establishment Is Registered)	☐	☐
4. Class Into Which The Device Is Classified Under (21 CFR Parts 862 to 892)	☐	☐
5. Classification Panel	☐	☐
6. Action Taken To Comply With Section 514 Of The Act	☐	☐
7. Proposed Labels, Labeling And Advertisements (If Available) That Describe The Device, Its Intended Use, And Directions For Use (Blue Book Memo #G91-1)	☐	☐

90

8. A 510(k) Summary Of Safety And Effectiveness Or A 510(k) Statement That Safety And Effectiveness Information Will Be Made Available To Any Person Upon Request	0	0
9. For Class III Devices Only, A Class III Certification And A Class III Summary	0	0
10. Photographs Of The Device	0	0
11. Engineering Drawings For The Device With Dimensions And Tolerances	0	0
12. The Marketed Device(s) To Which Equivalence Is Claimed Including Labeling And Description Of The Device	0	0
13. Statement Of Similarities And/Or Differences With Marketed Device(s)	0	0
14. Data To Show Consequences And Effects Of A Modified Device(s)	0	0
15. Truthful And Accurate Statement	0	0
II. Additional Information That Is Necessary Under 21 CFR 807.87(h):	0	0
A. Submitter's Name And Address	0	0
B. Contact Person, Telephone Number And Fax Number	0	0
C. Representative/Consultant If Applicable	0	0
D. Table Of Contents With Pagination	0	0
E. Address Of Manufacturing Facility/Facilities And, If Appropriate, Sterilization Site(s)	0	0
III. Additional Information That May Be Necessary Under 21 CFR 807.87(h):	0	0
A. Comparison Table Of The New Device To The Marketed Device(s)	0	0
B. Action Taken To Comply With Voluntary Standards	0	0
C. Performance Data	0	0
MARKETED DEVICE:	0	0
Bench Testing	0	0
Animal Testing	0	0
Clinical Data	0	0
NEW DEVICE:	0	0
Bench Testing	0	0
Animal Testing	0	0

Clinical Data	☐	☐
D. **Sterilization Information**	☐	☐
E. **Software Information**	☐	☐
F. **Hardware Information**	☐	☐
G. **If This 510(k) Is For A Kit, Has The Kit Certification Statement Been Provided?**	☐	☐
H. **Is This Device Subject To Issues That Have Been Addressed In Specific Guidance Document(s)?**	☐	☐
If Yes, Continue Review With Checklist From Any Appropriate Guidance Documents.	☐	☐
If No, Is 510(k) Sufficiently Complete To Allow Substantive Review?	☐	☐
I. **Other (Specify)**	☐	☐

REVISED: 3/14/95

THE 510(K) DOCUMENTATION FORMS ARE AVAILABLE ON THE LAN UNDER 510(K) BOILERPLATES TITLED "DOCUMENTATION" AND MUST BE FILLED OUT WITH EVERY FINAL DECISION (SE, NSE, NOT A DEVICE, ETC.).

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

K_____

Reviewer: _____

Division/Branch: _____

Device Name: _____

Product To Which Compared (510(K) Number If Known): _____

	YES	NO	
1. Is Product A Device			If NO = Stop
2. Is Device Subject To 510(k)?			If NO = Stop
3. Same Indication Statement?			If YES = Go To 5
4. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If YES = Stop NE
5. Same Technological Characteristics?			If YES = Go To 7
6. Could The New Characteristics Affect Safety Or Effectiveness?			If YES = Go To 8
7. Descriptive Characteristics Precise Enough?			If NO = Go To 10 If YES = Stop SE
8. New Types Of Safety Or Effectiveness Questions?			If YES = Stop NE
9. Accepted Scientific Methods Exist?			If NO = Stop NE
10. Performance Data Available?			If NO = Request Data
11. Data Demonstrate Equivalence?			Final Decision:

Note: In addition to completing the form on the LAN, "yes" responses to questions 4, 6, 8, and 11, and every "no" response requires an explanation.

1. Intended Use:

2. Device Description: Provide a statement of how the device is either similar to and/or different from other marketed devices, plus data (if necessary) to support the statement. Is the device life-supporting or life sustaining? Is the device implanted (short-term or long-term)? Does the device design use software? Is the device sterile? Is the device for single use? Is the device product as a component? Is this device a kit? Provide a summary about the devices design, materials, physical properties and toxicology profile if important.

EXPLANATIONS TO "YES" AND "NO" ANSWERS TO QUESTIONS ON PAGE 1 AS NEEDED

1. Explain why not a device:

2. Explain why not subject to 510(k):

3. How does the new indication differ from the predicate device's indication:

4. Explain why there is or is not a new effect or safety or effectiveness issue:

5. Describe the new technological characteristics:

6. Explain how new characteristics could or could not affect safety or effectiveness:

7. Explain how descriptive characteristics ar not precise enough:

8. Explain new types of safety or effectiveness questions raised or why the questions are not new:

9. Explain why existing scientific methods can not be used:

10. Explain what performance data is needed:

11. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

ATTACH ADDITIONAL SUPPORTING INFORMATION

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DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

December 13, 1996

BIOMET, INC.
AIRPORT INDUSTRIAL PARK
P.O. BOX 587
WARSAW, IN 46581
ATTN: MARY L. VERSTYNEN

510(k) Number: K964970
Received: 12-DEC-96
Product: BIOMET BONE SCREW

The Center for Devices and Radiological Health (CDRH), Office of Device Evaluation (ODE), has received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in any future correspondence that relates to this submission. We will notify you when the processing of your premarket notification 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.

On January 1, 1996, FDA began requiring that all 510(k) submitters provide on a separate page and clearly marked "Indication For Use" the indication for use of their device. If you have not included this information on a separate page in your submission, please complete the attached and amend your 510(k) as soon as possible. Also if you have not included your 510(k) Summary or 510(k) Statement, or your Truthful and Accurate Statement, please do so as soon as possible. There may be other regulations or requirements affecting your device such as Postmarket Surveillance (Section 522(a)(1) of the Act) and the Device Tracking regulation (21 CFR Part 821). Please contact the Division of Small Manufacturers Assistance (DSMA) at the telephone or web site below for more information.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the Document Mail Center will not be considered as part of your official premarket notification submission. Because of equipment and personnel limitations, we cannot accept telefaxed material as part of your official premarket notification submission, unless specifically requested of you by an FDA official. Any telefaxed material must be followed by a hard copy to the Document Mail Center (HFZ-401).

You should be familiar with the manual entitled, "Premarket Notification 510(k) Regulatory Requirements for Medical Devices" available from DSMA. If you have other procedural or policy questions, or want information on how to check on the status of your submission (after 90 days from the receipt date), please contact DSMA at (301) 443-6597 or its toll-free number (800) 638-2041, or at their Internet address DSMO@FDADR.CDRH.FDA.GOV or me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman
Consumer Safety Officer
Premarket Notification Staff

 K964970

Corporate
Headquarters

Mailing Address:
P.O. Box 587
Warsaw, IN 46581-0587

Shipping Address:
Airport Industrial Park
Warsaw, IN 46580

(219) 267-6639 Office
(219) 267-8137 FAX

December 11, 1996

Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville, MD 20850

RE: 510(k) Notification
Biomet Bone Screw

Dear Sir or Madam:

Please find the enclosed 510(k) Notification for the Biomet Bone Screw. This screw is made of the exact same material used in the LactoSorb® Trauma Plating System (K955729, K960988) LactoSorb® Suture Anchor (K954443), LactoSorb® Pop Rivet (K951658) and LactoSorb® Bone Pin (K953194).

We consider our intent to market these devices as confidential commercial information and request that it be considered as such by the FDA. We trust that you will find this submission in compliance with the regulations.

Sincerely,

Mary L. Verstynen

Mary L. Verstynen
Clinical Research Manager

MLV/clb

96 OR 2

Superceded

510(k) Number (if known): _____

Device Name: Biomet Bone Screw

Indications For Use:

The Biomet Bone Screw is indicated for fixation of cancellous bone fractures, osteotomies, arthrodeses or bone grafts.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use____ OR Over-The-Counter Use____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH
Premarket Submission Cover Sheet

Date of Submission: 12/11/96

FDA Document Number: K964970

Section A — Type of Submission

- ☒ 510(k)
- ☐ 510(k) Add'l information
- ☐ IDE
- ☐ IDE Amendment
- ☐ IDE Supplement
- ☐ IDE Report
- ☐ PMA
- ☐ PMA Amendment
- ☐ PMA Report
- ☐ PMA Supplement - Regular
- ☐ PMA Supplement - Special
- ☐ PMA Supplement - 30 day
- ☐ PMA Supplement - Panel Track

Section B1 — Reason for Submission — 510(k)s Only

- ☒ New device
- ☐ Additional or expanded indications
- ☐ Change in technology, design, materials, or manufacturing process
- ☐ Other reason (specify):

Section B2 — Reason for Submission — PMAs Only

- ☐ New device
- ☐ Withdrawal
- ☐ Additional or expanded indications
- ☐ Licensing agreement
- ☐ Labeling change:
  - ☐ Indications
  - ☐ Instructions
  - ☐ Performance Characteristics
  - ☐ Shelf life
  - ☐ Trade name
  - ☐ Other (specify below)
- ☐ Change in ownership
- ☐ Change in correspondent
- ☐ Other reason (specify):
- ☐ Change in design, component, or specification:
  - ☐ Software
  - ☐ Color Additive
  - ☐ Other (specify below)
- ☐ Process change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager
- ☐ Response to FDA correspondence (specify below)
- ☐ Request for applicant hold
- ☐ Request for removal of applicant hold
- ☐ Request for extension
- ☐ Request to remove or add manufacturing site
- ☐ Location change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager
  - ☐ Distributor
- ☐ Report submission:
  - ☐ Annual or periodic
  - ☐ Post-approval study
  - ☐ Adverse reaction
  - ☐ Device defect
  - ☐ Amendment

Section B3 — Reason for Submission — IDEs Only

- ☐ New device
- ☐ Addition of institution
- ☐ Expansion / extension of study
- ☐ IRB certification
- ☐ Request hearing
- ☐ Request waiver
- ☐ Termination of study
- ☐ Withdrawal of application
- ☐ Unanticipated adverse effect
- ☐ Emergency use:
  - ☐ Notification of emergency use
  - ☐ Additional information
- ☐ Other reason (specify):
- ☐ Change in:
  - ☐ Correspondent
  - ☐ Design
  - ☐ Informed consent
  - ☐ Manufacturer
  - ☐ Manufacturing
  - ☐ Protocol – feasibility
  - ☐ Protocol– other
  - ☐ Sponsor
- ☐ Report submission:
  - ☐ Current investigator
  - ☐ Annual progress
  - ☐ Site waiver limit reached
  - ☐ 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
- ☐ IOL submissions only:
  - ☐ Change in IOL style
  - ☐ Request for protocol waiver

FDA Document Number:

Section C — Product Classification

Product code: 87HWC	C.F.R. Section: 888.3040	Device class: ☐ Class I ☒ Class II ☐ Class III ☐ Unclassified
Classification panel: Orthopedic		

Section D — Information on 510(k) Submissions

Product codes of devices to which substantial equivalence is claimed:

1	2	3	4
87HWC			
5	6	7	8

Summary of, or statement concerning, safety and effectiveness data:
☒ 510(k) summary attached
☐ 510(k) statement

Information on devices to which substantial equivalence is claimed:

510(k) Number	Trade or proprietary or model name	Manufacturer
1 K920188	1 Biofix SR-PGA Screw	1 Bioscience Ltd.
2	2	2
3	3	3
4	4	4
5	5	5
6	8	8

Section E — Product Information — Applicable to All Applications

Common or usual name or classification name:
Screw, fixation, bone

Trade or proprietary or model name	Model number
1 Biomet Bone Screw	1 see Exhibit 1
2	2
3	3
4	4
5	5
6	6

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

1	2	3	4	5	6
K954443	K951658	K953194			
7	8	9	10	11	12

Data included in submission: ☒ Laboratory testing ☒ Animal trials ☐ Human trials

Indications (from labeling):
The Biomet Bone Screw is indicated for fixation of cancellous bone fractures, osteotomies, arthrodeses or bone grafts.

FDA Document Number:

Section F — Manufacturing / Packaging / Sterilization Sites

☒ Original ☐ Add ☐ Delete	FDA establishment registration number: 1825034	☒ Manufacturer ☐ Contract manufacturer	☐ Contract sterilizer ☐ Repackager / relabeler

Company / Institution name: Biomet, Inc.

Division name (if applicable): NA	Phone number (include area code): (219) 267-6639
Street address: Airport Industrial Park P.O. Box 587	FAX number (include area code): (219) 268-2742

City:	State / Province:	Country:	ZIP / Postal Code:
Warsaw	Indiana	USA	46581-0587

Contact name: Mary Verstynen

Contact title: Clinical Research Manager

☒ Original ☐ Add ☐ Delete	FDA establishment registration number:	☐ Manufacturer ☐ Contract manufacturer	☒ Contract sterilizer ☐ Repackager / relabeler

Company / Institution name: (b) (4)

Division name (if applicable):	Phone number (include area code): (b) (4)
Street address: (b) (4)	FAX number (include area code): (b) (4)

City:	State / Province:	Country:	ZIP / Postal Code:
(b) (4)	(b) (4)	(b) (4)	(b) (4)

Contact name: (b) (4)

Contact title: (b) (4)

☒ Original ☐ Add ☐ Delete	FDA establishment registration number:	☐ Manufacturer ☐ Contract manufacturer	☒ Contract sterilizer ☐ Repackager / relabeler

Company / Institution name: (b) (4)

Division name (if applicable):	Phone number (include area code): (b) (4)
Street address: (b) (4)	FAX number (include area code): (b) (4)

City:	State / Province:	Country:	ZIP / Postal Code:
(b) (4)	(b) (4)	(b) (4)	(b) (4)

Contact name: (b) (4)

Contact title: (b) (4)

10

	FDA Document Number:

Section G — Applicant or Sponsor

Company / Institution name: Biomet, Inc.			FDA establishment registration number: 1825034
Division name (if applicable):			Phone number (include area code): (219) 267-6639
Street address: Airport INdustrial Park P.O. Box 587			FAX number (include area code): (219) 268-2742
City: Warsaw	State / Province: Indiana	Country: USA	ZIP / Postal Code: 46581-0587
Signature: Mary L. Verstynen			
Name: Mary L. Verstynen			
Title: Clinical Research Manager			

Section H — Submission correspondent (if different from above)

Company / Institution name:			
Division name (if applicable):			Phone number (include area code): ( )
Street address:			FAX number (include area code): ( )
City:	State / Province:	Country:	ZIP / Postal Code:
Contact name:			
Contact title:			

Your voluntary completion of this Premarket Submission Cover Sheet will not affect any FDA decision concerning your submission, but will help FDA's Center for Devices and Radiological Health process your submission more efficiently. The information you provide should apply *only* to a single accompanying submission. Please do not send cover sheets for any previous submissions. See the instructions for additional information on completing the cover sheet. If you have a question concerning completion of the cover sheet, please contact the Division of Small Manufacturers Assistance at (800) 638-2041 or (301) 443-6597.

01

Super cede it

SUMMARY OF SAFETY AND EFFECTIVENESS

The Biomet Bone Screw is indicated for fixation of cancellous bone fractures, osteotomies, arthrodeses, or bone grafts. The screws are made of a resorbable copolymer comprised of polylactic acid (PLA) and polyglycolic acid (PGA). In histological animal studies, the bone screw was completely resorbed by 15 months IN VIVO.

The Biomet Bone Screw is made of bioresorbable and biocompatible polymers that have been used in surgical procedures for years. LactoSorb® resorbable copolymer is a synthetic polyester derived from lactic and glycolic acids. Polylactic/polyglycolic acid copolymer degrades and resorbs IN VIVO by hydrolysis to lactic and glycolic acids which are then metabolized by the body. The safety of PLA/PGA material has been well documented since the early 1970's when the FDA first approved the use of resorbable PLA/PGA sutures. The exact same LactoSorb® material has been implanted in humans for over 10 years in a ligating clip. The LactoSorb® material has been found to be biocompatible in both soft tissue and bone tissue.

The effectiveness of the Biomet Bone Screw was determined by mechanical testing. The LactoSorb® screws were found to provide the same healing as a stainless steel screw in an animal model. There was no adverse tissue response to either the metal or LactoSorb® screws.

In summary the Biomet Bone Screw is safe and effective for fixation of cancellous bone. Mechanical testing demonstrated the Biomet Bone Screw to be as effective as the comparative metal and PGA resorbable cancellous screw.

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510(k)

510(k) Notification

DEVICE IDENTIFICATION

Proprietary name: Biomet Bone Screw

Common Name: Bone Screw

Classification Name and Reference: Screw, Fixation, Bone (888.3040)

Regulatory Class: Class II

Device Product Code: 87HWC

DEVICE DESCRIPTIVE INFORMATION

This device is indicated for fixation of cancellous bone fractures, osteotomies, arthrodeses, or bone grafts.

Device Description

Referring to Figure 1 on the next page, the Biomet Bone Screw is comprised of a hex head driver, a permanent head, a smooth shaft, and a distal threaded region. The bone substrate is first drilled and tapped. Next, the socket-type screwdriver is engaged with the hex head of the screw. The distal tip of the screw is inserted into the tapped bone hole and the screw is torqued into the hole until the underside of the permanent head comes into contact with the bone surface. Additional torque applied to the screw then shears the hex head from the permanent head at the neck, or juncture, between the two heads. The detached hex head is then ejected from the screwdriver. A substantial region of 3.5 mm (0.138 inch) diameter smooth shaft exists between the permanent head and the distal threaded region. This permits the proximal bone fragment to be lagged to the distal fragment. Opposing sides of the permanent head include two flat surfaces to enable the screw to be grasped with needle holders, or other grasping instrument, so that the screw can be countertorqued for removal. The 5 mm diameter (0.197 inch) threads are a buttress type configuration which are relatively blunt, compared to the V-threads typical of metal screws. This configuration increases the strength of the thread, but contributes to the requirement that the hole be tapped prior to screw introduction.

There is a family of twelve screws, the overall length (including permanent head) ranging from 35 to 70 mm, or 1.378 to 2.756 inches. Specific lengths are 35, 40, 45, 50, 60, and 70 mm. Screws of each length may be cannulated or solid.

If cannulated, the screws contain a central through-hole of 1.25 mm (0.059 inch) diameter, to permit the bone fragments to be reduced with a 1.1 mm diameter K-wire, with the screw introduced over the K-wire. The instrumentation set is composed of a screwdriver, a tap, and a drill bit. Any standard stainless steel K-wire, up to a diameter of 1.1 mm, may be used with the cannulated screw.

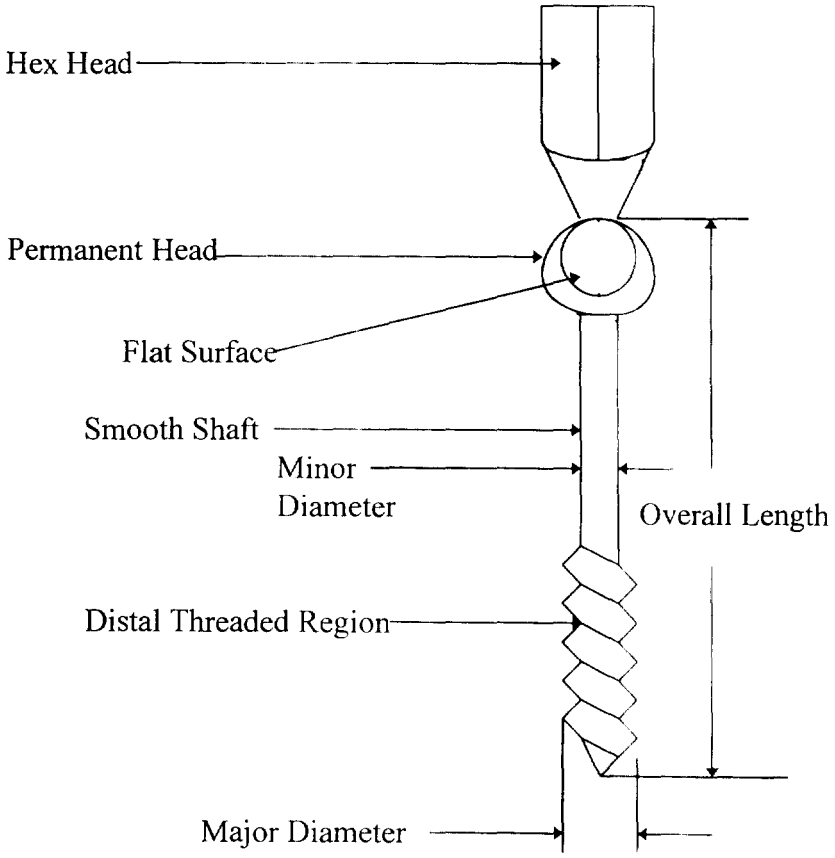


Figure 1. Schematic drawing of the Biomet bone screw.

See Exhibit 1 for a device listing, photographs, and engineering drawings of the devices.

MATERIALS

Biomet®: 82% L-Lactide
18% Glycolide

LABELING

A sample of proposed labeling is found in Exhibit 2. No promotional material is currently available.

STERILITY INFORMATION

Radiation Type: Ethylene Oxide (ETO)
Residuals: Residuals are below the 1978 Federal Register limits.
250ppm ETO
5000ppm ETG
250ppm ETCH
Sterility Assurance Level: 10^{-6}
Sterility Validation Method: AMMI
Pyrogen-Free: The devices are not labeled as "Pyrogen Free" Pyrogen testing is performed as part of auditing procedures by United States Surgical Corporation.

Sterilization Site: United States Surgical Corporation
195 McDermott Road
North Haven, Connecticut 06473
or
Griffith Micro Science
7775 Quincy Street
Willowbrook, IL 60521-5531

See Exhibit 3 for detailed sterilization information.

PACKAGING DESCRIPTION

The final product will be supplied in individual sterile packages. The Biomet Bone Screws are packaged with desiccant in a Tyvek pouch and this pouch resides in a foil pouch.

SUBSTANTIAL EQUIVALENCE INFORMATION

The Biomet Bone Screw is substantially equivalent to:

1. Biofix® SR-PGA Screw manufactured by Bioscience Ltd., Tampere, Finland; K920188

   A Biofix SR-PLLA Screw has also received marketing clearance K925098.

The following "Comparison to Marketed Device" shows that the Biofix Screws have the same indication and intended use in a similar design as the Biomet Bone Screw. See information in Exhibit 4 on the Biofix Screws.

- Package Insert
- Device Listing
- Surgical Techniques

The Biofix SR-PGA Screw is 100% PGA and the Biomet Screw is 18% PGA. PGA is generally a faster resorbing material than PLLA. Because the Biomet Screw is 82% PLLA, it will retain its strength for a longer time period.

The following information is provided demonstrating that the device does not raise any new types of safety questions (see Exhibit 5).

1. Biocompatibility Testing Summary
   The resorbable material was found to be non-pyrogenic, non-toxic, non-mutagenic, causing minimal irritation in soft tissue with a mild tissue response in bone.

2. Stability Test Data- real time data justifying a 36 month expiration date.

3. Sterilization Information

4. "Tissue Response To Absorbable Bone Screws"

5. Clinical Use of the LactoSorb® Suture Anchor is Bankart Procedures

6. Clinical Use of the LactoSorb® Trauma Plating system in Midface Fractures

   Note: Both studies demonstrated the safety and effectiveness of the LactoSorb® devices in both soft tissue attachment and bone fixation applications.

The following test reports are provided demonstrating that the device does not raise any new types of effectiveness questions (see Exhibit 6).

1. Fracture Fixation Using Bioabsorbable Screws in the Canine Femur (see the following Animal Study Summary)

   This study implanted the Biomet Bone Screws comprised of the exact same LactoSorb® material as clinical product. This report describes LactoSorb® as 20% PGA/80% PLLA.

COMPARISON TO MARKETED DEVICE

Biomet® Bone Screw

1. **Indications:** fixation of
   - cancellous bone fractures
   - osteotomies
   - arthrodeses
   - bone grafts

2. **Intended Use:**
   - cancellous bone (not cortical bone)
   - predrilled bone hole, tap, countersink

3. **Design:**
   a. dimensions:
   5.0mm x 35-70mm

   b. cannulated and non-cannulated

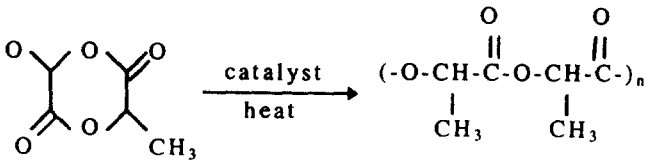
   c. Distal threads only

4. **Material:** PLLA/PGA
   a. 82% poly-l-lactic acid (PLLA) and 18% polyglycolic acid (PGA) copolymer

   b. maintains its strength for at least 12 weeks.

   c. complete absorption by 15 months.

5. **Chemical Structures**



lactide polylactide

Biofix® Screw

1. **Indications:** fixation of
   - cancellous bone fractures
   - osteotomies
   - arthrodeses
   - bone grafts

2. **Intended Use:**
   - cancellous bone (not cortical bone)
   - predrilled bone hole, tap countersink

3. **Design:**
   a. dimensions:
   4.5mm x 25-70mm

   b. non-cannulated

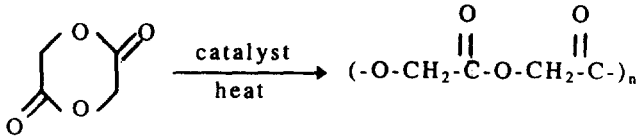
   c. Full thread

4. **Material:** SR-PGA
   a. 100% polyglycolic acid (PGA) reinforced with PGA fibers

   b. maintains its strength for 5-7 weeks.

   c. complete absorption by 12 months

5. **Chemical Structures**



glycolide polyglycolide

ANIMAL STUDY SUMMARY

Mechanical Test Results

Mechanical tests were performed after two months IN VIVO at fracture sites in dog femurs to study the strength of the callus formed. Torsional testing was used for the cortical bone model and an indentation test for the cancellous model. No significant difference was seen in femurs treated with either LactoSorb® screws or stainless steel screws. The LactoSorb® screws used in the animal study are identical to those to be used clinically.

	Torsional Results (in newtons)	Indentation Results (in MPA)	
		bone plug	surrounding bone
LactoSorb® Screw	830±180	11.97±2.36	18.68±1.69
Stainless Steel (SS)	964±156	13.24±1.95	18.40±1.95

Histology Results

1. 2 Months Postimplantation
   Polymer Screws - 90% of bone plugs had bony union
   - osteotomies fully healed
   SS Screws - 80% of bone plugs had bony union
   - osteotomies fully healed

2. 9 Months Postimplantation
   Polymer Screws - all bone plugs healed
   - no inflammatory response
   - polymer still in screw track but much less than 2 months postop
   SS Screws - all bone plugs healed
   - no inflammatory response

3. 15 Months Postimplantation
   Polymer Screws - completely resorbed, screw track still present and filled with fibrous and adipose connective tissue.

4. 17 Months Postimplantation
   Polymer and SS Screws - all osteotomies healed, no adverse inflammatory response.
   - polymer screws were completely resorbed

The sponsor describes LactoSorb® as 18% PGA/82% PLLA. The following is the actual specification for LactoSorb®.

PGA 17.5 - 19.8%
PLLA 80.2 - 82.5%

2. Biomechanical Comparison of LactoSorb® Screw Blanks with Biofix Polyglycolic Acid and Poly-L-Lactic Acid and Orthosorb Polydioxanone Material

3. Biomechanical Comparison of 5.0mm Diameter LactoSorb® Screws with 4.5mm Diameter Biofix PGA Screws

In summary, this device is substantially equivalent in indication, intended use, and design to Biofix screws Mechanical testing has found the Biomet Bone Screws to be as safe and effective for its intended use as the predicate devices.

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DEVICE LISTING

Biomet Bone Screws

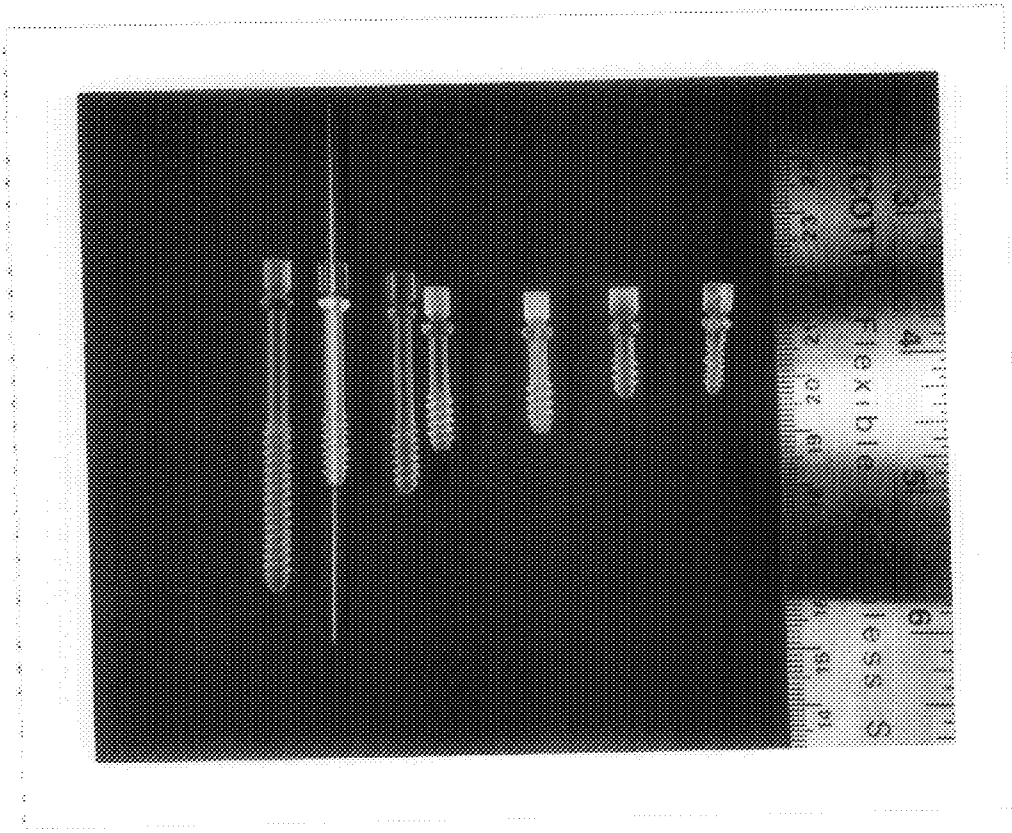
Part No.	Description (width x length)
RD-4101-86	5.0mm x 35mm
RD-4104-87	5.0mm x 40mm
RD-4101-88	5.0mm x 45mm
RD-4101-89	5.0mm x 50mm
RD-4101-90	5.0mm x 60mm
RD-4101-91	5.0mm x 70mm
RD-4101-92	5.0mm x 35mm, cannulated
RD-4101-93	5.0mm x 40mm, cannulated
RD-4101-94	5.0mm x 45mm, cannulated
RD-4101-95	5.0mm x 50mm, cannulated
RD-4101-96	5.0mm x 60mm, cannulated
RD-4101-97	5.0mm x 70mm, cannulated

Instrumentation

Part No.	Description
35-463009	3.5mm Twist Drill
34-513505	Tap Handle
RD-4101-98	Bone Screw Socket Driver
RD-4101-99	Bone Tap

12

BIOMET BONE SCREWS



13

(b)(4) Schematic Drawing

(b)(4) Schematic Drawing

(b)(4) Schematic Drawing

b)(4) Schematic Drawing

2

Pouch Label

Part No. XX-XXXXXX LOT NO. 123123
Biomet Bone Screw

Description

PLA/PGA (Resorbable Polymer) LactoSorb* EXPIRATION DATE: XX/XX
*LactoSorb is a TM of Biomet, Inc.

STERILE - SINGLE USE - DO NOT RESTERILIZE
Sterile if package not opened or damaged

CAUTION: Inner sterile material is moisture sensitive. Once this package has been opened, its contents must be used immediately.
DO NOT STORE ABOVE 120°F OR 49°C.
DO NOT USE PRODUCT IF TEMPERATURE INDICATOR DOT IS BLACK.

QTY 1 Biomet, Inc.
P.O.Box 587
Airport Industrial Park
Warsaw, IN 46581-0587 (USA)

Biomet, Inc.
Airport Industrial Park
P.O. Box 587
Warsaw, Indiana 46580
USA

WARNINGS AND PRECAUTIONS FOR USE OF THE BIOMET BONE SCREW

ATTENTION OPERATING SURGEON

DESCRIPTION:

The Biomet Bone Screw is a resorbable device used for the fixation of cancellous bone fractures, osteotomies, arthrodeses or bone grafts. The device is made of a resorbable copolymer, a polyester derivative of lactic acid and glycolic acid. Polylactic/polyglycolic acid copolymer degrades and resorbs IN VIVO by hydrolysis to lactic and glycolic acids which are then metabolized by the body. The screws are completely resorbed by 15 months IN VIVO.

WARNINGS:

While these devices are generally successful in the alignment and fixation of bone they do not replace normal healthy body structures. The use of appropriate immobilization and postoperative management is indicated as a part of treatment until healing has occurred.

The surgeon is to be familiar with the implant, instruments, and surgical procedure. In using the device, a judgment must be made as to the holding power of the bone, as a significant degree of osteoporosis will weaken the hold in the bone. In all cases sound orthopedic practice is to be followed and the surgeon must select the type of device appropriate for treatment.

The patient is to be warned that the device can break or loosen as a result of stress, excessive activity or load bearing. The patient is to be made aware of surgical risks and possible adverse effects prior to surgery, and warned that failure to follow postoperative care instructions can cause failure of the implant and the treatment.

INDICATIONS:

The Biomet Bone Screw is indicated for fixation of cancellous bone fractures, osteotomies, arthrodeses or bone grafts.

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CONTRAINDICATIONS:

1. Active infection.
2. Fractures and osteotomies of cortical bone.
3. Patients with mental or neurologic conditions who are unwilling or incapable of following postoperative care instructions.
4. Patient conditions including: blood supply limitations, insufficient quantity or quality of bone, or latent infections.

WARNINGS AND PRECAUTIONS:

1. Patients that engage in stressful physical activities are to be warned that injury at or near the implant site can lead to subsequent failure of the device and/or the treatment.
2. The device can break or be damaged due to excessive activity, and stress caused by full or partial load bearing can cause failure of the device.
3. The Biomet Bone Screw is intended to aid in alignment and bone fixation during the healing process and is not intended to replace normal body structures.
4. Care is to be taken to assure adequate fixation of the bone tissue at the time of surgery. The failure to achieve adequate fixation through improper positioning or placement of the device can contribute to a subsequent undesirable result.
5. DO NOT USE if there is loss of sterility of the device.
6. Discard and DO NOT USE opened or damaged devices, and use only devices that are packaged in unopened, or undamaged containers.
7. **CUTTING OF SCREWS:** The screw can be cut with an oscillating or reciprocating saw. NO OTHER CUTTING METHOD MAY BE USED. After implantation, screws can be cut ONLY at the distal protrusion.

POSSIBLE ADVERSE EFFECTS:

1. Infection can lead to failure of the procedure.
2. Neurovascular injuries can occur due to surgical trauma.
3. Bending, fracture, loosening, rubbing, and migration of the implant may occur as a result of excessive activity, trauma, or load bearing.
4. Delayed or non-union can occur

STERILITY:

Biomet Bone Screws are sterilized by exposure to Ethylene Oxide (ETO) Gas. DO NOT RESTERILIZE.
DO NOT STORE ABOVE 120°F OR 49°C

CAUTION: Federal Law (USA) restricts this device to sale, distribution, or use by or on the order of a physician.

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3

Sterilization Validation Protocol
Lactomer®/Suture Cycle

(b) (4)

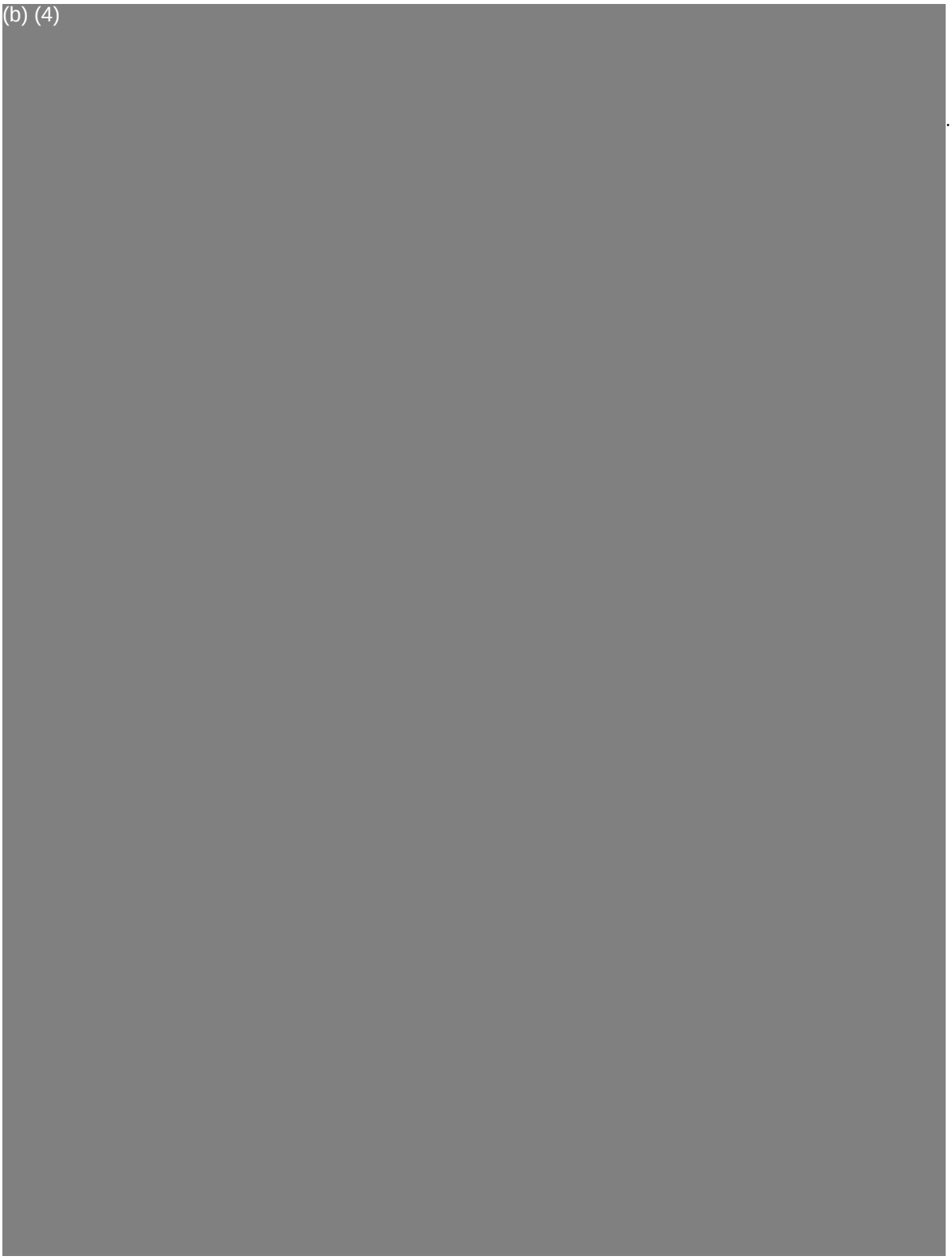
(b) (4)

(b) (4)

(b) (4)

[redacted]

(b) (4)



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BIOMET, INC.

	SIGNATURE	DATE
PREPARED BY GMS OPERATIONS SUPERVISOR	[signature]	10-17-96
REVIEWED BY GMS ASSOCIATE DIRECTOR, LABORATORY	[signature]	10-18-96
APPROVED BY BIOMET, INC CLINICAL RESEARCH MANAGER	Mary L. Verstynen	

TABLE OF CONTENTS

ATTACHMENTS

4

BIOFIX®

ABSORBABLE FIXATION SCREW

INSTRUCTIONS FOR USE

BIOFIX® SR-PGA SCREW

FOR FIXATION OF CANCELLOUS BONE FRACTURES, OSTEOTOMIES, ARTHRODESES AND BONE GRAFTS

DESCRIPTION

Biofix® SR-PGA absorbable screws, diameter of 4.5 mm, are constructed of ultra-high strength self-reinforced polyglycolide (SR-PGA) composite material. The manufacturing process preserves high initial mechanical strength and stiffness of the screws which allows secure fixation in combination with suitable immobilization. The *Biofix® SR-PGA* screws lose their strength during 6 to 8 weeks in vivo. Within a corresponding period of time, a fracture of cancellous bone is normally consolidated. *Biofix® SR-PGA* screws are absorbed by cancellous bone tissue during ca. 1 year in vivo. This eliminates the need of a second operation to remove non-absorbable fixation devices after the healing of fracture, osteotomy or arthrodesis. *Biofix® SR-PGA* screws are sterile, non-collagenous, non-antigenic and non-pyrogenic.

ACTIONS

Properly used, in the presence of adequate immobilization, *Biofix® SR-PGA* screws maintain accurate alignment of cancellous bone fractures after open reduction.

As a cancellous bone fracture gains strength during healing, the *Biofix® SR-PGA* screw gradually loses its strength during 6 to 8 weeks. Absorption follows strength loss and is complete in 1 year post-operatively.

Biofix® self-reinforced polyglycolide composite screws have been shown to be biocompatible in both animal and clinical evaluations.

INDICATIONS

Biofix® SR-PGA screw is indicated for maintenance of alignment and fixation of cancellous bone fractures, osteotomies, arthrodeses or bone grats in the presence of appropriate immobilization.

CONTRAINDICATIONS

1. Fractures and osteotomies of cortical bone. (diaphyseal area)
2. Situations where internal fixation is otherwise contraindicated, e.g., active or potential infection and where patient cooperation cannot be quaranteed (e.g. alcoholism).

PRECAUTIONS & WARNINGS

1. Premature bending, loosening, fracture or migration of the screws may result from early weight bearing, stress and activity.
2. Transient local fluid accumulation and/or sinus formation may occur in sterile circumstances. Aspiration (simple drainage) may yield implant remnants and usually results in healing of the sinuses without adverse effect to fracture healing.
3. **Sterility and Handling:** Biofix® SR-PGA screws have been sterilized with ethylene oxide. Removal from the sterile package using aseptic techniques should only take place after the correct size screw has been determined immediately before use. **THE SCREWS MUST NOT BE RESTERILIZED BY ANY METHOD.**
4. **Postoperative or Intraoperative Cutting of Screws:** The screw must not be cut by pressing or twisting. The screw can be cut with an oscillating or reciprocating saw, an electrical knife or a heated wire. **NO OTHER CUTTING METHOD MAY BE USED.** Do not cut the distal end of the screw. The screw must be cut only after implanting.
5. Discard open, unused screws.

ADVERSE EFFECTS

Complications are similar to those of any method of internal fixation.

HOW SUPPLIED

Biofix® SR-PGA screws are available with major thread diameter of 4.5 mm and core diameter of 3.5 mm in various lengths from 25 mm to 70 mm.

Biofix® SR-PGA screws are provided sterile, in individual unit packages. Store at room temperature (15 to 30°C or 60 to 85°F) at normal relative humidity.

KIRSCHNER®
MEDICAL PRODUCTS
9690 Deereco Road
Timonium, MD 21093
1-800-367-7764

SURGICAL TECHNIQUE

As for other methods of internal fixation:
- Proper Local, Regional or General Anesthesia
- Aseptic Conditions
- Proper Exposure
- X-Ray Control
- Perioperative Antibiotics are recommended.

Figure 1 shows schematically in cross-sectional view the operating principles with *Biofix® SR-PGA* screw.

The operating principles follow very much the ones of the AO school. First the area around the fracture is exposed by the standard principles of bone surgery. Major arteries and all nerves should be preserved by careful dissection. Good alignment of the fracture (1) must be obtained followed by fixation with clamp(s). A suitable channel (3.5 mm drill bit) (2) is drilled through the fracture plane for the screw (Fig. 1a). The channel is tapped with the *Biofix®* tapping device (3) to make the accurate thread (it must be observed that the profile of the *Biofix®* screw is different from the metallic screws) Fig. 1b).

If it is decided to use the screw head as additional support the *Biofix®* countersink (4) is used in order to make space for the screw head (Fig. 1c). The *Biofix® SR-PGA* screw (6) needs a screwdriver of its own (5) (Fig. 1d). It is important to use the right size since the screw head sticks to the instrument. If it is decided not to use the screw head or if the screw seems to be too long the countersink is not used but instead the screw is simply cut along the bone surface (Fig. 1e). The screw fragment must be removed and disposed. If the reduction is done properly and if the drilling and tapping are done in an accurate way there should be no problems in inserting a *Biofix®* screw (Fig. 1f). Since the torsion resistance is less than that of metal screws extra attention should be paid not to use too much torque when implanting the screw.

If the osteosynthesis is already stable the screw can probably be cut. If this is not the case the drilling and tapping must be checked. If the screw breaks after all it can be cut and the left overs disposed. After this a new channel can be drilled (also straight through the old screw if necessary). A plaster of Paris is used postoperatively.

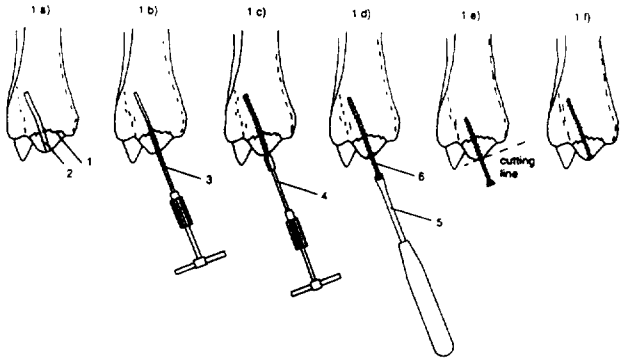

Figure 1. Operating principles with *Biofix® SR-PGA* screws.

The special instruments needed with *Biofix® SR-PGA* screws are (Fig. 2):
- a bone tap (a)
- a countersink (b) and
- a screwdriver (c)

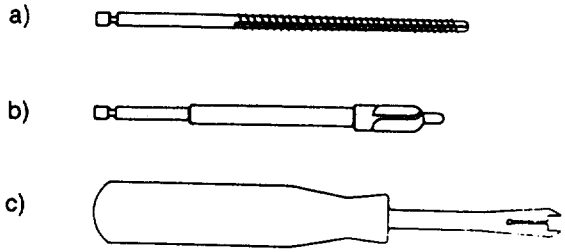

Figure 2. The special instruments needed with *Biofix® SR-PGA* screws.

The tap and countersink are used with standard AO-type tap handle (T-handle) equipped with a quick-coupling socket for the 4.5 mm tap and countersink.

Other instruments are normal operation room instruments for orthopaedic and traumatological procedures.

If more detailed information is needed, please do not hesitate to contact your local Biofix representative and ask the Biofix Screw Surgical Technique - manual.

MANUFACTURED BY: BIOSCIENCE, LTD. P.O.BOX 3, FIN-33721 TAMPERE, FINLAND

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KIRSCHNER®
MEDICAL CORPORATION

9690 Deereco Road
Timonium, Maryland 21093

To place an order or for additional ordering information, contact Customer Service at:

1-800-367-7764

Ordering Information

BIOFIX® SR-PGA® SCREWS

Sold in boxes of five (5) eaches (Sterile)

Cat. No.	Description
21-4570	4.5mm x 70mm Biofix Screw
21-4565	4.5mm x 65mm Biofix Screw
21-4560	4.5mm x 60mm Biofix Screw
21-4555	4.5mm x 55mm Biofix Screw
21-4550	4.5mm x 50mm Biofix Screw
21-4545	4.5mm x 45mm Biofix Screw
21-4540	4.5mm x 40mm Biofix Screw
21-4535	4.5mm x 35mm Biofix Screw
21-4530	4.5mm x 30mm Biofix Screw
21-4525	4.5mm x 25mm Biofix Screw

BIOFIX® 4.5MM SCREW INSTRUMENTATION

Cat. No.	Description
22-4501	4.5mm Screw Tap
22-4502	4.5mm Screw Countersink
22-4503	4.5mm Screw Driver
22-4504	4.5mm Drill Guide
22-4505	3.5mm Drill Guide Sleeve
22-3507	3.5mm x 5" Drill Bit
22-4507	4.5mm x 5" Drill Bit
22-5001	Bone Holding Forceps, Pointed
22-5002	Bone Holding Forceps, Curved
22-5003	Tap and Countersink Handle
35-9030-0	Depth Gauge

BATTERY OPERATED ELECTROCAUTERY

AA1000	Loop Cautery (Sterile)

CASE

22-9000	Biofix Screw Instrument Case

31006-5M-8/94-HN

BIOSCIENCE Ltd
P.O. Box 3
SF-33721 Tampere
Finland

4.9.1992

SCREW Self reinforced (SR)
PLLA Full thread 4.5 mm

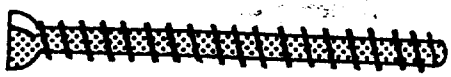
Outer Ø 4.5 mm
Inner Ø 3.5 mm

Notice

Use the 4.5 mm BIOFIX screw instruments when implanting this screw.

70 mm 
Cat.Nr 224570

65 mm 
Cat.Nr 224565

60 mm 
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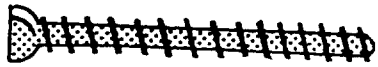
55 mm 
Cat.Nr 224555

50 mm 
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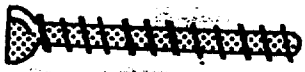
45 mm 
Cat.Nr 224545

40 mm 
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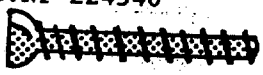
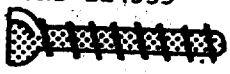
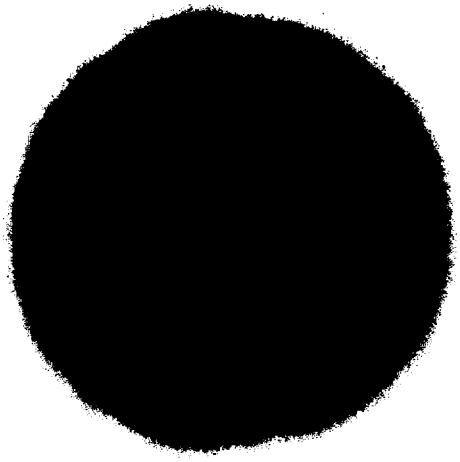
35 mm 
Cat.Nr 224535

30 mm 
Cat.Nr 224530

25 mm 
Cat.Nr 224525

GENERAL

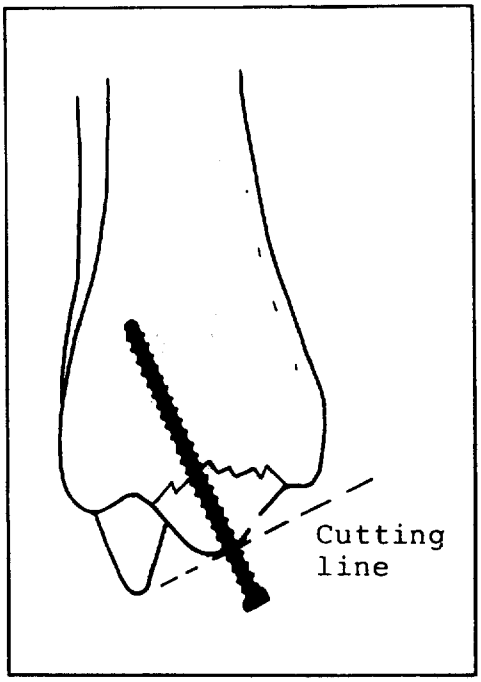
The BIOFIX® screw differs in design from the basic AO screw. The two deviations are the screw head and the thread. Both of these features are explained by totally different material properties. It is much more easy to make screws of metals than of absorbable high-strength composites.



OPERATING PRINCIPLES

The operating principles follow very much the ones of AO. Exact reduction is essential. This is done with the reduction clamps to keep the fracture in place and to produce the initial compression. The drill bit is chosen in accordance with the diameter of the screw. Screw dia 4.5 mm = drill bit 3.5 mm and screw dia 3.5 mm = drill bit 2.7 mm.
The 4.5 mm screw is available in 10 lengths from 25 mm to 70 mm and the 3.5 screw is available in 9 lengths from 10 mm to 40 mm.
After the drilling the BIOFIX® tapping device is used to make the accurate thread (it must be observed that the profile of the BIOFIX® screw is different from the AO screw). The right diametric size must be chosen.

Now the BIOFIX® F-SCREWS can be used in two ways. If it is decided to use the screw head as additional support the BIOFIX® countersink is used in order to make space for the screw head. If it is decided not to use the screw head or if the screw seems to be too long the counter sink is not used but instead the screw is simply cut along the bone surface. The screw fragment must be removed and disposed.



The BIOFIX® F-screw can be easily cut with an oscillating saw. Do not cut by pressing.

The BIOFIX® screw needs a screw driver of it's own. It is important to use the right size since the screw head sticks to the instrument. If the reduction is done properly and if the drilling and tapping are done in an accurate way there should be no problems in inserting a BIOFIX® screw. Since the torsion resistance is less than that of metal extra attention should be paid not to use too much torque when implanting the screw. The screw driver is designed with a special fissure at the top. It can be seen and felt in the hands when the fissure opens. At this stage there is a risk for screw head breakage. If the osteosynthesis is already stabile the screw can propably be cut. If this is not the case the drilling and tapping must be checked.

If the screw breaks after all it can be cut and the left overs disposed. After this a new channel can be drilled (also straight through the old screw if necessary).

The lag screw principle can be adapted by over-drilling the fragmental bone. However a 90 degree angle is required.
When light osteoporosis is observed the tapping is not necessary.

INDICATIONS

The BIOFIX® F-Screws are intended for the fixation of cancellous bone fractures, osteotomies and arthrodeses.
Generally the BIOFIX® 4.5 mm F-screw can be adapted to indications where large rods (4.5 and 3.2 mm) are used. Many of the small rod indications are suitable for the BIOFIX® 3.5 mm screw. Very good results can be achieved in the indications of ankle fractures, bone grafting and arthrodeses.
BIOFIX® screws are ideal to be used as syndesmosis screws.

[redacted]) SR-PLLA

General

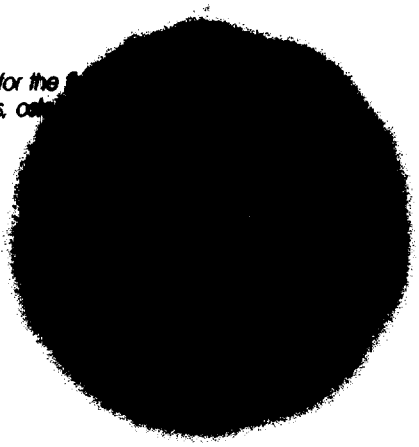
In the area of cancellous bone the issue of compression has been discussed much. To define compression is difficult due to the nature of the semi hard cancellous bone tissue. It has been known for a long time that cancellous bone compression does not last for very long and that too much compression may prevent blood from circulating which could lead to necrosis.

Operating Principles

The BIOFIX® L-screw differs in design and in function from the F-screw. The L-screw is constructed to create compression between the fragment and the main bone. The L-screws are available in dia 4.5 mm (lengths from 25 mm to 70 mm) and in dia 3.5 mm (lengths from 10 mm to 45 mm).
The L-screw operating principles follow those of the F-screw with the exception that L-screw must not be cut since the screw head is the compression creating part of the screw. It must be observed that the torsion resistance is lower than that of metal which means that attention must be paid to the control of power used when implanting a BIOFIX® L-screw.

Indications

The BIOFIX® L-screws are intended for the f[redacted] ation of cancellous bone fractures, os[redacted] mies and arthrodeses.

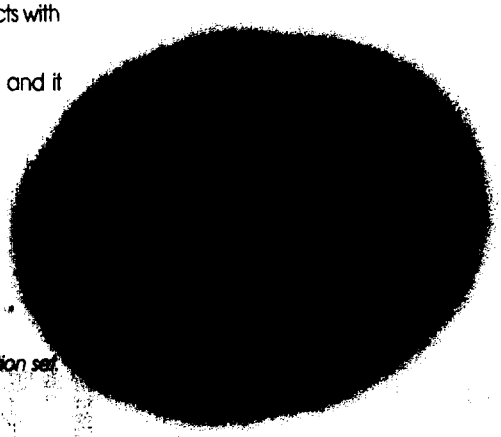


[redacted] ALL TYPES of SCREWS

Special screw instruments are required for the BIOFIX® screws due to the design and construction of the screw. The set of instruments consists of a screw driver, a counter sink tool and a tapping device. The instruments are especially manufactured to fit the BIOFIX® products with great accuracy.

The BIOFIX® screw instrumentation is manufactured of highest quality stainless steel and it can be cleaned and sterilized under normal hospital routines.

There are different sets for different screw sizes.



BIOFIX® screw instrumentation set

[redacted] NT

Plaster of Paris or other immobilizating support is required in all cases and the patient should stay in the hospital until capable to use crutches when the lower extremities are concerned. No weight bearing is allowed during the first three weeks before the first control at the outpatient department. Max 30 kg load during the next two weeks and full load after five weeks. After six weeks second control and removal of the plaster of Paris. Conducted mobilization if required.
The latest experience is that in some cases immobilizating support can be avoided and the early mobilization can be started.

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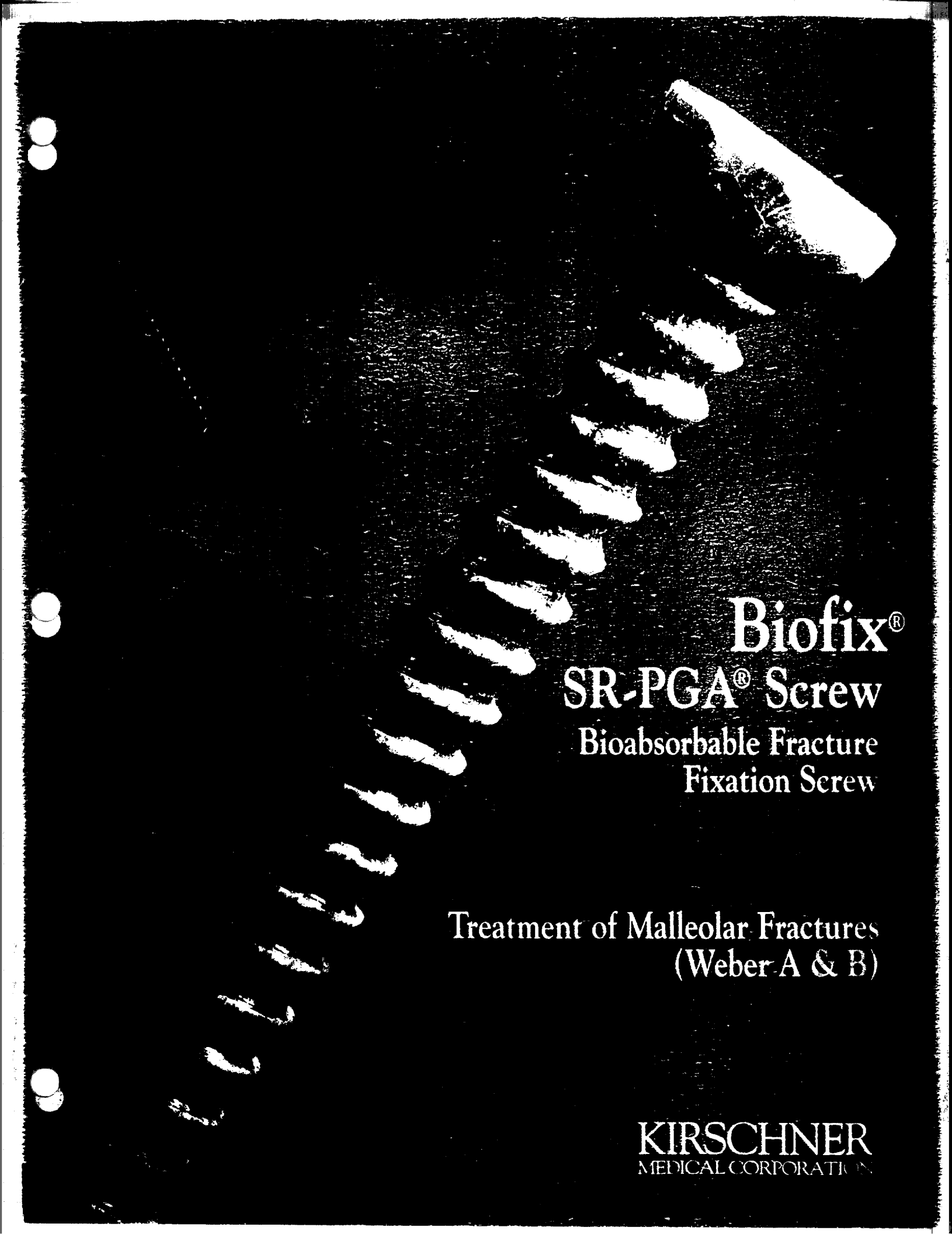

Biofix®
SR-PGA® Screw
Bioabsorbable Fracture Fixation Screw

Treatment of Malleolar Fractures (Weber A & B)

KIRSCHNER
MEDICAL CORPORATION

BIOFIX®-SCREW

ABSORBABLE CANCELLOUS BONE FRACTURE FIXATION SCREW

SURGICAL TECHNIQUES I

Treatment of Malleolar Fractures of Weber A and B Type

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Eero Hirvensalo, M.D.
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Biomaterials Laboratory
Tampere University of Technology
Tampere, Finland

Helsinki University Central Hospital
Department of Orthopaedics and Traumatology
1989

Contents

1. INTRODUCTION

Absorbable BIOFIX®-screws* are intended for the fixation of cancellous bone fractures, osteotomies or arthrodeseis.

The raw-material of BIOFIX®-screws is biodegradable (absorbable), tissue compatible polyglycolide which for many years has been applied as absorbable sutures (Dexon®)** all over the world.

Absorbable BIOFIX®-screws are constructed of patented, self-reinforced polyglycolide (SR-PGA) composite material (Törmälä *et al.* 1987, Törmälä *et al.* 1988). A patented manufacturing process guarantees high initial mechanical strength and elastic modulus of screws which preserves a secure fixation in combination with a plaster cast. The screws lose their strength during 5—7 weeks *in vivo*. Within a corresponding period of time a fracture of cancellous bone can be considered as practically consolidated. BIOFIX®-screws are digested by cancellous bone tissue within 1—2 years.

Self-reinforced BIOFIX®-composite materials have been shown to be highly biocompatible in both animal and clinical evaluations (Vainionpää 1987).

BIOFIX®-screws correspond to standard bone drill sizes of 3.2 mm. The screw lengths between 25—70 mm are available (25, 30, 35, 40, 45, 50, 55, 60, 65 and 70 mm). A special thread geometry secures good fixation of the fracture. Figure 1 shows an example of BIOFIX®-screws.

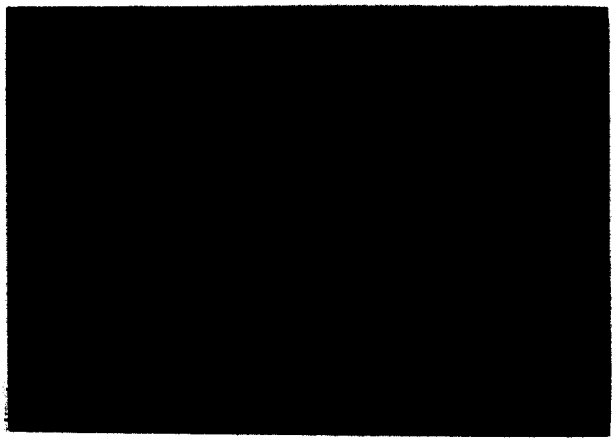

Figure 1. BIOFIX®-screw.

BIOFIX®-screws give to a patient an initially strong and gradually decreasing internal fixation of cancellous bone fracture, osteotomy or arthrodesis against loads originating from muscular activity or from external sources.

2. MATERIAL AND ITS PROPERTIES

The initial shear strength of SR-PGA BIOFIX®-screws is 160 MPa and their bending strength is 250—300 MPa. These values exceed ca. 20 times the strength of cancellous bone and guarantee therefore the sufficient fixation which is still secured by means of a plaster cast.

The screws gradually lose their mechanical strength *in vivo* during 5—7 weeks.

The decline in strength of the screws as the healing fracture gains in strength counteracts the development of osteoporosis.

When the BIOFIX®-screws have lost their mechanical strength, the breakdown becomes more rapid and degradation is complete in 1—2 years.

3. STERILIZATION OF BIOFIX®-SCREWS

BIOFIX®-screws are sterilized by ethylene oxide. Resterilization by any method is not allowed. Repeated gas sterilization (with ethylene oxide, formaldehyde etc.) or radiation (with α-, β- or γ-radiation etc.) causes degradation of the material. Chemical sterilization (with alcohol, desinfection chemicals etc.) may damage the structure of material.

4. ADVANTAGES OF BIOFIX®-SCREWS IN FIXATION OF FRACTURES IN COMPARISON WITH METALLIC OSTEOSYNTHESIS

- The stiffness of BIOFIX®-screws is close to that of bone, decreasing the risk of development of osteoporosis and giving a natural isoelastic fixation.
- BIOFIX®-screws support the fracture the necessary period of time and degrade thereafter into small molecules which are totally metabolized. SINCE THE BIOFIX®-SCREWS ARE ENTIRELY ABSORBABLE, IT IS NOT NECESSARY TO REMOVE THEM SURGICALLY.
- The risks of long-term complications are eliminated.
- Hospital costs/patient are reduced.
- The efficiency of the use of hospital personnel is increased.
- Operation capacity can be shifted to other operations, which shortens the operation lines.

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**Dexon® is a registered trademark of American Cyanamid Company

— The risks of patients and the need of sick-leave are/is decreased

5. THE USE OF BIOFIX®-SCREWS

So far, BIOFIX®-screws are indicated for internal fixation of Weber A and B type ankle fractures. Clinical trials to use BIOFIX®-screws in fixation of other cancellous bone fractures, osteotomies and arthrodeses are in progress. However, because there is not yet sufficient clinical data on the use of BIOFIX®-screws in other indications, their use is still recommended only in fixation of Weber A and B type ankle fractures.

The BIOFIX®-screws should not be used for the treatment of fractures in old (over 70 years of age) people. Severely comminuted and osteoporotic fractures are unsuitable to this method.

More accurate information of contraindications, warnings and precautions is given in package insert of products.

6. OPERATING PRINCIPLES

6.1. The use and contraindications of BIOFIX®-screws

Criteria for the use of BIOFIX®-screws are:

— Bimalleolar fractures where neither reduction of fixation of an associated fracture of the posterior triangle nor fixation of the tibiofibular syndesmosis is needed.
— Dislocation of malleolar fragments must be at least 2 mm.

Contraindications against the use of BIOFIX®-screws are chronic alcoholism or psychiatric sickness which limit the patient's ability to cooperate. Likewise the equipment should not be used for the treatment of ankle fractures in old (over 70 years of age) people or of epiphyseal fractures in ankles of children.

6.2. Operating techniques when using BIOFIX®-screws for the treatment of displaced ankle fractures

6.2.1. Special instruments

Figure 2 shows the special instruments which are needed in surgical operations with BIOFIX®-screws:
(a) Tapping device,
(b) Countersink for the head of the screw and
(c) Screwdriver
Otherwise the instrumentation is the same as in metallic fixation.

The tap (a) and countersink (b) are used with the standard AO-type tap handle (H) equipped with a quick-coupling socket for the 4.5 mm tap and countersink.

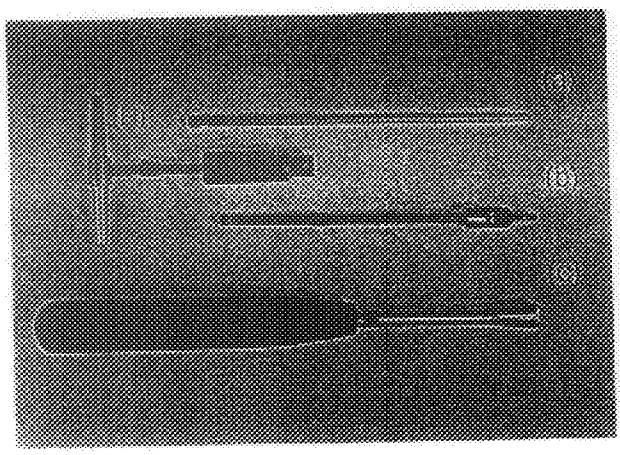

Figure 2. Tap (a), countersink (b), screwdriver (c) and the standard AO-type tap handle (H).

6.2.2. Steps of fixation

The essential and necessary steps of the fixation operation are:

1. A bloodless field.
2. Cleaning the fracture surfaces and exact reduction using clamps.
3. Drillchannel in 3.2 mm against the dislocating force (Figure 3).
4. Tapping with a special instrument.
5. Use of special countersink.
6. Douche of the drillchannel.
7. Inserting of BIOFIX®-screw.
8. Cutting off head of the screw if necessary
9. Suturing the ligaments and wound.
10. Applying the plaster cast.

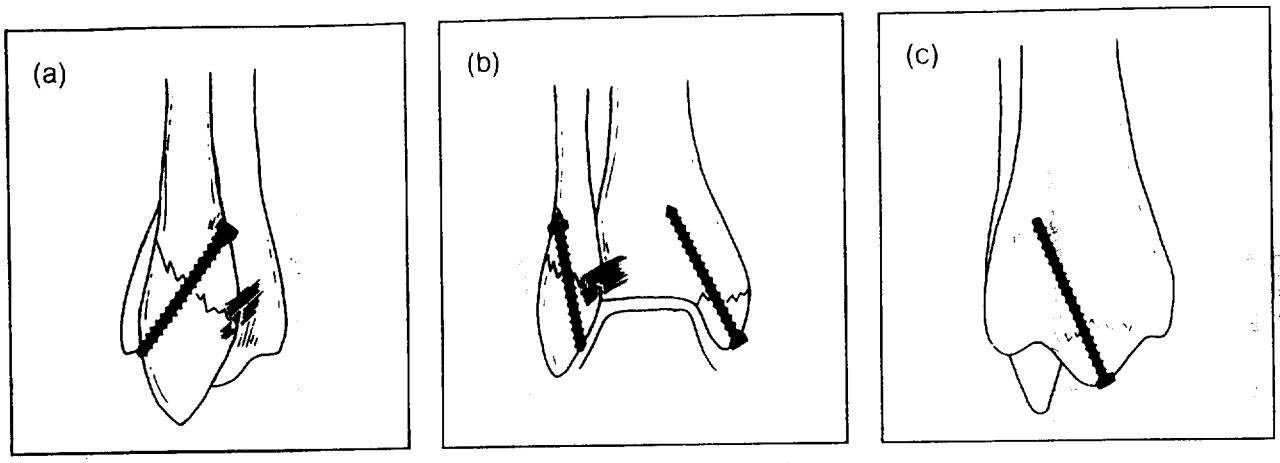

Figure 3. Schematic pictures of fixation of ankle fractures with BIOFIX®-screws: (a) a fracture of the lateral malleolus (a lateral view), (b) a bimalleolar fracture (an anterior view), (c) a fracture of the medial malleolus (a medial view).

6.2.3. Postoperative treatment

Stay in hospital until the patient can use crutches. Closure of the plaster is recommended before the discharge from the hospital. The first check-up at three weeks at outpatient department and start of partial weight bearing 15 to 30 kg. After 5 weeks full weight bearing is allowed. At 6 weeks the second check up, and the plaster discharged. Mobilization of the ankle will be started.

In some patients a postoperative local fluid accumulation may develop in a primarily uneventfully healed wound typically 4—12 weeks after operation. The patients should be informed of the possibility of the fluid accumulation so, that they can contact the doctor if fluid accumulation is present. Usually the tissue reaction is small and painless, it should only be observed. If it is red, painful or more than 1.5 cm in diameter, it should be treated by needle aspiration with 1.1 mm needle. Needle aspiration may be repeated, if necessary. A few patients may form a sinus in spite of aspiration, and incision in such cases is recommended. The fluid is typically solid and yellow and there is usually no bacterial growth, and antibacterial drugs are needed only if the culture is positive. This fluid accumulation does not influence the functional recovery.

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6.2.4. Examples

* Lateral malleolus (Figures 4A – 4I).

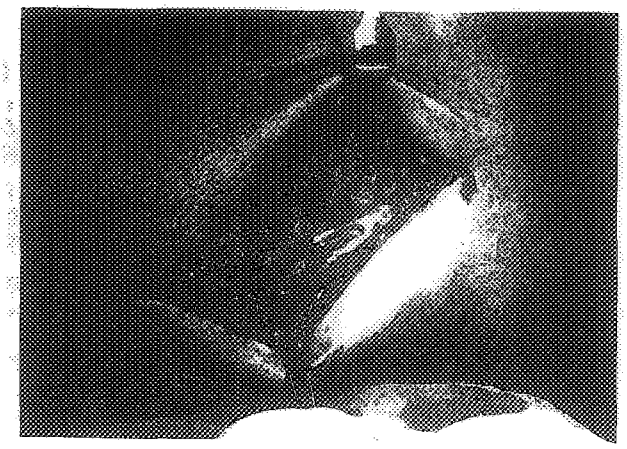

Figure 4A. Exposing the fracture

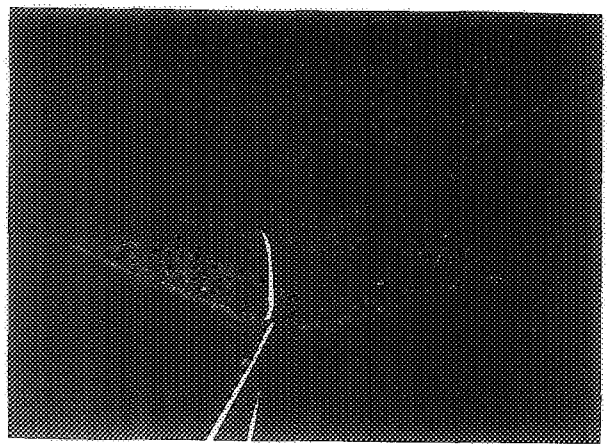

Figure 4B. Exact reduction with one or two clamps.

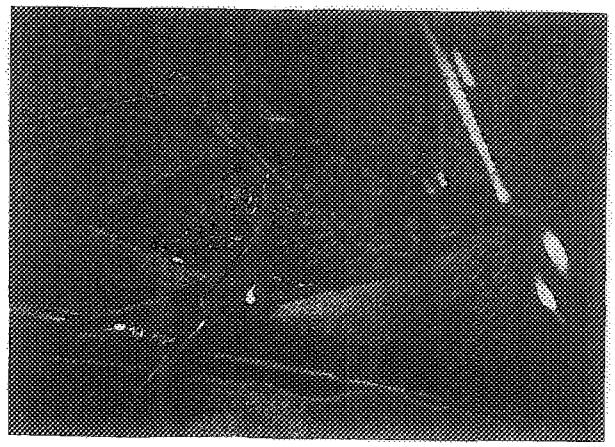

Figure 4C. Drilling (Observe the direction).

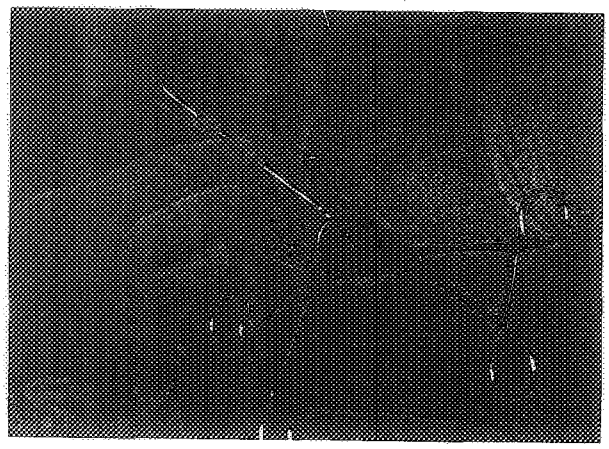

Figure 4D. Measuring the drill channel.

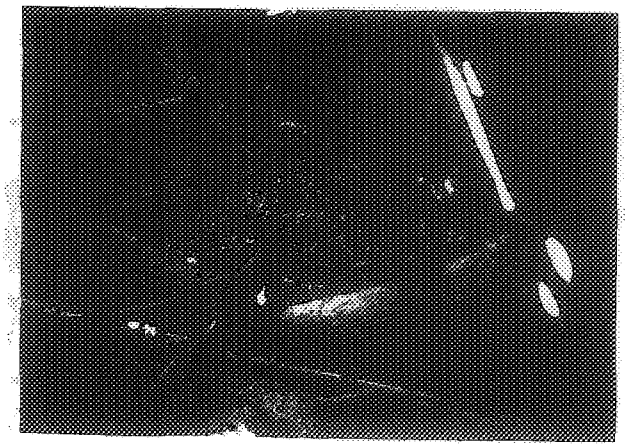

Figure 4E. Tapping with a special tapping device

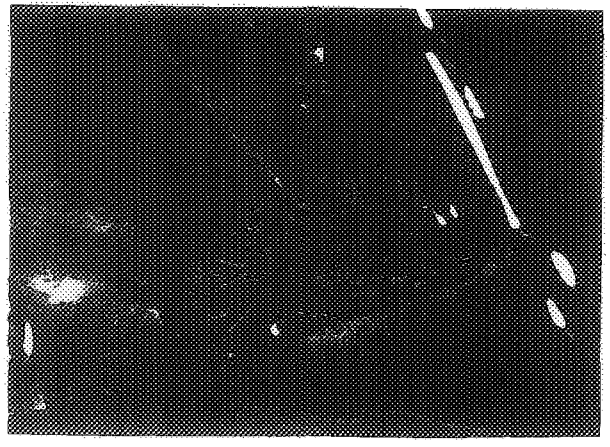

Figure 4F. The use of countersink. In order to avoid sinking through the cortex manual use of countersink is recommended

Figure 4G. Douche of the drillchannel for the removal of little pieces of bone.

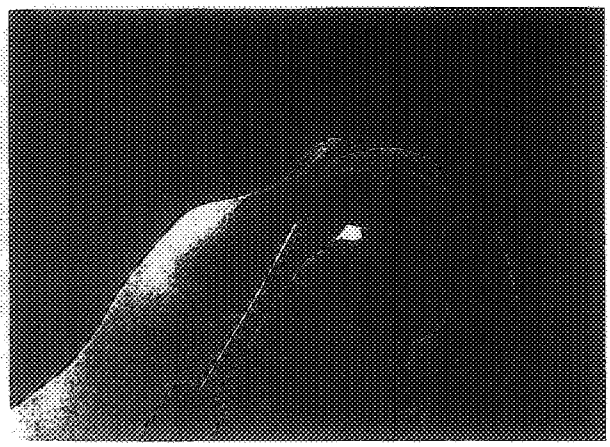

Figure 4H. Inserting the screw into the screw driver. The screw is manufactured of non-colored (beige) raw material

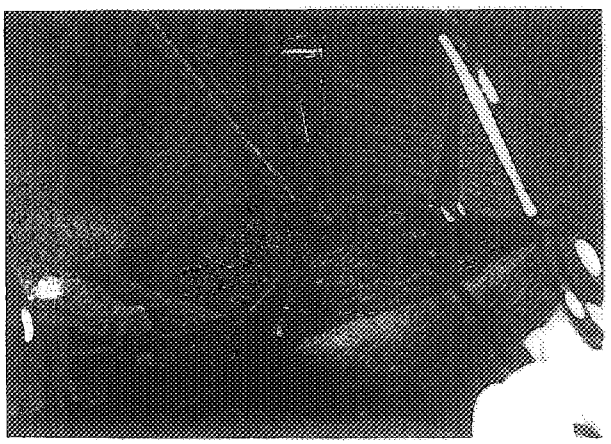

Figure 4I. Inserting the screw into the drillhole

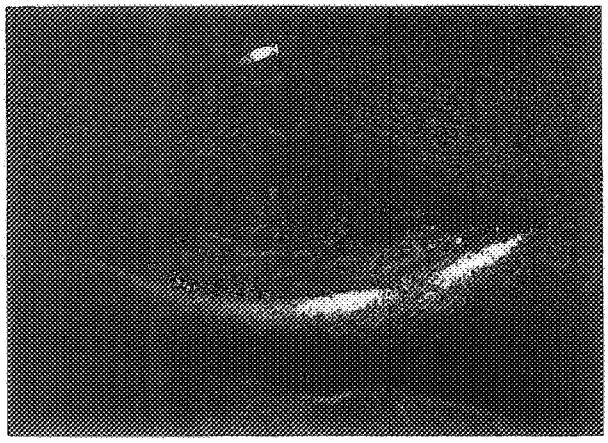

Figure 4J. The picture of the ready fixation.

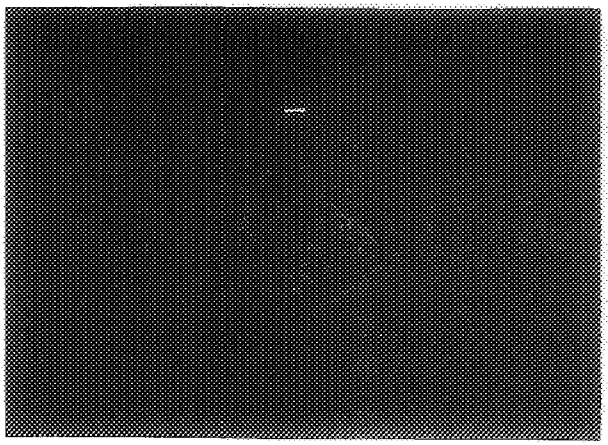

Figure 5A. Exposing and cleaning of the fracture surfaces.

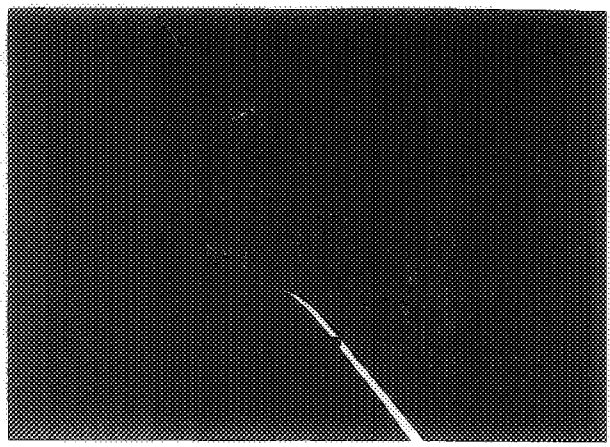

Figure 5B. Exact reduction, compression with clamps.

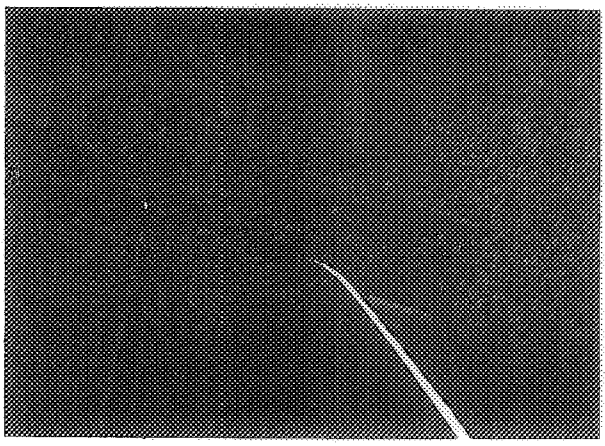

Figure 5C. Drilling. Observe the direction

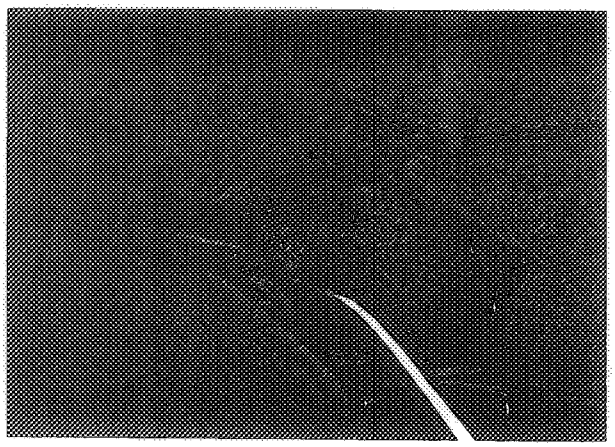

Figure 5D. Measuring the drillchannel.

Figure 5E. Tapping.

Figure 5F. The use of countersink. Do not damage the articular surface.

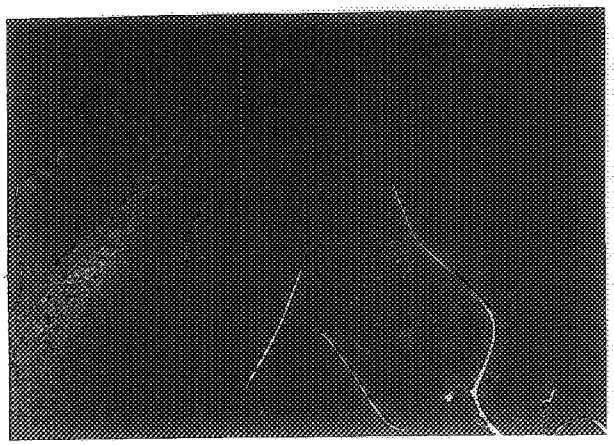

Figure 5G. Douche of the drillchannel.

Figure 5H. Inserting the screw into the drillhole. Notice the screwdriver; when the small fissure at its tip seems to begin to open, the fixation is firm enough and do not use more force because you may damage the head of the screw.

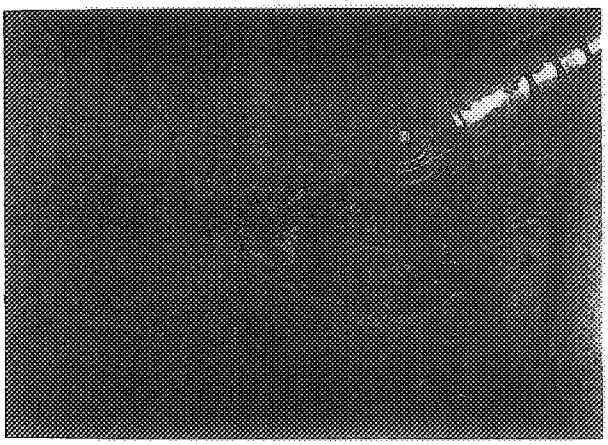

Figure 5I. Cutting off the head of the screw with a saw, if necessary. One mm is recommended to be left of the head above the cortex.

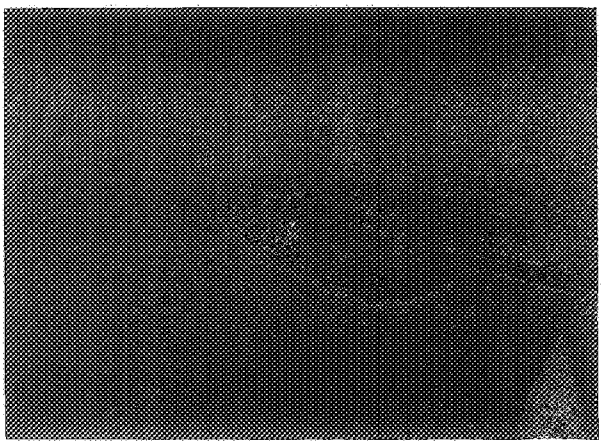

Figure 5J. The picture of the ready fixation.

6.2.5. Special comments

- ★ If the screw gets stuck before it is totally inserted, examine that the reduction is exact. If so, turn the screw out and over-drill with a 3.5 mm drill and reuse the tapping device. You can also cut the screw with a saw. If the threads of the screw are in the both cortices, you can accept the fixation. If the screw is broken and the fixation is not sufficient, over-drill with a 3.5 mm drill and reuse the tapping device. Insert a new screw.
- ★ In some cases, when the cortex is thick and very hard, it is better to drill directly with a 3.5 mm drill bit in order to reduce the friction between the cortical bone and the screw.
- ★ In areas, where the cortex is thin or the soft tissues over the bone are scanty, the head of the screw can be cut partially or totally with a saw to avoid mechanical stress of subcutaneous tissue which may lead to local fluid accumulation.
- ★ Lag screw principle is possible with over-drilling, but you must notice that then the direction of the drillchannel must be near 90 degrees against the fracture line.
- ★ If you have difficulties with these screws, you are free to contact the authors at the Dept Orthop and Traum in Helsinki University Central Hospital, Topeliuksenkatu 5, SF-00260 Helsinki, Finland. Tel 358-0-402 61.

Figure 6 shows as an example radiographs of an ankle fracture preoperatively and postoperatively.

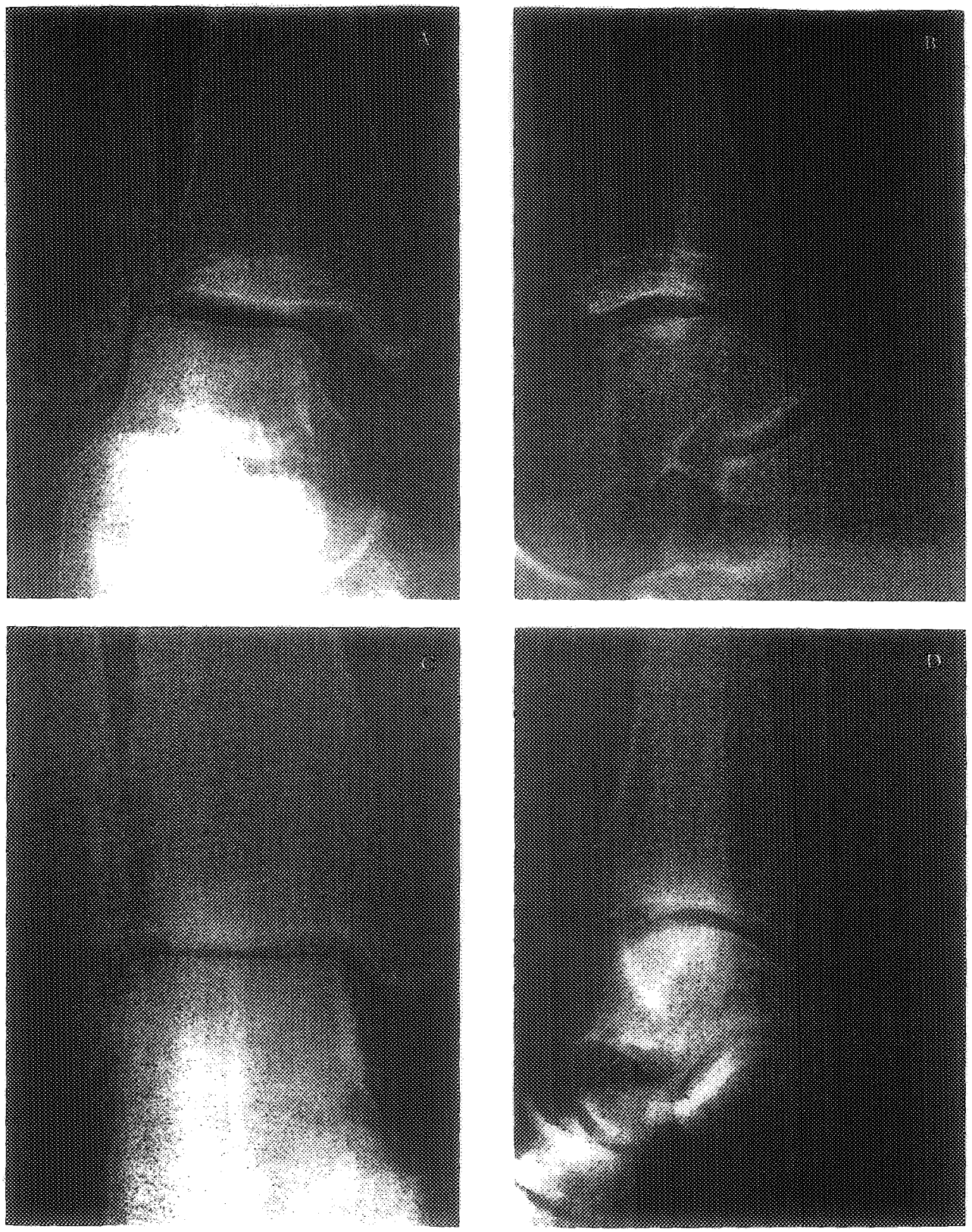

Figure 6. Radiograph of a fracture of a lateral malleolus and of posterior triangle with the rupture of deltoid ligament:
(A) Preoperative antero-posterior (AP) projection.
(B) Preoperative lateral projection.
(C) AP-projection one year postoperatively.
(D) Lateral projection one year postoperatively.

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BIOFIX®

BIODEGRADABLE FIXATION DEVICE FOR INTERNAL FIXATION OF CANCELLOUS BONE FRACTURES, OSTEOTOMIES AND ARTHRODESES

Surgical Technique

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Helsinki University Central Hospital
Department of Orthopaedics and Traumatology
1988

Contents

1. INTRODUCTION

Biodegradable BIOFIX®-rods* are intended for the fixation of cancellous bone fractures, osteotomies or arthrodeses.

The BIOFIX®-device comprises 1—3 cylindrical, biodegradable composite rods (rods with diameters from 1.5 mm to 4.5 mm are available). These are driven by an applicator (see Figure 2) in predrilled channels through the fracture to fix the fracture and prevent it from reopening. One or two additional biodegradable fixing sutures (Dexon "S" suture size 1 or 2) which is/are knotted over the fracture can be used to secure the fixation (Törmälä *et al.* 1987(1)).

Biodegradable BIOFIX®-rods are constructed of patented, self-reinforced polyglycolide composite material (Törmälä *et al.* 1988(1), Törmälä *et al.* 1987(2)). A patented manufacturing process guarantees high initial mechanical strength and elastic modulus of rods which preserves a secure fixation in combination with a plaster cast. The rods lose their strength during 30—50 days *in vivo* depending on the size of the rod (Törmälä *et al.* 1988(2)). Within a corresponding period of time a fracture of cancellous bone can be considered as practically consolidated. BIOFIX®-rods are digested by cancellous bone tissue within 6—12 months.

Self-reinforced BIOFIX®-composite rods have been shown to be highly biocompatible in both animal and clinical evaluations (Vainionpää 1987).

The raw-material of BIOFIX®-fixation rods is biodegradable (absorbable), tissue compatible polyglycolide which for many years has been applied as absorbable sutures (Dexon®) all over the world.

BIOFIX®-rods correspond to standard bone drill sizes (1.5 mm, 2.0 mm, 3.2 mm and 4.5 mm). The actual diameters of BIOFIX®-rods exceed somewhat those of standard bone drill sizes. This produces frictional forces when the rod is tapped into the drilled channel. If a blunt drill is used or the cancellous bone is porous or small fragments are fixed and therefore a strong fixation is not achieved, one or two additional biodegradable fixing sutures (Dexon "S" suture, size 1 or 2) which is (are) knotted over the fracture and function as tension band(s), can be used to secure the fixation.

BIOFIX®-rods give to a patient an initially strong and gradually decreasing internal fixation of cancellous bone fracture, osteotomy or arthrodesis against shear loads originating from muscular activity or from external sources.

2. MATERIALS AND THEIR PROPERTIES

The shear strength of self-reinforced polyglycolide composite material is 180—200 MPa and its bending

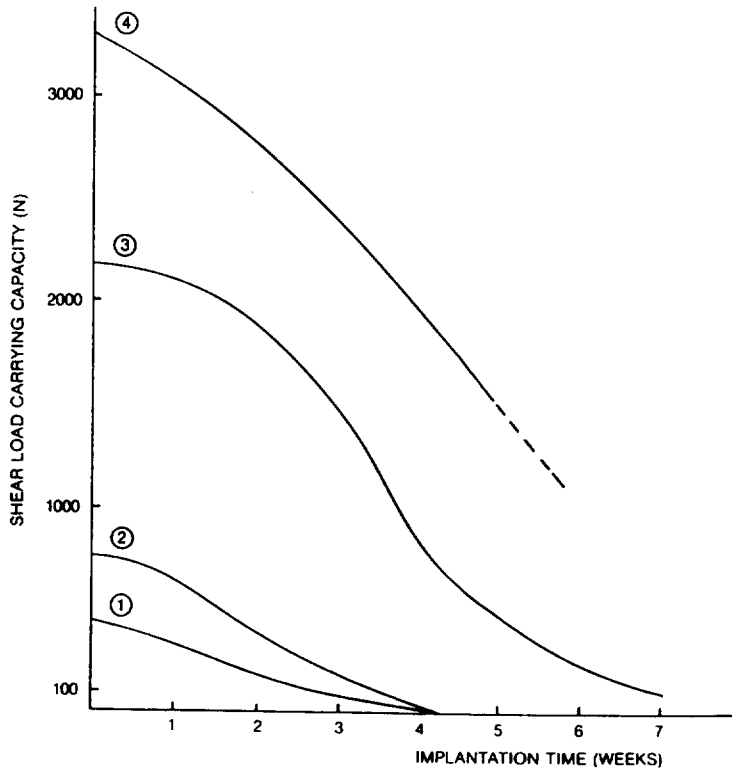

Figure 1. Shear load carrying capacity of BIOFIX®-rods after implantation in subcutis of rabbits. Rod sizes: (1) 1.5 x 50 mm. (2) 2.0 x 50 mm. (3) 3.2 x 50 mm. and (4) 4.5 x 50 mm.

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strength is 300—350 MPa (depending on the rod size). These values exceed 20—30 times the strength of cancellous bone and guarantee therefore the sufficient fixation which is still secured by means of a plaster cast.

Figure 1 shows as an example the shear load carrying capacity of different BIOFIX®-rods as a function of implantation time in the subcutis of rabbits (Törmälä *et al.* 1988(2)).

The bigger rods (diam. 3.2 mm and 4.5 mm) gradually lose their mechanical strength *in vivo* during 40—50 days. Smaller rods (diam. 1.5 and 2.0 mm) lose their strength during ca 30 days.

The decline in strength of the fixation device as the healing fracture gains in strength counteracts the development of osteoporosis.

When the BIOFIX®-device has lost its mechanical strength, the breakdown becomes more rapid and degradation is complete in 6—12 months.

3. STERILIZATION OF BIOFIX®-DEVICES

Components of BIOFIX®-devices (rods and possible fixing sutures) are sterilized by ethylene oxide. Resterilization by any method is not recommended. Repeated gas sterilization (with ethylene oxide, formaldehyde etc.) or radiation (with α-, β- or γ-radiation etc.) causes degradation of the material. Chemical sterilization (with alcohol, desinfection chemicals etc.) may damage the structure of material.

4. ADVANTAGES OF BIOFIX® DEVICES IN FIXATION OF FRACTURES IN COMPARISON WITH METALLIC OSTEOSYNTHESIS

- The stiffness of BIOFIX®-rods is close to that of bone, decreasing the risk of development of osteoporosis and giving a natural isoelastic fixation.
- Tissue irritation caused by metallic corrosion is eliminated.
- BIOFIX®-device supports the fracture the necessary period of time and degrades thereafter into small molecules which are totally metabolized. SINCE THE BIOFIX®-DEVICE IS ENTIRELY ABSORBABLE, IT IS NOT NECESSARY TO REMOVE IT SURGICALLY.
- Hospital costs/patient are reduced.
- The efficiency of the use of hospital personnel is increased.
- Operation capacity can be shifted to other operations, which shortens the operation lines.
- The risks of patients and the need of sick-leave are/is decreased.

The high shear load carrying capacity of BIOFIX®-rods prevents displacement of fragments. Friction between the biodegradable rod and the bone channel and swelling of the rod prevent the widening of the fracture line. Later, when material loses its strength the stresses are gradually transferred to the healing bone tissue thus diminishing the risk of the development of osteoporosis.

Disturbing implant prominences are avoided. In problematic regions, where subcutaneous tissue is scanty (*e.g.* in ankle), the risk of pressure necrosis and infection caused by metallic implants are decreased. The fixation with biodegradable rods through an articular surface is possible with a minimal damage.

The removal of these biodegradable osteosynthesis devices is unnecessary resulting in human and economic savings for the patient and the society and making it possible to use hospital resources to other operations.

5. THE USE OF BIOFIX®

BIOFIX®-rods are indicated for internal fixation of nonloaded cancellous bone fractures, osteotomies or arthrodeses. E.g. following fractures and/or osteotomies can be treated by BIOFIX®:

- Osteotomy of the coracoid process in Boytschev's procedure
- Condylar fractures of the humerus
- Fracture of the olecranon
- Fractures of the radial head and neck
- Delayed union and non-union of the scaphoid bone
- Bennett's fracture
- Fractures of the metacarpals and phalanges of the hand
- Arthrodesis of the metacarpophalangeal or carpometacarpal joint of the thumb
- Marginal fractures of the patella
- Osteochondritis dissecans of the knee
- Condylar fractures of the femur or tibia
- Repair of recurrent dislocation of the patella (Hauser technique)
- Fractures of the ankle: Weber A or B type fracture, Weber C type fracture
- Fracture of the posterior triangle of the tibia
- Fracture of the talus
- Chevron osteotomy for hallux valgus

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6. CONTRAINDICATIONS

The use of BIOFIX®-devices is contraindicated in the fractures of load bearing cortical bone. Likewise the equipment should not be used for the treatment of fractures in old (over 70 years of age) people. Severely comminuted and osteoporotic fractures are unsuitable to this method. The use of BIOFIX®-rods in fixation of cancellous bone fractures of children is under examination. The use of small BIOFIX®-rods (diameter 1.5 mm) in fixation of epiphyseal fractures of children is under examination, too. Because of still insufficient clinical data the BIOFIX®-rods should not yet be used for treatment of fractures or osteotomies of children.

More accurate information of contraindications, warnings and precautions is given in package insert of products.

7. OPERATING PRINCIPLES

7.1 Technique in general

Spinal, intravenous or general anaesthesia can be used. A bloodless field is recommonded. After cleaning of fractured surfaces the reduction must be performed exactly. The fracture is compressed and fixed with a clamp. This is important because with rods it is not possible to compress the fractured surfaces as *e.g.* with lag screws. However, reduction can be maintained by fixation with rods. Friction between rod and bone channel is sufficient to keep bone fragments together. Reduction is secured using two diagonally placed rods.

The reduced bone fragments are fixed with rods placed into standardized drill holes (bits 1.5 mm, 2.0 mm, 3.2 mm or 4.5 mm in diameter). Careful drilling is important because strength of fixation depends on the size of the hole and structure of the bone. The right starting point of drilling can be secured with a drill point. Sliding of the drill bit and dilatation of the aperture is avoided by this means. It is not allowed to move the bit to and from during drilling. The position of the bone fragments must be the same all the time during the operation. The aperture of the drill hole must be clean of soft tissue before tapping in the rod. A special applicator must be used when tapping the rod into place. This facilitates tapping and prevents damage to the head of the rod. The applicator consists of a cylinder and of a shaft which fits into the cylinder. There is an applicator for each rod diameter.

Figure 2 shows schematically in cross-sectional view the operating principles when one or two BIOFIX®-rods and possibly additional fixing suture(s) is (are) applied in internal fixation of a cancellous bone fracture.

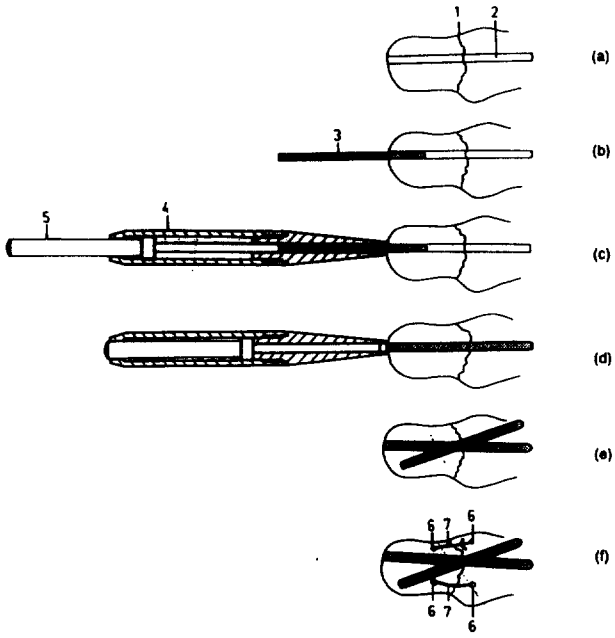

Figure 2. Operating principles with BIOFIX®-devices

First the area around the fracture is exposed by the standard principles of bone surgery. Good reduction of the fracture (1) or osteotomy is needed and it is fixed with clamp(s). A suitable hole (2) is drilled through the fracture plane (Fig. 2a). BIOFIX®-rod (3) is inserted by hand into the hole (Fig. 2b). The 30—70 mm long rod should sink 1 cm in the hole. When the rod is pressed properly into the hole, push applicator cylinder (4) on the rod and press applicator shaft (5) to contact with the BIOFIX®-rod (Fig. 2c). Tap the applicator shaft into the cylinder so that the rod is forced totally into the drill hole (Fig. 2d). Two or more holes with fixing rods can be applied if necessary (depending on the nature and size of the fracture) (*e.g.* Fig. 2e).

The rod can be tapped into the hole also directly with the applicator. In this case the rod is inserted firstly in the applicator cylinder.

If an additional strength of fixation is needed biodegradable fixing sutures (Dexon "S" sutures, size 1 or 2) can be applied in the following way: Suitable holes (6) are drilled for fixing suture(s) (7) which is (are) knotted over the fracture (Fig. 2f). In most cases the use of fixing suture is not necessary.

Postoperative radiographs are taken from two directions. If the fixation is good the wound is closed in two layers. Standard principles of othopaedics and traumatology are followed in reconstruction of the

anatomic continuity of surrounding tissues, such as periosteum, muscle, fascia, skin *etc.* Meticulous hemostasis and complete primary skin closure over the implant are essential. At last a padded, split plaster cast is applied.

7.2 Osteotomy of the coracoid process in Boytschev's procedure (Figure 3)

The indication for operation is recurrent anterior dislocation of the humerus. Before operation an axial radiograph of glenohumeral joint is taken in order to visualize the coracoid process. An anterior delto-pectoral approach is used. The deltoid muscle is retracted laterally and the pectoralis major medially. A channel with diameter of 3.2 mm and length of 30 mm is drilled into the coracoid process and an osteotomy is performed with oscillating saw at a point about 15 mm from its tip. The detached tip of the coracoid process and its attached muscles (the short head of the biceps and the coracobrachialis muscle) are now passed through the created tunnel between the subscapularis muscle and the capsule and re-attached to the base of coracoid temporarily with clamp. A biodegradable rod (3.2 by 30 mm) is placed into channel and fixation is secured with a few absorbable sutures. The wound is closed.

The arm is immobilized in a "Velpeau" dressing for three weeks, after which physiotherapy with active exercise is commenced.

a b c

Figure 3. Boytschev's operation for recurrent anterior dislocation of the humerus. Fixation of the coracoid process after osteotomy (a). Radiograph of the axillary projection seen preoperatively (b) and six months after osteotomy and fixation with one 3.2 by 30 mm BIOFIX®-rod (c).

7.3 Condylar fractures of the humerus (Figure 4)

Fractured capitellum or lateral condyle is exposed by lateral approach. Medial (epi) condyle is exposed medially in front of sulcus of the ulnar nerve. After exact reduction the fracture is fixed temporarily with a clamp if possible. A bone channel is drilled with the bit of 2.0 mm. Drill point or bit can be left in drilled channel to secure the position after measuring the length of the channel. The rod is placed by using applicator into the channel. If the rod is placed through articular surface the end must be at the level of articular cartilage. 1—3 rods are used when the bone fragment is great enough. Also the rod of 3.2 mm can be used.

The elbow is immobilized in plaster cast for 3 weeks.

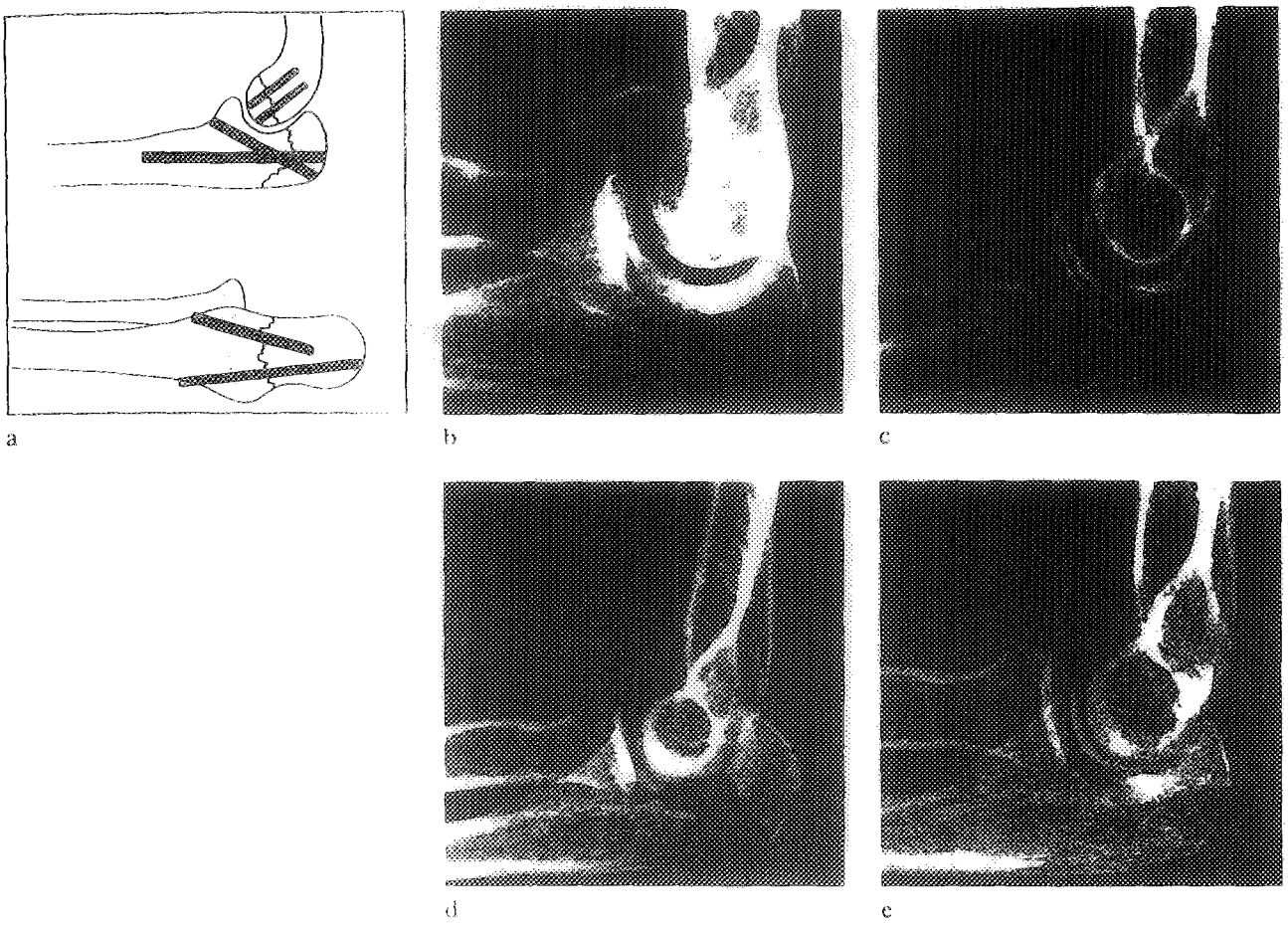

Figure 4. Fixation of fractures of the olecranon and capitellum humeri (a). Radiograph of a displaced fracture of the humeral capitellum seen on admission (b) and as healed one year after fixation with two 2 by 30 mm BIOFIX®-rods (c). Radiograph of a displaced fracture of the olecranon seen on admission (d) and as healed one year after fixation with one 3.2 by 70 mm and one 3.2 by 50 mm BIOFIX®-rod (e).

7.4 Fracture of the olecranon (Figure 4)

The fracture line must be at least 1.5 centimeter from the tip of olecranon to have a fragment of sufficient size. Patient lies in prone position. The olecranon is exposed by a longitudinal dorsal approach. Reduction and fixation may be helped by drilling a 2 mm hole for the distal jaw of the clamp distal to the fracture. The anatomy and directions of drilling must be assured after cleaning of surfaces of fracture. Right directions of drilling are essential. Compression must extend to the articular side of fracture when reduction is perfect. This is achieved by placing the jaws of the clamp into the drilled hole and in the top of olecranon. Exact cortical reduction ensures exact articular reduction, too. Channels are drilled with bit of 3.2 mm. Two rods of 3.2 mm are used. The first, 50 mm in length, is directed to coronoid process and the second, 70 mm in length, from the tip of olecranon through the ulnar cortex. The wound is closed.

The elbow is immobilized in plaster cast for 3 weeks.

7.5 Fractures of the radial head and neck (Figure 5)

The indications for operation are a displacement of 2 mm or more of the fracture, and the size of the fragment one third or more of the articular surface. The radial head is exposed through a straight lateral incision from the lateral humeral epicondylus over the center of the radial head while the elbow in 90 flexion. The annular ligament is severed. The displaced fragment is gently reduced with dissectors and held in right position by fingers. No clamps are needed. A 2 mm drill-hole is made perpendicular to the fracture surfaces.

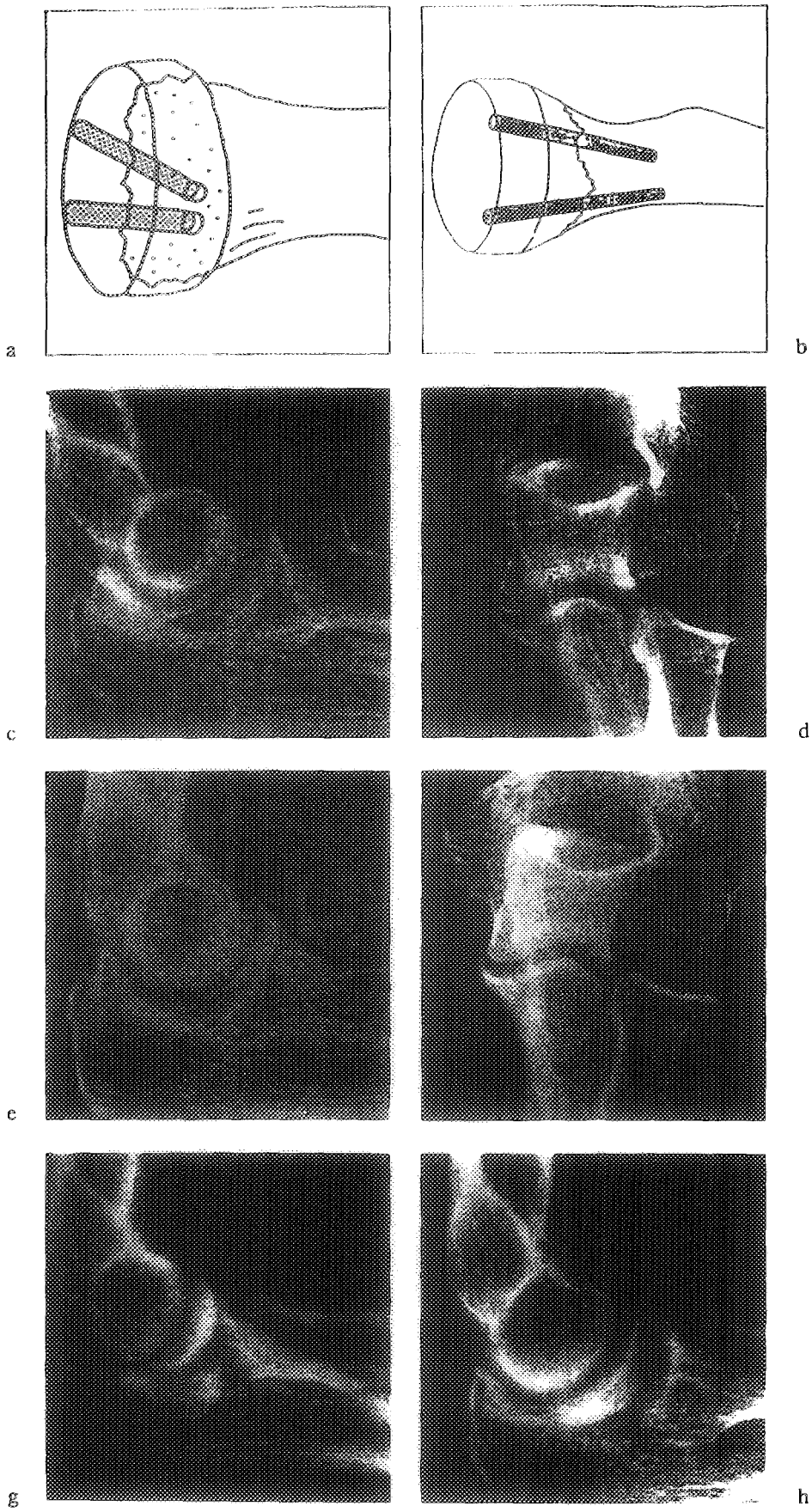

Figure 5. Fixation of marginal fracture of the radial head (a) and of the neck of the radius with a totally displaced radial head (b). Radiograph of a displaced marginal fracture of the radial head seen in lateral and in anteroposterior view on admission (c-d) and as healed one year after fixation with two 2 by 20 mm BIOFIX®-rods (e-f). Radiograph of a totally displaced fracture of the radial neck seen on admission (g) and as healed one year after fixation with two 2 by 30 mm BIOFIX®-rods (h)

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The opposite side of the head gives the direction of the drilling in marginal fractures. One or two rods are needed. When comminuted, the unstable fragments should be fixed separately. The wound is closed.

In subcapital fractures of the radius at least two oblique drillholes are made. These should reach the cortex of the distal fragment. The first drillhole can be secured with a K-wire while drilling the other. Finally the 2 mm Biofix-rods are tapped in with the applicator. The top of the rod should be at the articular cartilage level not interfering with the biomechanics of the joint. The torn periosteum is sutured, whenever possible. The wound is closed.

The elbow is immobilized in plaster cast for three weeks. Later on free mobilization is allowed.

7.6 Delayed union and non-union of the scaphoid bone (Figure 6)

A volar longitudinal incision radial to the tendon of flexor carpi radialis is made. This tendon is identified and retracted medially, and the radial artery laterally. The scaphoidal fracture is exposed. Dead sclerotic bone and fibrous tissue between the fracture fragments are excised. After reduction and temporary fixation a channel of 2 mm in diameter from tuberculum to the tip of scaphoid is drilled. In drilling the place of bone graft is noticed. A drill is left into the scaphoid to secure the fixation. A rectangular slot is created using a dental drill, and a cortico-cancellous graft from the iliac crest is fashioned and placed into the rectangular slot. The drill is removed and a rod is tapped into channel with applicator avoiding any separation of the abutting fragments. The wound is closed.

The postoperative management consists of immobilization with plaster cast for at least 6 weeks.

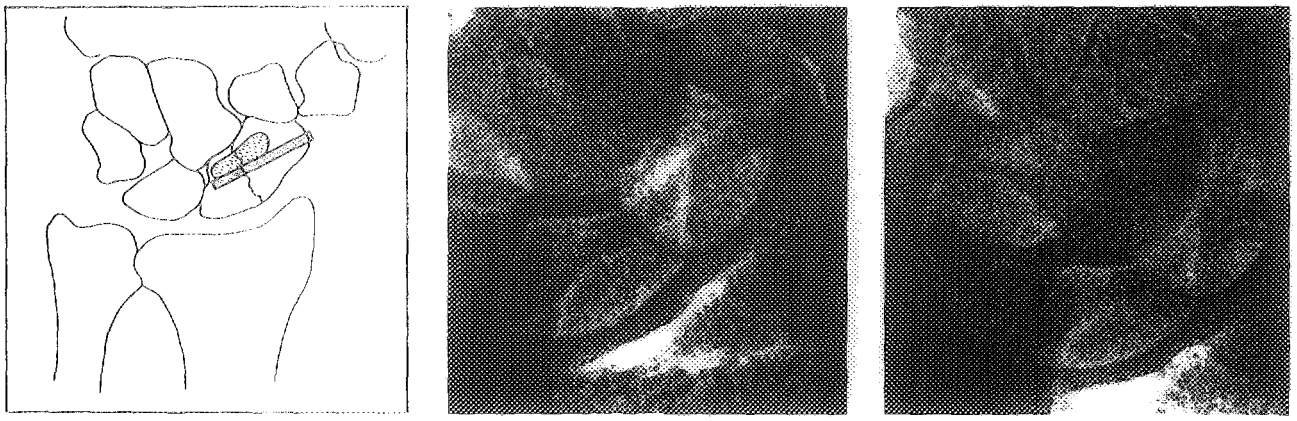

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Figure 6. Fixation and bone grafting for delayed union of the scaphoid bone (a). Radiograph of non-union of a fracture of the scaphoid bone seen before surgical intervention six months after trauma (b) and as healed one year after fixation with one 2 by 25 mm BIOFIX®-rod and bone grafting (c).

7.7 Bennett's fracture (Figure 7)

A curved incision is made on the volar aspect of the abductor pollicis longus tendon. The CMC-joint is exposed. Reduction is performed. The retention is possible with a dissector. A 2 mm hole is drilled from the radial side of the distal fragment through the fracture surfaces centering the proximal fragment. A temporary K-wire -fixation is done and, if needed, another drillhole is made. The Biofix-rods are inserted with the applicator while supporting the fragment with the dissector. The wound is closed.

Postoperatively a plaster cast is held for 5 weeks.

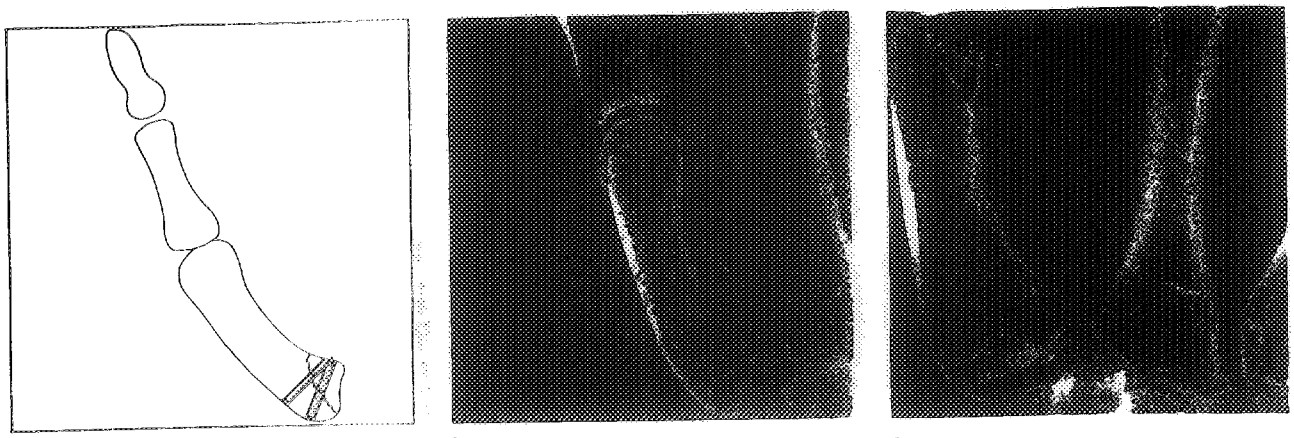

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Figure 7. Fixation of Bennett's fracture (a). Radiograph of a displaced Bennett's fracture seen on admission (b) and as healed six months after fixation with two 2 by 25 mm BIOFIX®-rods (c).

7.8 Fractures of the metacarpals and phalanges of the hand (Figure 8)

Dorsolateral or dorsomedial incisions are done, and the fracture is reduced and fixed with a clamp. A 2 mm drillhole is directed perpendicular to the fracture line and a BIOFIX®-rod is inserted. It is important to make the oblique drillhole carefuly because a channel through the cortices is essential for proper fixation. The wound is closed.

The plaster cast immobilization time is 4 weeks.

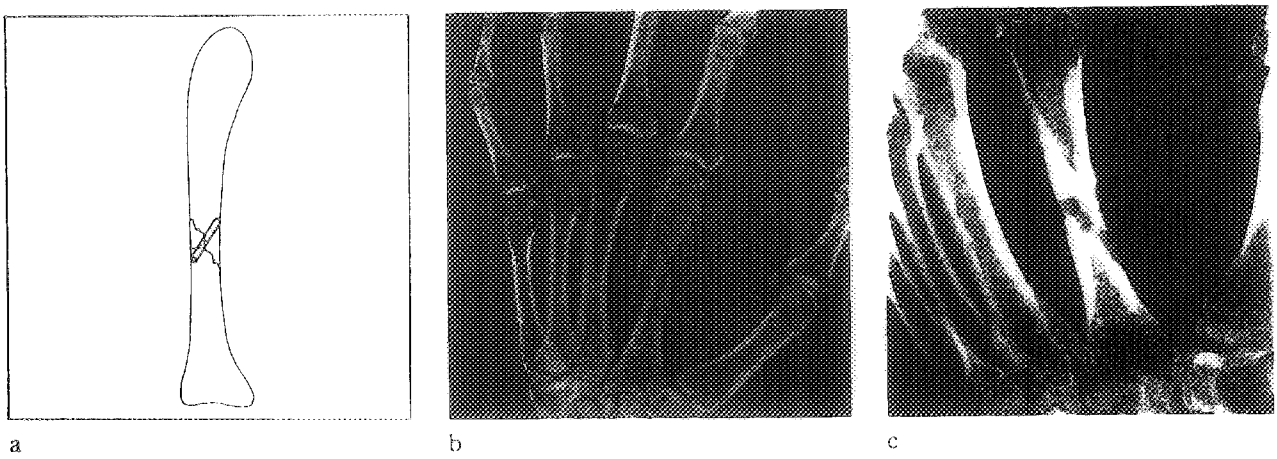

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Figure 8. Fixation of diaphyseal fracture of the metacarpal bone (a). Radiograph of a displaced diaphyseal fracture of the second metacarpal bone seen on admission (b) and three months after fixation with one 2 by 25 mm BIOFIX®-rod (c).

7.9 Arthrodesis of the (metacarpophalangeal or) carpometacarpal joint of the thumb

An incision is made along the radial aspect of the first metacarpal bone curving medially at the carpo-metacarpal joint. The abductor pollicis brevis muscle and a portion of the opponens pollicis muscle are reflected to expose the joint. The cartilaginous surface of the bones is excised with V-shaped resection. An assistant holds the first metacarpal in abduction and in the correct rotational position with resected surfaces well apposed. Two crossed channels with diameter of 2 mm are drilled from the first metacarpal bone to the trapezium and the drill is left into the first channel for temporary fixation. The channels are measured and rods with proper length are placed with applicator into channels. Cancellous bone chips are placed around the arthodesis. The wound is closed.

The postoperative management consists of immobilization in plaster cast for 8 weeks.

7.10. Marginal fracture of the patella (figure 9)

Marginal fractures of the patella can be fixed with two or three 2 mm BIOFIX®-rods. Medial or lateral arthrotomy is done. The reduction is secured with a clamp. The holes should be drilled in different directions through the fracture surfaces to prevent redisplacement. The wound is closed.

Plaster cast immobilization for 4 weeks is needed.

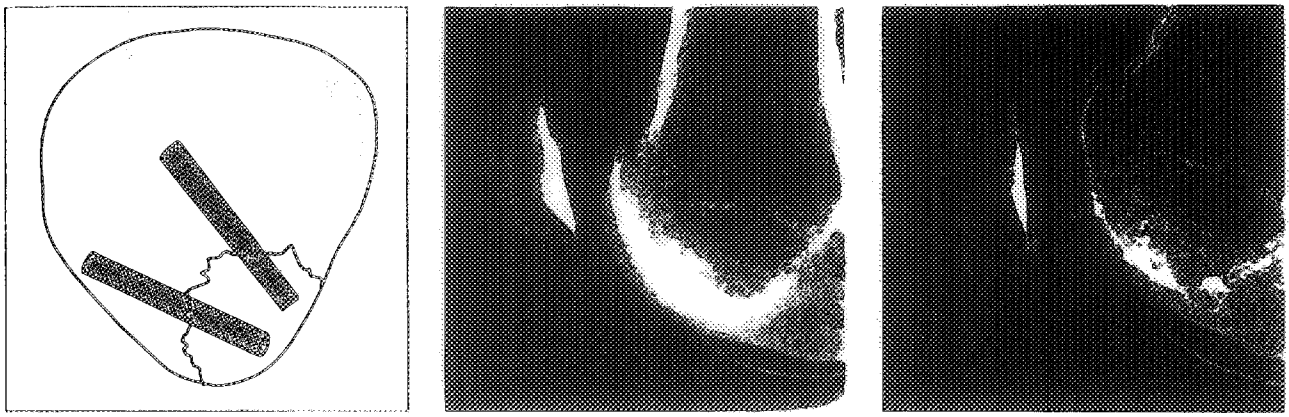

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Figure 9. Fixation of fracture of the patella (a). Radiograph of a marginal fracture of the patella seen on admission (b) and six months after fixation with two 2 by 30 mm BIOFIX®-rods (c).

7.11. Osteochondritis dissecans of the knee (Figure 10)

Medial or lateral approach is used with knee in 90 degrees' flexion. The crater of the loose body is prepared by excising from it all fibrous tissue. The loose body is trimmed to fit the crater, and 2—3 unparallel channels of 2 mm in diameter are drilled, measured and rods with correct length are placed into the channels to fix the loose body. The wound is closed.

The knee is not immobilized but weight-bearing is not started until 6 weeks after operation.

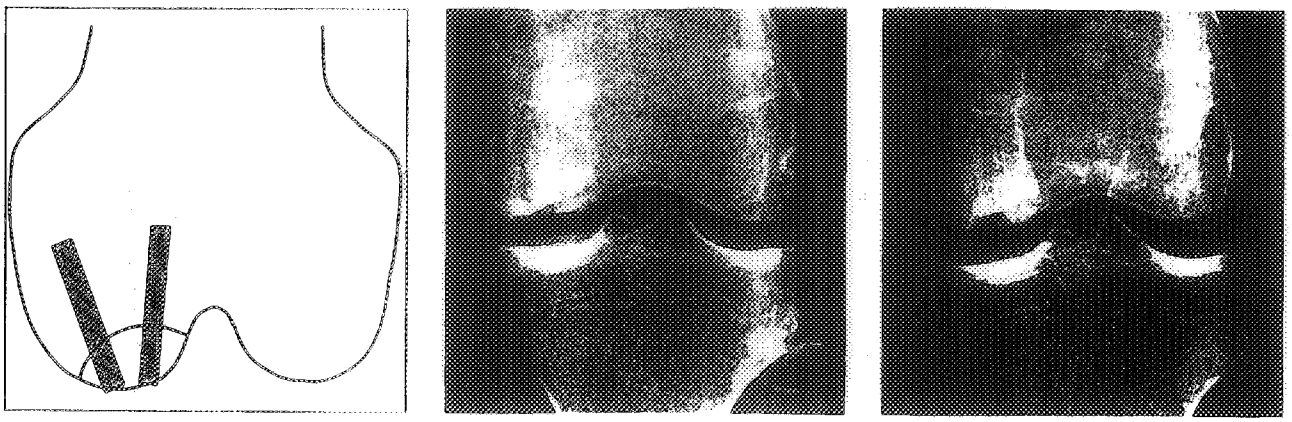

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Figure 10. Fixation of osteochondrol fragment in osteochondritis dissecans of the knee (a). Radiograph of the knee seen preoperatively (b) and one year after fixation with two 2 by 30 mm BIOFIX®-rods (c).

7.12. Condylar fractures of the femur and the tibia (Figure 11)

Intra-articular fractures can be fixed transarticularly with BIOFIX®-rods. Medial or lateral arthrotomy is done while the knee is held in 90 flexion. 3.2 mm drill-holes are done through the reduced fragment. Usually at least one rod has to be inserted through the articular surface. Marginal tibial condylar fractures, if not comminuted, can be fixed with BIOFIX®-rods instead of screws. A temporary clamp fixation is needed. The inserted two or three 4.5 mm rods perforate the opposite tibial cortex, otherwise the stability is not secured. The wound is closed.

The plaster cast immobilization time is 6 weeks. Full weight-bearing is allowed at 12 weeks postoperatively.

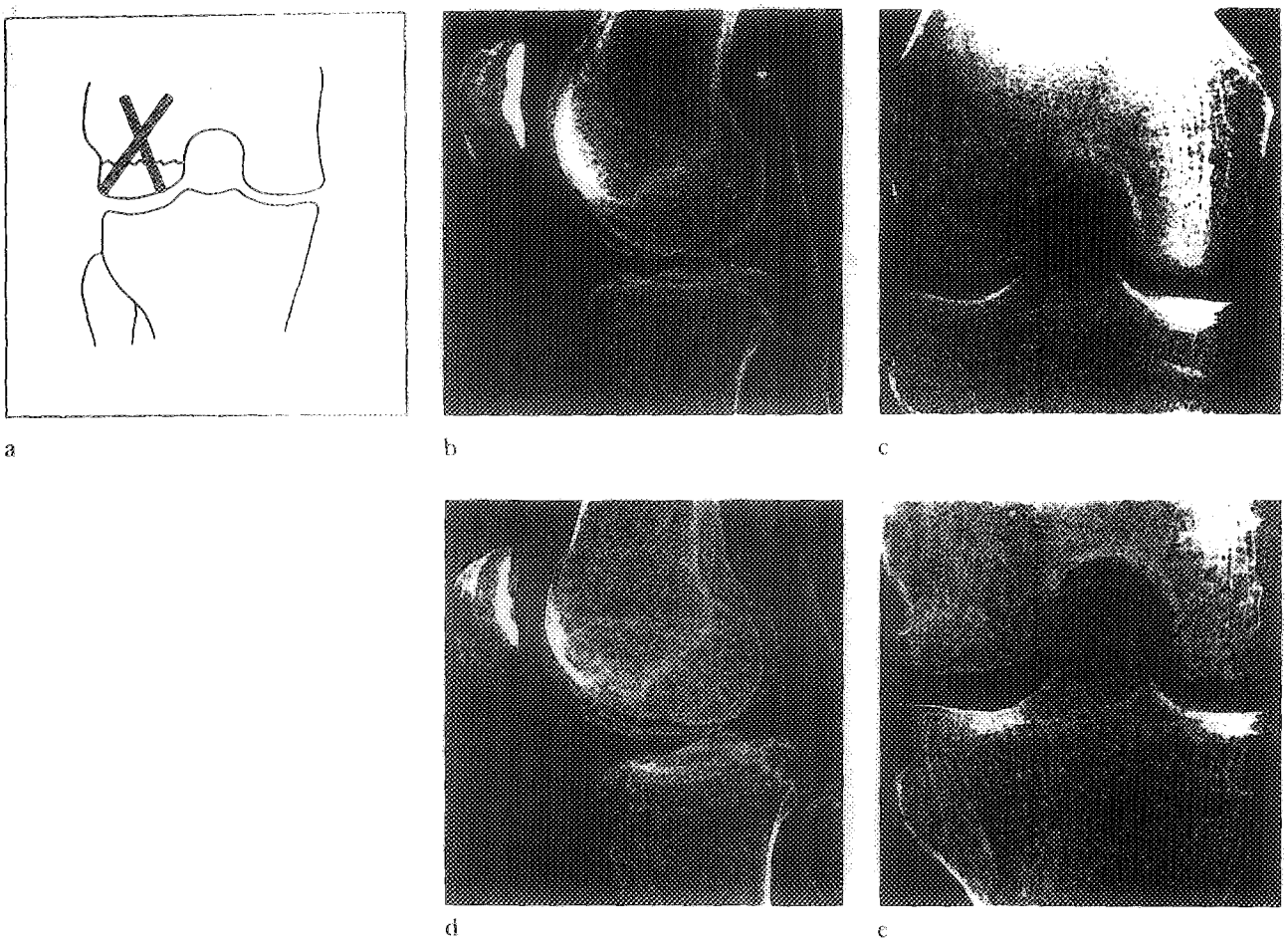

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Figure 11. Fixation of fracture of the femoral condyle (a). Radiograph of a displaced fracture of the lateral condyle of the femur in lateral view and in tunnel view on admission (b-c) and three months after fixation with two 3.2 by 50 mm BIOFIX®-rods (d-e).

7.13. Repair for recurrent dislocation of the patella (Hauser technique) (Figure 12)

Anteromedial approach is used. The dissection is carried down to the patellar tendon and the tibial tuberosity. A channel of 3.2 mm in diameter in posterior and proximal direction is drilled to a block of the tibial tuberosity containing the attachment of the patellar tendon, which is removed after drilling. The bone block with patellar tendon is placed to more distal and medial position on tibia. A channel of 3.2 mm in diameter is drilled through the drill hole of the block into the posterior and proximal direction carefully through the posterior cortex of the tibia. A biodegradable rod (3.2 mm by 50 to 70 mm) is placed into the channel by using applicator. The wound is closed.

A well-padded cylinder cast is applied with the knee in slight flexion for 6 weeks.

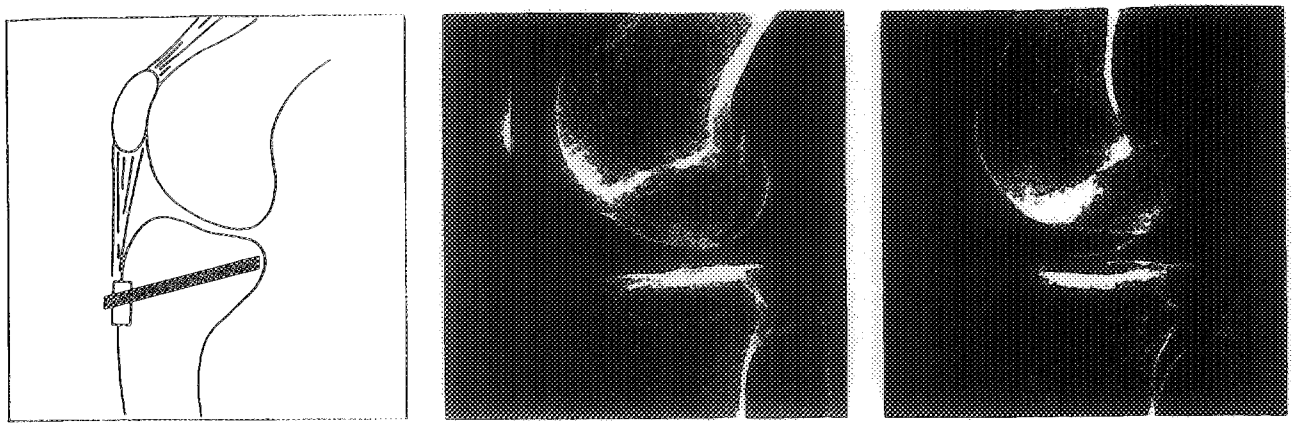

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Figure 12. Hauser's operation for recurrent patellar dislocation. Fixation of the block of the patellar tendon insertion (a). Radiograph of the knee seen preoperatively (b) and one year postoperatively (c). The block of the patellar tendon insertion was fixed with one 4.5 by 70 mm BIOFIX®-rod.

7.14. Fractures of the ankle

The Weber A-C classification for the fracture types is used. The indications for the operation are the same as for metallic fixation. Contraindications for the use of BIOFIX® are severe comminution of the fracture or marked osteoporosis.

7.14.1. Weber A or B type fracture of the ankle (Figure 13): Fracture of the lateral malleolus

The fracture and the tip of the malleolus are exposed by a vertical straight incision. The cutaneous nerve and the peroneal sheaths are preserved. The fracture is anatomically reduced, no shortening or displacement is allowed. The anterior tibiofibular ligament is examined and all soft-tissue interpositions are eliminated. Retention with two clamps is needed to compress the fragments during drilling and inserting the rod. A 4.5 or 3.2 mm hole is made from the tip of the malleolus, just lateral to the peroneal sheath, centering it through the fracture surfaces and further through the anteriomedial cortex of the fibula. The length of the hole should be 60 or 70 mm. The BIOFIX®-rod, 4.5 or 3.2 mm by 70 mm is inserted by using the applicator. If the hole is properly done, the rod will perforate the proximal cortex when tapped to the level of the malleolar tip, and the fixation is stable. The excess of the rod at the proximal part needs no further attention. Distally no prominence of the rod should be left to avoid the pressure against the subcutaneous tissue. The torn anterior tibiofibular ligament is sutured with 0-Dexon sutures. The wound is closed.

The ankle is immobilized postoperatively in a below-the-knee plaster cast for 6 weeks. After removing the stitches and applying a new plaster cast partial weight-bearing is started at three weeks and full weight-bearing at four week postoperatively.

7.14.2. Weber A or B type fracture of the ankle: Fracture of the medial malleolus

Very small fragments are not suitable for fixation with this method. Other indications and contraindications for the use of Biofix are discussed in the case of lateral malleolus fracture treatment.

Straight anteromedial incision is made. The medial joint surfaces are exposed. This ensures the exact reduction of the fragment after careful cleaning of the fracture surfaces. One clamp is needed to create compression. One or two 3.2 mm drill-holes are done being sure that the joint is not entered. The opposite tibial cortex can be penetrated. After insertion of the rods the torn periosteum is sutured over the fracture line. The wound is closed.

Postoperative care in plaster cast takes place as in the case of lateral malleolus fracture treatment.

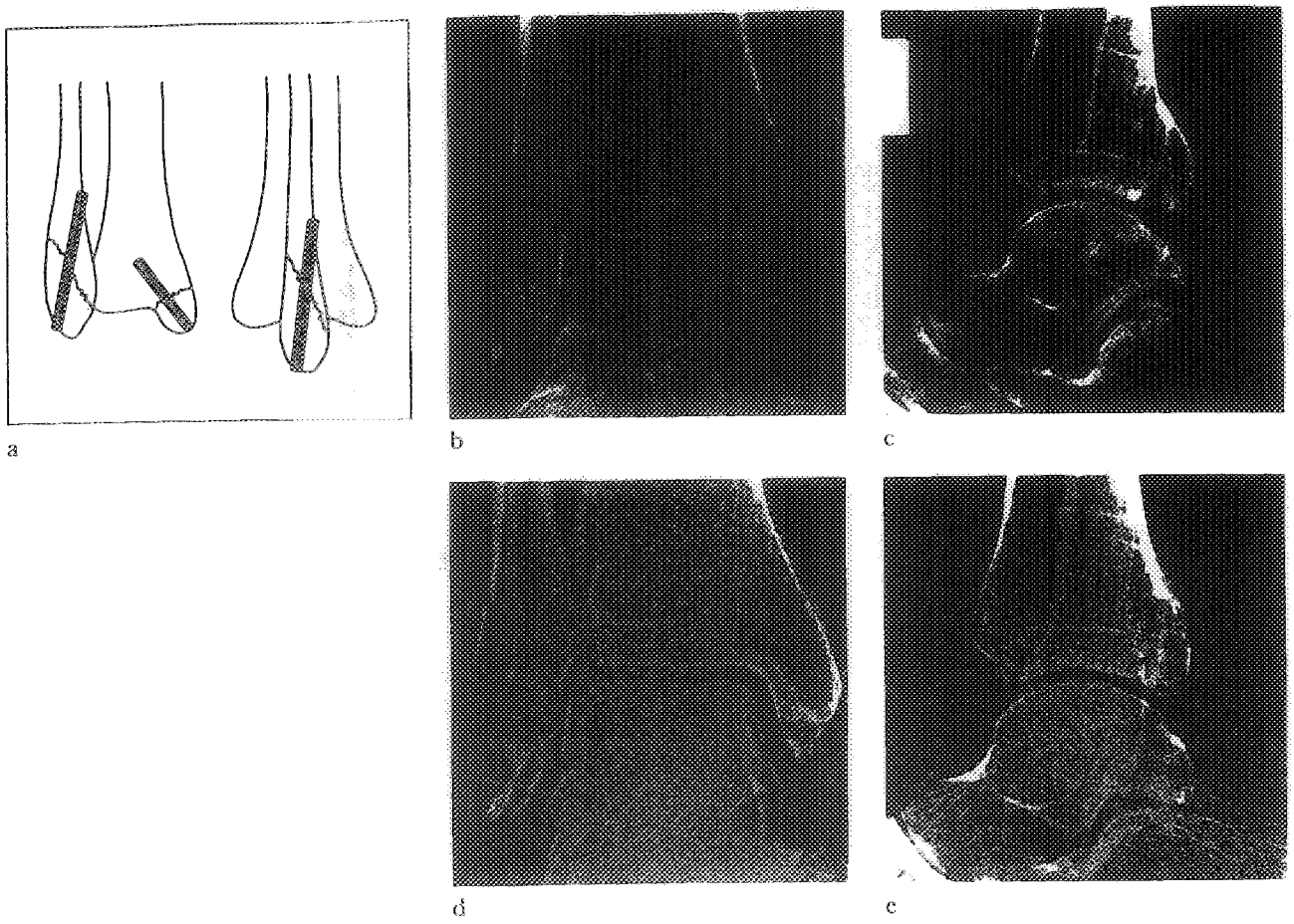

Figure 13. Fixation of bimalleolar fracture of the ankle (a). Radiograph of a displaced bimalleolar fracture seen in anteroposterior and in lateral view on admission (b-c) and as healed one year after fixation using one 4.5 by 70 mm BIOFIX®-rod on the lateral side and one 3.2 by 50 mm rod on the medial side (d-e).

7.14.3. Weber C type fracture of the ankle (Figure 14): Proximal fracture of the fibula with torn distal tibiofibular syndesmosis

Straight lateral and medial incisions are done. After correcting the possible shortening of the fibula the corrected anatomy of the mortise is secured with a clamp. The deltoid ligament is sutured being sure that no tissue interposition in the joint cavities is left. One 3.2 mm drillhole is done from the lateral side directing the drilling from the lateral malleolus through the syndesmosis, about 1.5—2 cm proximal to the tibiotalar joint, proximally against the medial tibial cortex. All four cortices are penetrated. A 3.2 mm by 50 mm or 70 mm BIOFIX®-rod is inserted, being sure that the clamp has kept the position of the bones exactly. Otherwise the insertion of the rod may be impossible. The ruptured anterior tibiofibular ligament is sutured. The wound is closed.

Postoperative care in plaster cast takes place as in the case of Weber A and B type fractures.

7.14.4. Weber C type fracture of the ankle: Oblique fracture of the distal fibula with rupture of the tibiofibular syndesmosis

The fracture is reduced and fixed temporarily with clamps. The fracture is fixed with 1 or 2 rods (diameter of 2 mm) perpendicularly to the fracture line. A shortening of the fibula is not accepted. Otherwise the management should follow the above procedure of Weber C fracture (with proximal fracture of the fibula) treatment.

The plaster cast is changed after 3 weeks when taking off the stitches. Partial weight-bearing is then started and full weight-bearing is allowed 4 weeks after the operation. The plaster cast is discarded 6 weeks after the operation.

7.14.5. Fracture of the posterior triangle of the tibia

The procedure can be performed either from the anterior or the posterior side. In anteromedial approach the fracture is exposed by reflecting the capsule and periosteum and retracting the tendons of the tibialis posterior, flexor digitorum longus, and flexor hallucis longus muscles together with the neurovascular bundle posteriorly and medially. After reduction the fragment of the posterior triangle is fixed with clamps. A channel of 3.2 mm in diameter is drilled from the front to distal and posterior direction.

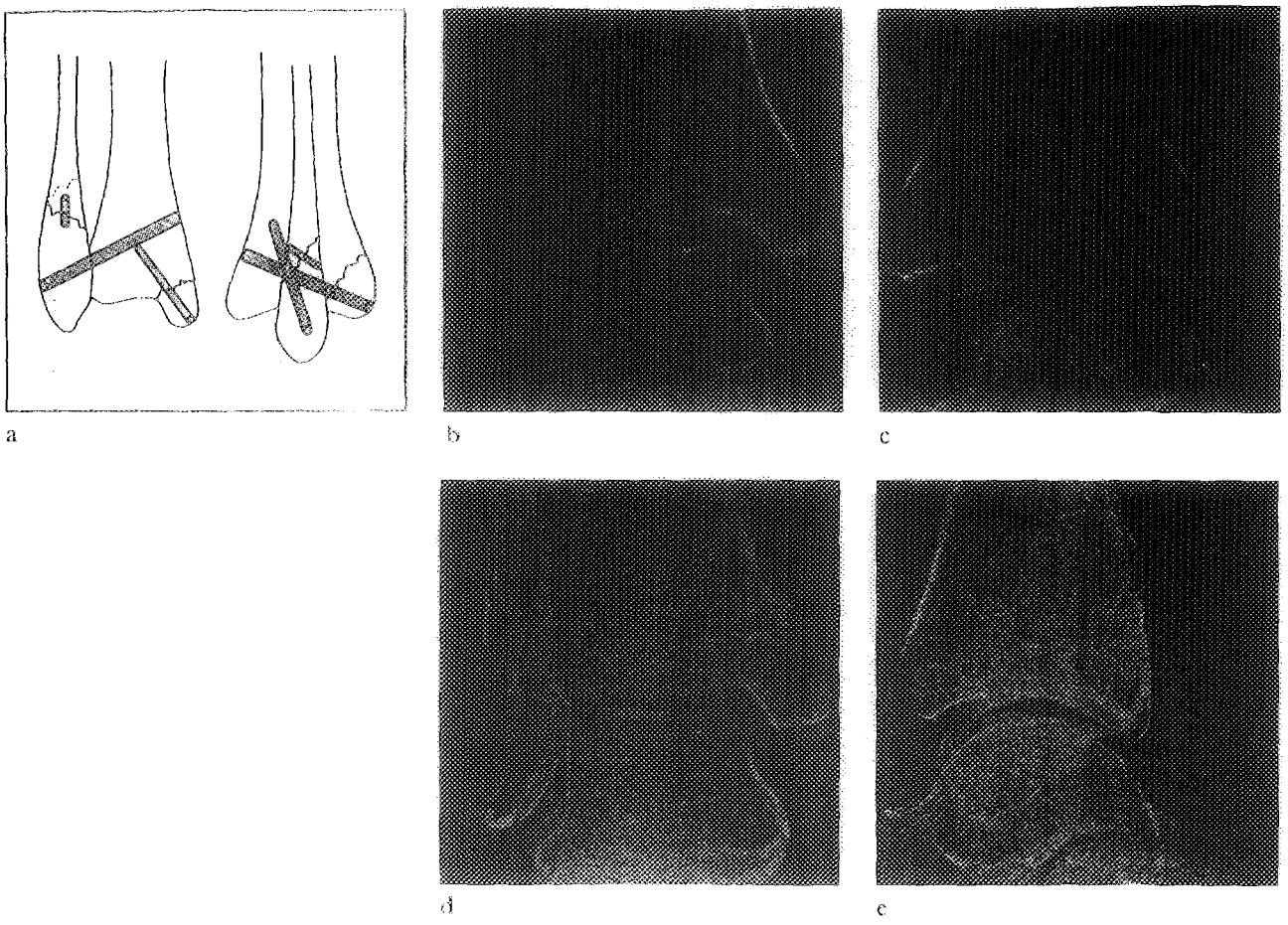

Figure 14. Fixation of severe trimalleolar fracture of the ankle (a). Radiograph of a displaced severe ankle fracture seen in anteroposterior and in lateral view on admission (b-c) and as healed one year after fixation with one 4.5 by 70 mm BIOFIX®-rod on the lateral side and two 3.2 by 50 mm rods in the posterior triangle (d-e).

A rod (3.2 by 50 mm) is placed by using the applicator into the channel and the clamps are removed after the fixation.

In posterior approach a longitudinal incision is made along the lateral border of the tendo Achillis. The tendo Achillis is retracted medially. The fragment of the posterior triangle should be exposed and after reduction fixed with clamps. A channel of 3.2 mm in diameter is drilled from the posterior side in proximal and anterior direction through the anterior cortex. The fragment is fixed with biodegradable rod(s) and closure of the wound is performed.

The plaster cast is changed after 3 weeks when taking off the stitches. Partial weight-bearing is started then and full weight-bearing is allowed 4 weeks after operation. The plaster cast is discarded 6 weeks after operation.

7.15. Fracture of the talus (Figure 15)

The anterolateral approach gives excellent access to the neck of the talus. A longitudinal incision anterior to the fibula across the talocrural joint level is made and carried distally to the navicular bone. The fascia and the transverse crural ligaments are incised down to the periosteum of the tibia and the capsule of the ankle joint. The extensor tendons, the dorsalis pedis-artery, and the deep peroneal nerve are retracted medially and fracture of the talus is exposed. Reduction is performed by changing the position of the ankle and with the aid of a dissector. A temporary fixation is made with Kirschner wires or with clamp. Two channels with diameter of 3.2 mm are drilled and rods (3.2 mm by 50 mm) are driven in. The wound is closed.

The postoperative management depends on the fracture type, immobilization with plaster cast is required for 6—12 weeks.

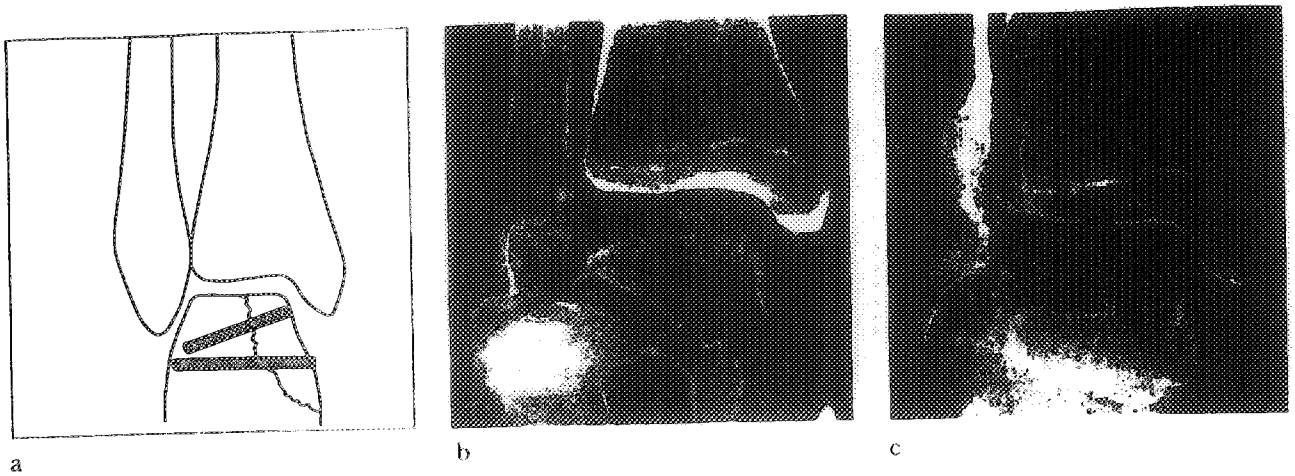

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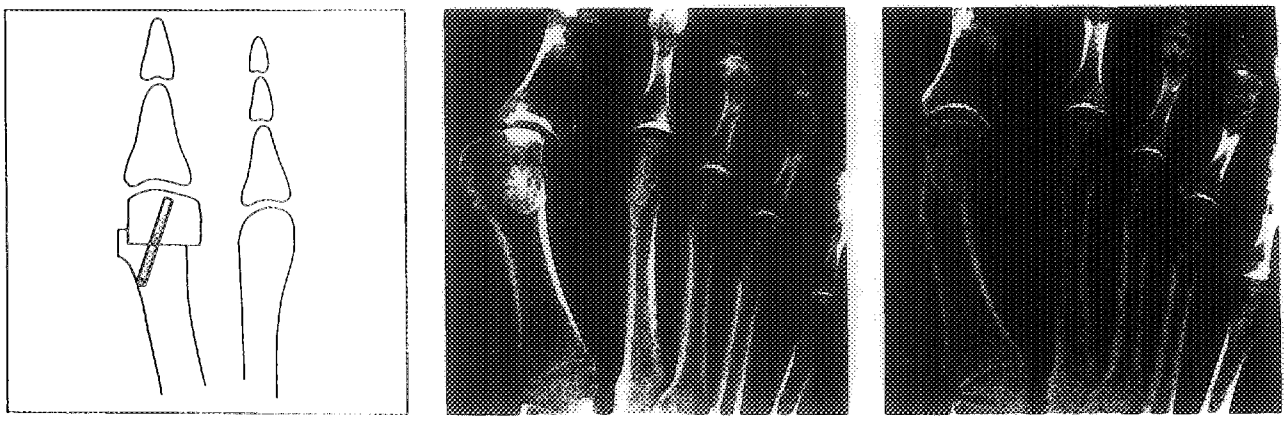
Figure 15. Fixation of fracture of the talus (a). Radiograph of a vertical fracture of the talus seen on admission (b) and as healed one year after fixation with two 3.2 by 50 mm BIOFIX®-rods (c).

7.16. Chevron osteotomy for hallux valgus (Figure 16)

The indication for operation is symptomatic varus malalignment of the first metatarsal with hallux valgus deformity (the angle between the first and the second metatarsal > 10 degrees). Standing radiographs are taken. Medial approach is used and the capsule of joint is opened with a Y-shaped incision. The exostosis is removed with an osteotome or oscillating saw. A V-shaped osteotomy with the tip of V pointing distally is performed in the cancellous, distal part of metatarsal by oscillating saw. The distal fragment is now displaced 4—5 mm laterally and held in this position by the assistent. A channel of 2 mm in diameter is drilled from the proximal fragment into the distal and lateral direction. A rod (2 mm by 25—30 mm) is tapped into channel to fix the osteotomy. The wound is closed.

A well-padded bandage is applied. Full weight-bearing of the heel and lateral part of pedis is allowed immediately. Full weight-bearing on the area of the osteotomy is started 4 weeks after osteotomy.



a b c

Figure 16. Chevron osteotomy. Fixation of the metatarsal head (a). Radiograph with full weight bearing of a foot with moderate hallux valgus seen preoperatively (b) and one year after Chevron osteotomy and fixation with one 2 by 25 mm BIOFIX®-rod (c). The intermetatarsal angle has been corrected from 17 to 9 and the metatarsophalangeal angle from 40 to 18 degrees.

8. CLINICAL EXPERIENCE WITH BIOFIX®

In a prospective clinical study 44 patients with a displaced fracture of the ankle were randomly allocated to two groups; one was treated with conventional metallic implants and the other with biodegradable implants. There were no differences between the two groups in the early results (Rokkanen et al. 1985).

56 patients with displaced malleolar fractures had open reduction and fixation of the fracture fragments using, by random selection, either biodegradable implants or metal AO plates and screws. The complications, radiographic results and functional recovery were studied prospectively. After follow-up of at least one year, no significant differences emerged in the complication rate or in the results of treatment between the two methods of fixation (Böstman *et al.* 1987).

In a prospective study 102 patients with displaced uni- or bimalleolar fractures of the ankle were managed using internal fixation by means of the biodegradable implants. The following results were achieved (Böstman *et al.* 1988):

— An anatomic initial reduction: 93 patients (91 %)
— A slight secondary displacement: 4 patients (3.9 %)
— A transient sinus formation without bacterial growth: 6 patients (5.9 %).

At the one-year follow-up examination there was no change in the ability to participate in sports and other physical activities in 89 patients (87 %).

Treatment of cancellous bone fractures, osteotomies or arthrodesis of 403 patients with BIOFIX®-rods between November 1984 and May 1987 gave the following results (Rokkanen *et al.* 1987):

— Uneventful postoperative course: 366 patients (91 %)
— Reoperations: 5 patients (1.2 %)
— Clinically insignificant secondary displacement: 12 patients (2.9 %)
— Superficial wound infection: 6 patients (1.4 %)
— Transient sinus formation without bacterial growth: 14 patients (3.4 %).

Postoperative local fluid accumulation:

In some patients a postoperative local fluid accumulation is developed in a primarily uneventfully healed wound typically 4—12 weeks after operation. This fluctuation may be accompanied by the redness of the skin and sometimes by pain. In such cases a puncture with a needle at least of 1.1 mm in diameter is performed. Bacterial culture of this aspirated fluid should be done. If any micro-organism is found, antibacterial treatment is started according to bacterial resistance, and a local incision should be done. If the bacterial culture is negative 1—3 punctures as a rule is enough for healing of fluid accumulation.

An incision is another choice of treatment of fluid accumulation. Incision is recommended it the puncture does not yield cure and fluid accumulation continues. Bacterial culture and abovementioned treatment must be done also in case of incision. The drained fluid may contain remnants of the degrading implant.

These minor draining procedures result in healing in a couple of weeks. This fluid accumulation does not have any influence on the radiographic result or fuctional recovery.

If the fluid accumulation is not treated properly it may lead to a transient sinus formation in the wound.

The incidence of this fluid accumulation has been approximately 6 per cent in the clinical use of Biofix polyglycolide composite rods (Rokkanen *et al.* 1988).

9. BIOFIX®-ROD SYSTEM

The following rods are commercially available for clinical use:

Rod diameter	Rod length
4.5 mm	70 mm
4.5 mm	60 mm
4.5 mm	50 mm
4.5 mm	40 mm
3.2 mm	70 mm
3.2 mm	60 mm
3.2 mm	50 mm
3.2 mm	40 mm
3.2 mm	30 mm
2.0 mm	70 mm
2.0 mm	60 mm
2.0 mm	50 mm
2.0 mm	40 mm
2.0 mm	30 mm
2.0 mm	25 mm
2.0 mm	20 mm
1.5 mm	70 mm
1.5 mm	60 mm
1.5 mm	50 mm
1.5 mm	40 mm
1.5 mm	30 mm
1.5 mm	20 mm
1.5 mm	10 mm

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Self-Reinforced Absorbable Screws in the Fixation of Displaced Ankle Fractures: A Prospective Clinical Study of 152 Patients

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Summary: The series consisted of 152 patients with ankle fractures treated between May 1987 and August 1989 using absorbable screws of self-reinforced polyglycolide 3.4 mm in inner diameter and 25–70 mm in length. The mean follow-up time was 2 years, 5 months (range, 1 year, 7 months–3 years, 10 months). After open reduction, a channel was drilled through the fracture surfaces and the fragments were fixed with one absorbable screw or screws. A plaster cast was used postoperatively. At 1-year follow-up observation, the radiographical result was anatomical in 93.3% of 104 patients with unimalleolar and bimalleolar ankle fractures (Weber A or B) and in 80.5% of 41 severe ankle fractures. Seven patients were unavailable for follow-up observation. Two reoperations were performed because of primary or secondary failure of fixation. In all unimalleolar and bimalleolar fractures and in 95.1% of severe ankle fractures the functional recovery score was at least satisfactory. Sinus formation as a sign of tissue reaction was observed in 10 patients 2–6 months postoperatively, but this did not influence the healing of the fracture or the functional recovery. This report is the first extensive publication on the clinical use of absorbable screws. Key Words: Ankle—Fracture—Absorbability—Biodegradability—Implant.

Absorbable synthetic polymers have been in worldwide use as sutures for 18 years and their physical and chemical properties are well known (10,11,26). Multiple experimental studies on absorbable or partially biodegradable implants in orthopaedic surgery have been published in recent years (1,6,8,12–14,16,17,19,21,31,37–39).

Absorbable polylactide-glycolide copolymer rods (28), later self-reinforced polyglycolide (SR-PGA) rods, have proved useful in fracture treatment (5, 15,27). The results in the fixation of ankle fractures have been similar compared to metallic fixation devices (3,28). The SR-PGA and SR-poly-L-lactide (SR-PLLA) screws were developed for clinical use (23,35). Later, screws with the same self-reinforced structure possessing the properties required for fracture fixation were manufactured also for experimental surgery (36). However, very few reports on the clinical application of absorbable screws have been published previously and those series have been small, with short follow-up times (2,7,21).

In this prospective study the clinical and radiographic results of 152 ankle fractures treated with absorbable screws are presented.

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IMPLANTS, PATIENTS AND SURGICAL TECHNIQUE

Implants

The screws were manufactured (Biofix from Bioscience Ltd., Tampere, Finland) of polyglycolide (raw material from Dexon suture, Davis & Geck, England) utilizing a method of partial sintering of the polyglycolide fibers at a high temperature and pressure (35). The nominal inner diameter of the screws was 3.2 mm (true, 3.4 mm), the outer diameter was 4.5 mm, and the length, 25–70 mm. The thread geometry of the screws was pitch, 1.75 mm; pitch angle, 10°; and side angle of thread on the tip side, 50–55°, and on the head side, 10–15°. The initial bending strength of the SR-PGA screw was 300 MPa, the shear strength 180 MPa, and the elastic modulus 10–15 GPa. The torsion strength was at least 0.45 nm (0.45–0.70). The loss of strength of the screw was gradual, being at 6 weeks at the level of that of cancellous bone in vivo. Polyglycolide degrades principally by hydrolysis and partially by an enzymatic process (16,26,31,38). Screws manufactured of a raw material with dye (green) were used at early operations, and later without dye.

Patients

From May 1987 to August 1989, fixation of displaced ankle fractures with absorbable screws was carried out in 152 patients, 82 male and 70 female. Patients with psychiatric disorders or alcoholism were excluded. The mean age was 36.6 years (range, 16–71). The mean weight of the patients was 75.2 kg (50–118). There were nine trimalleolar, 46 bimalleolar, and 53 lateral malleolar fractures with a rupture of the deltoid ligament, 27 lateral malleolar fractures without the rupture of the deltoid ligament, and 17 medial malleolar fractures in the series. Moreover, a small fragment of posterior triangle without any need of fixation was observed in 35 patients. Utilizing the Weber (40) classification, the distribution was A, 3; B, 113; and C, 36 fractures. All Weber C fractures and large fractures of the posterior triangle (more than one third of the articular surface) were classified as severe ankle fractures. Preoperatively, two patients had arthrosis of the ankle. The displacement of the fragments was at least 2 mm (mean, 6 mm) in the series (2–35 mm). The indications for operation in this study were otherwise the same as for internal fixation with metallic implants. All patients were operated on within 2 days of the accident. The mean stay in the hospital was 2.9 days (1–23). A plaster cast was used postoperatively for 6 weeks except for three patients; two used a plaster cast for 3 weeks and one for 4 weeks.

The patients visited the outpatient department for clinical and radiological checkup at 3, 6, and 12 weeks and at 6 and 12 months postoperatively and later if necessary. The mean follow-up time was 29 months (19–46). The clinical and radiological results were analyzed recording the achieved reduction, healing of the fracture, complications, and radiographic and functional results. Postoperative displacement of the fixed fragment less than 2 mm was accepted as an insignificant displacement and 2 mm or more as a poor result. For the syndesmosis an insignificant displacement was defined as a widening of the tibiofibular distance not more than 6 mm and a failure as more than 6 mm. The functional results were scored using the scale of Olerud and Molander (22) (Table 1).

Surgical Technique

We carried out all operations, with 148 (97.4%) performed by E.K.P. A bloodless field was used in 150 of 152 operations (98.7%). The fractures, as well as a ruptured syndesmosis if present, were reduced and compression was applied between the fragments using clamps to retain an exact reduction. In fractures of the lateral malleolus two screws were used in the early operations, and later only one (Fig. 1A and B). The drill used was 3.2 mm in diameter. The screws perforated both cortices, except in the medial malleolus. For the fixation of small fragments, small absorbable rods 2 mm in diameter, were used in severely comminuted fractures as well. The lag-screw principle was used when necessary. A special screwdriver, tapping device, and countersink were developed for surgical use of these screws (Fig. 2). Especially in the beginning, when the screws were all 50 mm in length, long screws were cut with a small oscillating saw. Altogether, 276 SR-PGA screws were used (mean, 1.6, or 1–4/patient, in unimalleolar and bimalleolar fractures and 2.5, or 1–5/patient, in severe ankle fractures). In 43 fractures SR-PGA screws without dye were used. Concomitant ligamentous injuries were sutured. A padded split plaster cast was applied postoperatively. The patients were allowed to move around on crutches from the 1st postopera-

TABLE 1. *Functional outcome and radiographical results*

Functional results	Patients with unimalleolar and bimalleolar ankle fractures	Patients with severe ankle fractures	Total %/no. of patients
Scoring by Olerud and Molander,[a] no. (%)			
excellent	93 (89.6)	36 (87.8)	89.1/129
good	11 (10.4)	3 (7.3)	9.5/14
fair	0 (0)	1 (2.4)	0.7/1
poor	0 (0)	1 (2.4)	0.7/1
Patients' subjective opinions,[b] no. (%)			
good	105 (98.1)	41 (95.3)	97.3/146
fair	2 (1.9)	1 (2.3)	2.0/3
poor	0 (0)	1 (2.3)	0.7/1
Sport activity,[c] no. (%)			
as earlier	94 (89.7)	38 (88.4)	89.3/132
mild discomfort or change to lighter activity	11 (10.3)	3 (7.0)	9.3/14
stopped	0 (0)	2 (4.7)	1.3/2
Motion of the joint, mean (range), degrees			
flexion[a]	51 (38–61)	49 (20–60)	
dorsiflexion[a]	18 (9–40)	18 (5–32)	
Mean duration of sick leave, days[d]	64 (0–158)	74 (14–258)	
Radiographical placement results			
immediately postoperatively,[e] no. (%)			
exact	99 (90.8)	38 (88.4)	90.1/137
insignificant displacement	9 (8.3)	5 (11.6)	9.2/14
poor result	1 (0.9)	0 (0.0)	0.7/1
1 yr postoperatively,[f] no. (%)			
exact	97 (93.3)	33 (80.5)	89.7/130
insignificant displacement	6 (5.8)	6 (14.6)	8.3/12
poor result	1 (0.9)	2 (4.9)	2.0/3

[a] Total number of patients with Weber A or B ankle fractures was 104 and with severe ankle fractures was 41.
[b] Total number of patients with Weber A or B ankle fractures was 107 and with severe ankle fractures was 43.
[c] Total number of patients with Weber A or B ankle fractures was 105 and with severe ankle fractures was 43.
[d] Total number of patients with Weber A or B ankle fractures was 105 and with severe ankle fractures was 38. Six patients were retired preoperatively.
[e] Total number of patients with Weber A or B fractures was 109 and with severe ankle fractures was 43.
[f] Total number of patients with Weber A or B fractures was 104 and with severe ankle fractures was 41.

tive day. Partial weight bearing was allowed at 3 weeks and full weight bearing 5 weeks postoperatively. The plaster was discarded at 6 weeks.

RESULTS

Seven of the 152 patients were totally or partially unavailable for follow-up observation. Five of these seven patients were contacted by telephone to obtain a record of subjective results. Results are presented in Table 2. The operating time was 34 min (range, 9–105) in unimalleolar and bimalleolar fractures and 46 min (range, 15–125) in severe ankle fractures.

Clinical Findings

Clinical and radiographical results are presented in Table 1. The mean functional score in unimalleolar and bimalleolar fractures was 96.4 (range, 78–100) and in severe ankle fractures, 94.3 (30–100) (maximum, 100). Dorsiflexion of the ankle joint was restricted 5° or less, as compared with the range of dorsiflexion of the healthy side in five unimalleolar and bimalleolar fractures, and was restricted more than 5° in two severe ankle fractures and one bimalleolar fracture. Two patients with bimalleolar fractures and one with a severe ankle fracture had a minimal restriction in plantar flexion. One significant restriction was observed in plantar flexion in a patient with a severe ankle fracture.

Radiographical Findings

No displacements of the fixed fragments were detected on the postoperative radiographs in 137 (90.1%) of the 152 patients and no abnormal radiographical findings in 130 (89.7%) of 145 of the pa-

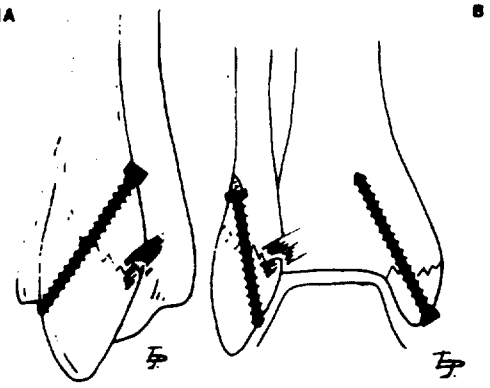

FIG. 1. Schematic lateral view (A) of the fixation of lateral malleoli and schematic anteroposterior view (B) of the fixation of a bimalleolar ankle fracture with absorbable screws.

tients at the 1-year checkup. Two cases with slight arthrosis and two with insignificant talar tilting were observed at the 1-year checkup. At 1 year, two patients had a poor result without any need of reoperation, one of them immediately postoperatively.

FIG. 2. The absorbable self-reinforced polyglycolide screw, screwdriver, countersink, and special tapping device.

TABLE 2. *The ankle score modified of the score of Olerud and Molander*[a]

	Points
Pain	
none	25
while walking on uneven surface	20
while walking on even surface outdoors	10
while walking indoors	5
constant and severe	0
Stiffness	
none	10
stiffness	0
Swelling	
none	10
only evenings	5
constant	0
Stair climbing	
no problems	10
impaired	5
unable	0
Running	
possible	5
impossible	0
Jumping	
possible	5
impossible	0
Squatting	
no problems	5
unable	0
Supports	
no support	10
taping, wrapping	5
stick or crutch	0
Work; activities of daily life, including sport activities	
same as before injury	20
loss of tempo	15
change to a simpler job/half time	10
disabled, strongly impaired work capacity	0
Total	100

[a] From *Arch Orthop Trauma Surg* 103:190–194, 1991.

An insignificant displacement improved to anatomic by remodelling in 1 year in seven patients, and the position of the fragments was insignificantly displaced during the healing in the other seven patients. Eight insignificant and one significant postoperative displacement were in the same position as after fixation.

Complications

The complications encountered in 107 less severe unimalleolar and bimalleolar fractures were one deep infection (0.9%), one superficial infection (0.9%), one deep venous thrombosis (0.9%), one reoperation because of poor reduction (0.9%) and one because of peroneal tendinitis (0.9%), one stress fracture in the distal tibia a half year postoperatively after heavy physical activity (0.9%), and

modified of the score of Molander[*]

	Points
	25
:e	20
outdoors	10
	5
	0
	10
	0
	10
	5
	0
	10
	5
	0
	5
	0
	5
	0
	5
	0
	10
	5
	0
	20
	15
ne	10
rk capacity	0
	100

g 103:190–194, 1991.

ent improved to ana-
ear in seven patients,
ents was insignificantly
in the other seven pa-
d one significant post-
in the same position as

ions

ered in 107 less severe
r fractures were one
superficial infection
rombosis (0.9%), one
reduction (0.9%) and
ndinitis (0.9%), one
ia a half year postop-
l activity (0.9%), and

one Sudecks atrophy (0.9%). In the 43 severe ankle fractures there was one deep infection (2.3%), one superficial infection (2.3%), two deep venous thromboses (4.7%), and one reoperation because of failure of fixation (2.3%).

The minor but harmful side effect of this method is the transient tissue reaction causing fluid accumulation. In the beginning of this study this was always aspirated with a needle, and later only if it was painful or if there was a diameter of more than 10 mm, to avoid a sinus formation. The bacterial culture of this aspirate was always negative and its pH was between 7.65–8.00 (mean, 7.88, analyzed in four patients). Cytological analysis revealed a nonspecific reaction to the foreign material. Altogether there were 10 sinus reactions in the series. Nine (8.4%) of them occurred in the early 107 operations when using screws made of raw material with dye, as compared to one (2.3%) in 43 patients treated with screws without dye.

DISCUSSION

Displaced ankle fractures are treated by internal fixation to achieve anatomic reduction and union (20,25). Although fixation with metallic devices has proved successful, it does have some disadvantages. Foremost of these is the need for a second surgical procedure for metal removal after fracture healing. Stiff metallic fixation devices may also cause osteoporosis beneath the fixation material (33,41) or damage the blood supply beneath the plate (24). The flexible fixation of the tibiofibular syndesmosis has proven successful in biomechanical testing and clinical practice (32).

Encouraged by good clinical results with cylindrical rods of polyglycolide since November 1984 (5, 15,27,28), we further have developed absorbable self-reinforced screws for clinical use. A few reports on the use of poly-L-lactide (PLA) screws and plates or polydiaksanone (PDS) screws in zygomatic or ankle fractures in a limited number of patients have been published. It appears that the principal problem is the strength of the screw (2,7). So far, our SR-PGA screws show the highest initial strength values reported for absorbable screws. The elasticity of the implants used in this study is almost that of bone. Thus the implant allows normal stress initially and gradually increasing stress with healing of the bone.

The end results in this series, i.e., radiographical results and the functional recovery achieved, did not differ from the results of comparable fractures treated with metallic fixation devices (18,25). Moreover, the remodelling of bone is possible when using more elastic and gradually strength-loosening absorbable implants during healing. Although there were two failures in the series of severe ankle fractures, one of them needing reoperation, with further development of SR-PGA screws and SR-PLLA screws with longer strength retention it may be possible to widen the indications for absorbable fixation of fractures.

We used a plaster cast postoperatively. This has been a disadvantage of the method in the opinion of some surgeons. However, in two recent randomized studies 6-week plaster immobilization of the ankle joint caused only a minor transient increased morbidity as compared with early mobilization (9,34). The plaster cast can probably be avoided when using absorbable screws in the fixation of ankle fractures and a trial of early mobilization of ankle fractures treated with absorbable screws is currently under way.

Fluid accumulation as a sign of transient tissue reaction is easily cured by aspiration or incision to avoid sinus formation, which is known to occur with absorbable sutures (3,11). This reaction did not influence union of the fracture or functional recovery. The reaction is not an infection and antibiotics are recommended only if bacterial culture is positive. Nor is it an immunological reaction (30). Additionally, the incidence of the reaction had decreased during the study when using SR-PGA screws made of colorless raw material in the later operations. However, all foreign materials, even metallic implants, may cause a tissue reaction (29).

The implants used in this study are not visible in the radiographs, but the drill channel is usually visible (Fig. 3). In some patients the drill channel is visible at 1 year, but in others it seems to be closed by new bone formation before 1 year. This phenomenon may depend on the individual's ability to biodegrade polyglycolide implants.

In this series we used absorbable screws 4.5 mm in outer diameter, a size relatively large compared to the metallic screws usually used in the fixation of the lateral malleolus. Although there were no problems with these screws, it may be better to use absorbable screws 3.5 mm in outer diameter, which are now available. The use of one screw in the fixation of the lateral malleolus is possible if the reduction is exact and the screw is not directed perpendicularly to the fracture line. This will avoid rotation of the fragment around the screw. This

91

FIG. 3. Anteroposterior and lateral radiographs of a bimalleolar fracture (Weber B type) preoperatively (A, B) and 1 year postoperatively (C, D).

technique is simple compared to the use of a plate and screws in the fixation of the lateral malleolus, and multiple drill holes in the lateral malleolus will be avoided. The operating times were rather low in this series as the operative technique is simple and few implants are used for fixation. The other reason is that the operations were performed by a surgeon who was familiar with these implants. We favor such techniques of internal fixation, where the use of foreign material is kept to a minimum.

Within a 6-year period 700 hardware removals were avoided by using absorbable fixation devices in our department (4). When calculating the costs of the absorbable fixation devices with today's prices ($121 for one screw) the average costs are $221 per ankle fracture in this series. The average cost of metallic devices needed in the fixation of comparable ankle fractures is approximately $92 per ankle fracture. Although the initial price of absorbable screws is higher, the removal of metals will be avoided. The cost of the removal procedure performed at our outpatient department is $437. The duration of sick leave after removal is 10 days on average, or $656 per removal, not including the outpatient surgical charge. The main benefit of the use of absorbable implants in bone surgery is the avoidance of a removal procedure with its psychological and economic advantages. The results of this study showed that absorbable screws can be used successfully in the fixation of ankle fractures.

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Fixation with Bioabsorbable Screws for the Treatment of Fractures of the Ankle*

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Investigation performed at Parkland Memorial Hospital, Dallas; Columbia-University of Louisville Hospital, Louisville; and Harborview Medical Center, Seattle

ABSTRACT: **One hundred and fifty-five patients who had a closed, displaced medial malleolar, bimalleolar, or trimalleolar fracture of the ankle were managed with medial malleolar fixation with use of either 4.0-millimeter orientruded polylactide screws (eighty-three patients, study group) or 4.0-millimeter stainless-steel screws (seventy-two patients, control group). All lateral malleolar fractures were stabilized with standard metallic implants.**

At an average of thirty-seven months (range, twenty-one to fifty-nine months), the radiographic and functional results in the two groups were equivalent. Differences between the two groups with regard to the rates of operative and postoperative complications were not statistically significant. Late spontaneous drainage of the hydrolyzed polylactide was not noted in any patient in the study group. The prevalence of late tenderness over the medial malleolar implant was lower in the patients in whom the fracture had been stabilized with polylactide screws. We conclude that polylactide screws are a safe and effective alternative to stainless-steel screws for the fixation of displaced medial malleolar fractures.

A common problem following open reduction and internal fixation of fractures is pain over prominent metallic implants. Such tenderness is most frequent when subcutaneous implants are used to stabilize fractures of osseous prominences such as the medial malleolus, lateral malleolus, olecranon, femoral condyles, and greater trochanter. Chronic discomfort may necessitate elective removal of the hardware after fracture-healing. This complication of the use of metallic implants has stimulated investigation into the application of bioabsorbable screws for the treatment of such fractures. A variety of different polyester materials, similar to those widely used for sutures, have been fabricated into rods or screws and tested.

The purpose of this prospective, randomized study was to test the safety and efficacy of polylactide screws for the fixation of displaced malleolar fractures of the ankle.

Materials and Methods

One hundred and sixty-nine consecutive adult patients who had a closed, displaced medial malleolar, bimalleolar, or trimalleolar fracture necessitating open reduction and internal fixation were entered into the study. The patients were managed between 1988 and 1991 at one of three trauma centers: Parkland Memorial Hospital in Dallas, Texas; Columbia-University of Louisville Hospital in Louisville, Kentucky; or Harborview Medical Center in Seattle, Washington. All patients were randomized into either a study group (polylactide

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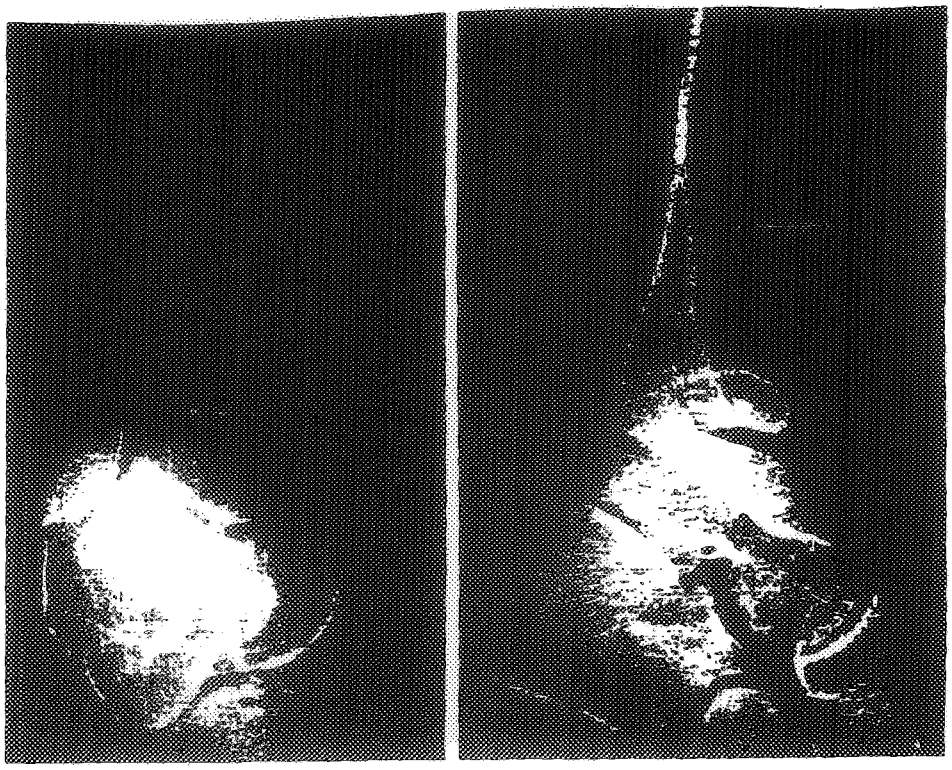

FIG. 1-A FIG. 1-B

Figs. 1-A through 1-D: Anteroposterior and lateral radiographs of a woman who had a displaced bimalleolar fracture at the age of thirty-five years.

Figs. 1-A and 1-B: The medial malleolus was fixed with two 4.0-millimeter polylactide screws, while the lateral malleolus was stabilized with an interfragmental screw and a one-third tubular plate.

screws) or a control group (stainless-steel screws) on the basis of the date (odd or even) of the injury. The study protocol was approved by the respective institutional review boards of the hospitals and was monitored by the Food and Drug Administration. Patients who had a non-displaced fracture, an open fracture, a large open wound about the ankle, a fracture with a very small medial malleolar fragment that was not amenable to fixation with screws, or an unstable fracture of the ankle with a rupture of the deltoid ligament were not entered into the study. The indications for open reduction and internal fixation included any medial malleolar, bimalleolar, or trimalleolar fracture with sufficient osseous and soft-tissue disruption that displacement of the talus of more than one to two millimeters was evident on the diagnostic radiographs. All isolated medial malleolar fractures had at least a two-millimeter gap between the major fracture fragments.

After stabilization of the patient and assessment of all associated injuries, open reduction and internal fixation of the fracture of the ankle was performed as soon as possible, with use of standard medial and lateral incisions. Lateral malleolar fractures were stabilized either with a one-third tubular plate or a dynamic compression plate after open reduction. The medial malleolar fragment was then reduced and stabilized with either 4.0-millimeter stainless-steel cancellous-bone screws or 4.0-millimeter orientruded polylactide bioabsorbable screws (Figs. 1-A and 1-B). Any large posterior malleolar fragments were fixed similarly with polylactide screws. Orientrusion is a manufacturing process by which the polylactide polymeric chains are aligned in a parallel fashion, enhancing the strength of the material. The design of the partially threaded polylactide screws was identical to that of AO screws designed for use in cancellous bone, except that the polylactide screws had a slightly enlarged head with a cruciate design and a slightly larger-diameter shank. Both the AO stainless-steel and the polylactide screws allowed for interfragmental compression of the medial malleolus.

Standard AO technique and a 2.5-millimeter drill-bit were used for the insertion of the stainless-steel screws. An attempt was made to insert two parallel screws that were forty to fifty-five millimeters in length. Sufficient torque was placed on the screws to allow for interfragmental compression of the medial malleolus with the underlying tibia. A 3.2-millimeter drill-bit was used for insertion of the bioabsorbable screws. The entire length of the drill-hole was tapped with use of a 4.0-millimeter tap. The screws were then inserted with use of a torque-limiting screwdriver, designed to prevent inadvertent breakage of the shank or head of the screw during insertion. The screwdriver allowed for torques of as high as 0.45 ± 0.05 newton-meter (4 ± 0.4 inch-pounds) of force to be applied to the head of the polylactide screw. Inter-

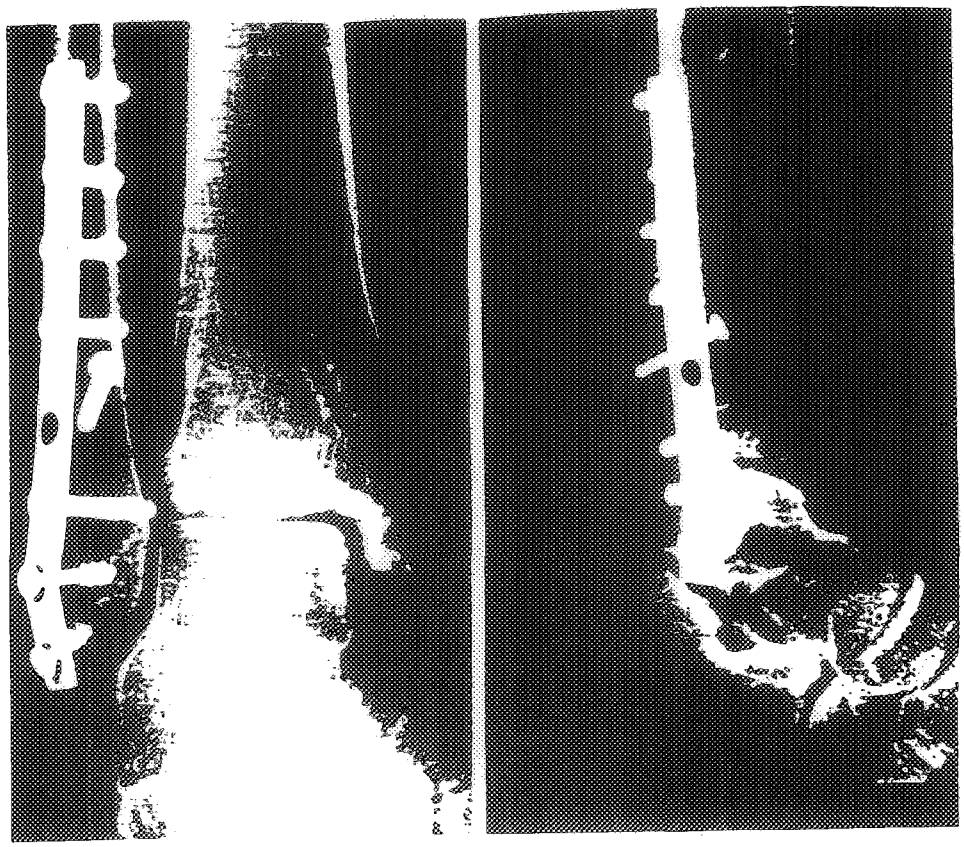

FIG. 1-C FIG. 1-D

At the three-year follow-up evaluation, there was complete healing and remodeling of the medial and lateral malleolar fractures. The outline of the radiolucent polylactide screws in the medial malleolus is defined by a rim of thickened bone. The patient had returned to a normal level of function.

fragmental compression was the goal in all patients.

All patients were managed with either a cast or a brace several days after the operation. The choice of postoperative immobilization was left to the discretion of the surgeon. The patients were instructed to use toe-touch weight-bearing for six weeks, followed by progressive weight-bearing.

The clinical and radiographic follow-up evaluations were at two weeks, six weeks, three months, six months, one year, two years, three years, four years, and five years after the operation. A detailed questionnaire was completed at each follow-up visit, and the ankle score (based on pain, stiffness, swelling, stair-climbing, running, jumping, squatting, and activities of daily living) was calculated according to the classification of Olerud and Molander[9,10]. Fourteen patients (eight in the study group and six in the control group) were lost to follow-up before the fracture united; however, no complications were evident in these patients at the time of the last visit to the clinic. The duration of follow-up for the 155 remaining patients (eighty-three in the study group and seventy-two in the control group) ranged from twenty-one to fifty-nine months (average, thirty-seven months).

Statistical comparison of the study and control groups and of the results was accomplished with use of the t test for all parameters except for tenderness at the most recent evaluation, which was analyzed with use of the chi-square test. The level of significance was ≤ 0.05.

Results

The demographic data and injuries of the study and control groups were similar. The average age of the patients who were managed with polylactide screws was forty years and that of the control-group patients was thirty-nine years. There were thirty-seven men and forty-six women in the study group and thirty-four men and thirty-eight women in the control group. The fracture patterns, as classified by the system of Weber[12], were similar, and the two groups had similar proportions of medial malleolar, bimalleolar, and trimalleolar fractures (eighteen medial malleolar, forty-six bimalleolar, and nineteen trimalleolar fractures in the study group, compared with twelve medial malleolar, thirty-nine bimalleolar, and twenty-one trimalleolar fractures in the control group). The amount of initial displacement of the fractures, as judged on the diagnostic radiographs, was similar in the two groups. The amount of lateral displacement of the talus on the distal part of the tibia ranged from two to forty millimeters (average, five millimeters) in the study group, compared with two to twenty millimeters (average, four millimeters) in the control group.

The number of screws used for fixation of the medial malleolar fragment was similar in the two groups.

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In the study group, twenty-five patients had only one screw; fifty-two patients, two screws; and six patients, three screws. In the control group, ten patients had one screw; fifty-six patients, two screws; and six patients, three screws. Postoperative immobilization was achieved with use of a cast or brace in a similar percentage of patients in each group.

With the numbers available, we could not detect a significant difference between the average operative times for the two groups ($p = 0.85$, t test). One polylactide screw broke during insertion and was left *in situ* without any sequelae. Two patients (one in each group) had minor sensory changes postoperatively, secondary to an intraoperative neural injury. Both patients reported numbness along the distribution of the sural nerve secondary to intraoperative retraction and injury of the nerve. No other notable intraoperative complications occurred in either group.

Fracture-Healing

Union (defined as complete obliteration of the fracture line) of the medial malleolar fragment (Figs. 1-C and 1-D) occurred in all but two patients in the study group. One of the two patients had been operated on through an extensile approach, which resulted in non-union of the medial and lateral malleoli and osteonecrosis of the tibial plafond. Fourteen months after the injury, an arthrodesis of the ankle was performed. The second patient, who had a traumatic quadriparesis from an injury to the cervical spine in addition to the fracture of the ankle, had a non-union of the medial malleolus fourteen months after fixation with a single polylactide screw, necessitating repeat fixation and bone-grafting. The remaining patients in the study group had radiographic union at an average of 3.1 months (range, three to seven months). The patients in the control group had complete healing at an average of 3.5 months (range, three to six months). The operative reduction was maintained with no more than two millimeters of displacement in all patients.

Complications

Complications included postoperative phlebitis in one patient in the study group, post-traumatic osteoarthrosis in four patients (one in the study group and three in the control group), two skin sloughs (one in each group), and nine wound infections. Of the nine wound infections, six (five in the study group and one in the control group) involved the lateral malleolus only and were treated with standard methods, including débridement, open care of the wound, administration of antibiotics, or a combination of these methods. The lateral plate was removed from two patients. None of the infections of the lateral malleolus involved the medial malleolar wound.

There were three isolated infections of the medial wound (one in the study group and two in the control group). In one patient in each group, operative débridement, removal of the implant, and therapy with antibiotics led to eradication of the infection. One patient in the control group who had poorly controlled diabetes had a breakdown of the medial wound, approximately four weeks after the operation. After radical débridement and subsequent use of a free muscle flap, an arthrodesis of the ankle was performed, nine months after the injury. No evidence of residual infection was noted at the latest follow-up visit.

None of the eighty-three patients in the study group had any late spontaneous drainage of hydrolyzed polylactide from the implanted screws.

Functional Results

The functional results in the two groups of patients were comparable. At the latest follow-up visit, an average of 3 to 4 degrees of dorsiflexion and 10 to 12 degrees of plantar flexion of the ankle had been lost on the affected side compared with the contralateral side in both groups. With the numbers available, we could not detect a significant difference between the two groups with respect to the ability to walk ($p = 0.95$), run ($p = 0.14$), jump ($p = 0.27$), or climb stairs ($p = 0.13$). The average ankle score at the one-year follow-up evaluation was 83 points for the patients in the study group, compared with 79 points for the patients in the control group ($p = 0.13$, t test). Most of the patients returned to their preinjury work status.

At the one-year follow-up evaluation, twenty-nine (35 per cent) of the patients in the study group and thirty-seven (51 per cent) of the patients in the control group complained of some tenderness and occasional discomfort over the medial malleolar implant ($p = 0.41$). Only three patients in the study group had symptoms that were severe enough to necessitate removal of the hardware from the medial malleolus, compared with thirteen patients in the control group. In two patients in the study group, the fracture healed in an anatomical position, but the patients complained of pain primarily over the lateral plate. They also noted some tenderness over the prominent polylactide screw-heads medially and agreed to removal and biopsy of the screw-heads at the time of the removal of the lateral plate, nine and twelve months, respectively, after the initial operation. The polylactide screw-heads were found to be partially biodegraded, with no continuity with the buried shank of the screw. Histological examination of the surrounding soft tissue showed a benign fibrous membrane with scattered macrophages and small fragments of polylactide. The third patient who had removal of the polylactide screws was an eighteen-year-old woman who had had two screws inserted into an isolated medial malleolar fracture. Fifteen months after the injury, she noted swelling just distal to the medial malleolus and had mild tenderness on palpation of this area. Operative excision of a cystic mass, which was located both superficial and

deep to the deltoid ligament, was performed. Histological examination of the specimen revealed fragmented polylactide material, fibrous tissue, granulation tissue, and abundant macrophages. The patient had an uneventful recovery with no recurrent symptoms.

Serial radiographs of the ankles in the study group, made at six, twelve, twenty-four, and thirty-six months, showed no increased osteopenia around the polylactide screws compared with that around the metallic screws; rather, the radiographs often demonstrated a sclerotic rim of cortical bone around the outline of the polylactide screws. In most of the patients, the radiographic appearance of the central radiolucent tract of the screw did not change over the follow-up period.

Discussion

Polylactide has been used for many years as a bioabsorbable implant material. The polymer degrades by hydrolytic depolymerization to lactic acid. This metabolite then enters the carbohydrate metabolic cycle and is converted by the body to carbon dioxide and water. The material has been studied extensively in the form of screws in a number of different animal models. These studies suggested that healing proceeds at a predictable rate, with no evident adverse effect of the polylactide[3,14].

Most investigators studying the use of polyesters as fracture implants in experimental animals and in humans have dealt with rods made of polyglycolide. These cylindrical rods, either 3.2 or 4.5 millimeters in diameter, have been used extensively in Scandinavia for the fixation of fractures of the ankle[2-4,8,12]. In addition to cylindrical rods, polyglycolide has been used in the form of screws for the fixation of displaced malleolar fractures[11]. All of these studies of the use of various forms of polyglycolide for the treatment of fractures of the ankle have demonstrated a high rate of union, with no apparent adverse effect of the polyglycolide on fracture-healing. However, a disturbing complication, late drainage, was reported in 5 to 10 per cent of these patients. Although the drainage often occurred several months after the operation and the specimens were sterile on culture, it was believed to be directly related to the hydrolysis of the polyglycolide. This reaction has been described by various authors as being a late inflammatory, non-infectious tissue response to the large volume of polyglycolide[1,2,7,13].

Polylactide screws have been used much less frequently than those made of polyglycolide. In a preliminary report of nineteen patients who had a fracture of the ankle that was treated with absorbable plates and screws made of polylactide, postoperative swelling developed in nine[4]. The clinical presentation of these inflammatory reactions was somewhat different from that seen with use of polyglycolide screws, in that the reactions were more delayed in onset and did not result in the formation of a sinus. No drainage was evident in any of the eighty-three patients in the current study group, and only one patient had an apparent inflammatory reaction.

The current clinical study had a number of serious limitations. Only three biopsy specimens were available for assessment of the degree of biodegradation of the polylactide. These specimens, obtained one year to eighteen months after insertion of the screws, demonstrated little loss of the mass of the screw. Biodegradation is impossible to assess radiographically. The radiodense line that forms around the implant at three to six months after implantation may be a sign that biodegradation is occurring at a very slow rate. The specific implications of this radiographic change, however, are unclear. A second limitation of the study is that the mechanical demands on the polylactide screw for this particular fracture pattern are minimum. The lateral plate in these ankles bears most of the load, thereby protecting the medial screws from stress. Most of the forces on the polylactide screws are tensile, and these forces have been shown to be well tolerated by polylactide. The application of these screws to anatomical sites that require stronger fixation should be done cautiously. The development of clinically useful polylactide plates is in its infancy.

Despite these limitations, several conclusions can be derived from this study. First, polylactide appears to be safe and effective for this specific application involving a limited mass of the material. Second, it is our clinical impression that polylactide screws do not provide the same degree of interfragmental compression as metal screws because of the design of the screws and the operative technique recommended by the manufacturers. Because the entire length of the drill-hole is tapped and a torque screwdriver is used, less interfragmental compression is achieved. This difference in the biomechanics of the implant compared with those of metallic screws did not seem to affect the clinical or radiographic results adversely. Finally, the prominence of the hardware and tenderness appear to be less of a problem with use of polylactide screws than with use of stainless-steel screws for medial malleolar fixation. This benefit of polylactide screws may result in less of a need to remove medial malleolar implants after the fracture has united.

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SURGICAL TREATMENT OF FRACTURE-DISLOCATIONS OF THE ANKLE JOINT WITH BIODEGRADABLE IMPLANTS: A PROSPECTIVE RANDOMIZED STUDY

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In a randomized study 43 patients with fracture-dislocations of the ankle joint were treated by open reduction and fixation with either steel or biodegradable implants. Results in both groups were favorable and the biodegradable material appears to be useful for some fracture-dislocations to obviate the need for a second operation.

FRACTURES OF THE ANKLE JOINT with dislocations larger than 2 mm are usually treated by open reduction and internal fixation in the hope of preventing posttraumatic arthrosis.[1] In 1989, 3480 patients were hospitalized to undergo this operation in the Netherlands alone.[2] Until recently all implants were made of metal alloys such as stainless steel, vitallium, or titanium. Rokkanen et al. were the first to report the use of biodegradable materials for the internal fixation of fracture-dislocations of the ankle joint.[3]

Polyglycolic acid is a suture material known by the brand name Dexon (Cyanamid of Great Britain, Ltd, Gosport, Hampshire, England). The orthopedic implants for internal fixation are produced by pressure-molding polyglycolic reinforcing threads and ground polyglycolic acid to form rods of different dimensions. The most obvious advantage of this material is that it eliminates the necessity for a second operation for removal of the implant. Other possible advantages of biodegradable materials for internal fixation are the elimination of long-term stress shielding and possible allergic reactions. Possible disadvantages are the development of sterile sinuses as a result of local irritation by the implant and the high costs of the material. Therefore a prospective clinical trial of biodegradable implants was undertaken from January 1988 through March 1990 in the trauma departments of three Dutch hospitals.

MATERIALS AND METHODS

Forty-three patients were admitted to the study. Patients aged between 16 and 70 years old with closed noncomminuted fractures of the lateral and or medial malleolus and dislocations of the fracture fragments greater than 2 mm were included in the study. Patients with high Weber C (and Maisonneuve type) fractures[4] and patients with contraindications for anesthesia or surgery were excluded, as were patients with other trauma or handicap that would make standardized aftertreatment impossible. Patients were allotted to two groups at random. The control group underwent surgery according to AO/ASIF standards with the use of metal implants.[4] In the experimental group open reduction and internal fixation were performed using Biofix (Bioscience, Tampere, Finland) rods and sutures (Fig. 1). Under general or regional anesthesia the fracture was reduced through a longitudinal incision and held in an anatomic position with a clamp. A hole 70 mm long and 4.5 mm in diameter was drilled, starting at the extremity of the lateral malleolus, in a proximal direction. A Biofix rod (Fig. 2) was tapped into place using a special introduction device. Care was taken not to let the rod protrude from the bone. Shortening of the rods with an oscillating saw was omitted to prevent sawdust from contaminating the wound. Subsequently a Vicryl suture was threaded through a drillhole in the distal fragment of the fracture and fixed to the periosteum of the distal tibia and to the syndesmosis (Fig. 3). If necessary, the same procedure was performed on the medial side. On this side usually one or two smaller rods were used. After the wound was rinsed with normal saline it was closed, leaving a vacuum drain in place. A padded slab of plaster was applied.

During the operation the surgeon decided whether the internal fixation was stable enough for immediate mobilization. In that case the plaster slab was discarded after 5 days; all other patients were subsequently treated with a plaster cast during a 4-week period. The patients visited the outpatient department 3, 6, and 12 months after their surgery, when roentgenograms were taken. The functional result was evaluated following the criteria of Olerud[5]; also on each occasion the patient and the physician gave a semiquantitative opinion of the functional result using a linear scale; one end of the scale signified a useless painful stiff ankle joint, the other end of the scale signified a normal painfree ankle. Distances from the points designated by patients and physicians to the point that signified a normal ankle were measured and a percentage of normal was calculated.

RESULTS

Forty-three patients were admitted to the study. They underwent internal fixation from January 1988 through

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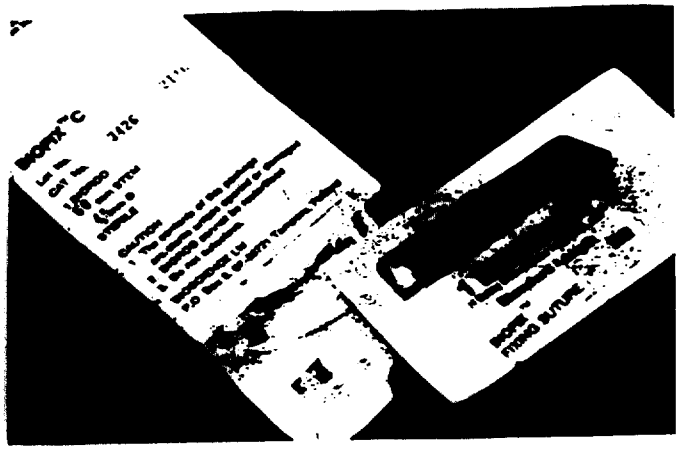

Figure 1. A biodegradable implant rod and sutures.

Figure 2. The dedicated tools required for introducing the biodegradable implant rods.

March 1990. Most patients were young men. There was no difference between the Biofix group and the control group regarding gender, fracture type, or trauma mechanism. The most common type of fracture was a single-fragment fracture of the lateral malleolus. In eight cases a bimalleolar fracture was surgically fixed, and once a trimalleolar fracture was fixed. Two patients included in the trial had complications during surgery; both were in the Biofix group. In one case there was insufficient fixation on the lateral side of the ankle, which made the use of an accessory metal plate necessary. In the other case a second fracture occurred during introduction of the biodegradable rod. A third patient was excluded from the trial after randomization. During the operation, a comminuted fracture was found that was unsuitable for rod fixation. In both groups both methods of postoperative treatment, i.e., functional treatment and plaster immobilization, were used in approximately an equal number of cases. The follow-up period lasted from 3 to 12 months, with an average of 5½ months. There were no postoperative complications. The anatomic results were good in both groups, i.e., no redislocations larger than 1 mm were seen. On average, the patients with biodegradable rods scored 94.5 points on Olerud's scale[5]

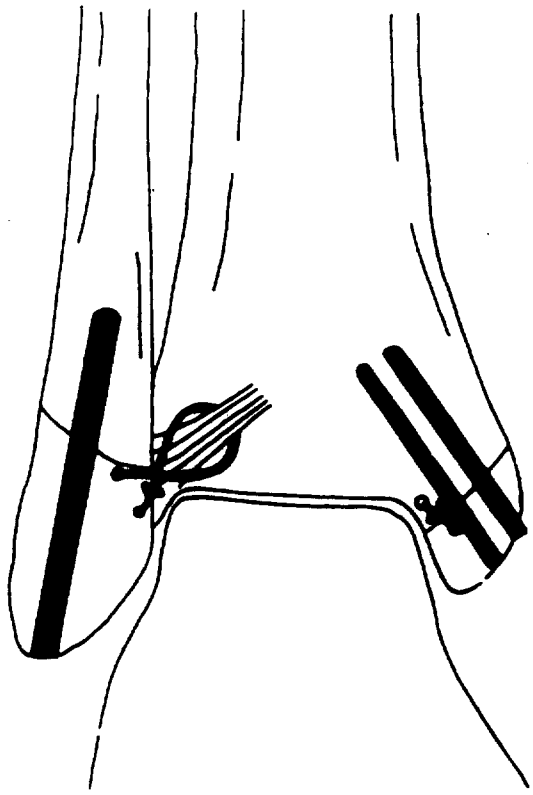

Figure 3. Diagram of the biodegradable implant rods and sutures in place.

Figure 4. Preoperative (A) AP and (B) lateral x-ray films of a fracture-dislocation of the ankle.

Figure 5. Postoperative (A) AP and (B) lateral x-ray films.

versus 90.4 points for the patients with stainless steel implants. On the linear analogue scale Biofix patients scored 89% and AO/ASIF patients 84%.

DISCUSSION

On the postoperative roentgenograms the fracture line was seen more readily in the Biofix group than in the control group, because there was no interfragmentary

compression in the Biofix group (Figs. 4, 5). This phenomenon had no effect on the healing of the fractures involved, which was uneventful in all cases. Aseptic sinuses as described by others[6] were not seen. This may be explained by not sawing off rods when they were in situ. Also, great care was taken to prevent the rod from protruding from the drill hole. The Biofix patients did slightly better both in the scoring system based on Olerud and on the linear scale.

Patients treated with the biodegradable material reported slightly less pain during the follow-up period and were found to have a slightly better function of the ankle joint. It is our opinion that Biofix biodegradable implants can be used for the internal fixation of a limited number of fracture dislocations of the ankle joint (i.e., noncomminuted simple fractures in nonosteoporotic patients).

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5

Biocompatibility Testing Summary
Resorbable Copolymer

Test	Results
(b)(4)	[redacted]

STABILITY TESTING

(b)(4) Test Data

18/82 Lactomer ® Stability Report Summary

(b)(4) Test Data

CONFIDENTIAL

24

(b)(4) Test Data

Appendix 1

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The Bankart Procedure

A Long-Term End-Result Study

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ABSTRACT: Of 161 patients with 162 shoulders operated on during a thirty-year period (1946 to 1976), 124 were re-examined and twenty-one answered a questionnaire. The lesions found at surgery were separation of the capsule from the anterior glenoid rim in 85 per cent, a Hill-Sachs lesion of the humeral head in 77 per cent, and damage to the anterior glenoid rim (including fracture) in 73 per cent. There were five recurrences (3.5 per cent) after repair by the method described in the 145 shoulders that were followed. Only one of the forty-six patients with dislocation on the dominant side and one of the thirty-one with dislocation on the non-dominant side failed to return to the competitive athletic activities in which they had participated prior to injury. The results at follow-up were rated excellent in 74 per cent, good in 23 per cent, and poor in 3 per cent. Ninety-eight per cent of the patients rated their result as excellent or good. Sixty-nine per cent of the shoulders had a full range of motion, and only 2 per cent of these shoulders redislocated. A fracture of the rim of the glenoid did not increase the risk of recurrence, while a moderate to severe Hill-Sachs lesion increased the risk only slightly.

We concluded that with the meticulous technique of the Bankart repair as described, postoperative immobilization is not necessary, early return of motion and function can be expected, and resumption of athletic activities with no limitation of shoulder motion is possible for most patients.

It has been fifty-five years since Bankart presented his concept of the pathological lesion responsible for recurrent anterior dislocation of the shoulder and his method of repair[3,4]. His comments prompted lively controversy, as was evident in an excellent review of shoulder dislocations published in 1948[19].

It is the purpose of this report to document the findings after long-term follow-up of shoulders repaired by one specific technique which had not varied, except for minor changes, since 1946. The procedure to be described closely parallels Bankart's original method. Only patients whose surgery was performed either by the senior author (C. R. R.) or while he was present were included. Therefore, the preoperative evaluation, operative technique, and postoperative care were uniform.

Clinical Material

One hundred and sixty-one patients (138 male and twenty-three female patients) had 162 shoulders operated on between 1946 and 1976. Patients with voluntary dislocations of the shoulder were excluded. Of the 161 patients included, sixteen could not be located for follow-up, although preoperative and operative findings were available; 124 were examined personally at follow-up and their results were graded according to a standard rating scale (Table I); and twenty-one, unable to come in for examination, answered a detailed questionnaire that included nine questions relative to recurrence, stability, the percentage of motion compared with the opposite shoulder, any limitations in sports or work, and current work and sports activities.

Pathological lesions were recorded for 158 of the 162 shoulders. The result was not evaluated in any patient whose surgery was performed less than one year prior to follow-up examination.

Of the 145 patients (146 shoulders), ninety-seven (67 per cent) were followed for one to five years and forty-

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TABLE I

RATING SHEET FOR BANKART REPAIR

Scoring System	Units	Excellent (100-90)	Good (89-75)	Fair (74-51)	Poor (50 or Less)
Stability					
No recurrence, subluxation, or apprehension	50	No recurrences	No recurrences	No recurrences	Recurrence of dislocation or Marked apprehension during elevation or extension
Apprehension when placing arm in certain positions	30	No apprehension when placing arm in complete elevation and external rotation	Mild apprehension when placing arm in elevation and external rotation	Moderate apprehension during elevation and external rotation	
Subluxation (not requiring reduction)	10	No subluxations	No subluxations	No subluxations	
Recurrent dislocation	0				
Motion					
100% of normal external rotation, internal rotation, and elevation	20	100% of normal external rotation; complete elevation and internal rotation	75% of normal external rotation; complete elevation and internal rotation	50% of normal external rotation; 75% of elevation and internal rotation	No external rotation; 50% of elevation (can get hand only to face) and 50% of internal rotation
75% of normal external rotation, and normal elevation and internal rotation	15				
50% of normal external rotation and 75% of normal elevation and internal rotation	5				
50% of normal elevation and internal rotation; no external rotation	0				
Function					
No limitation in work or sports; little or no discomfort	30	Performs all work and sports; no limitation in overhead activities; shoulder strong in lifting, swimming, tennis, throwing; no discomfort	Mild limitation in work and sports; shoulder strong; minimum discomfort	Moderate limitation doing overhead work and heavy lifting; unable to throw, serve hard in tennis, or swim; moderate disabling pain	Marked limitation; unable to perform overhead work and lifting; cannot throw, play tennis, or swim; chronic discomfort
Mild limitation and minimum discomfort	25				
Moderate limitation and discomfort	10				
Marked limitation and pain	0				
Total units possible	100				

eight (33 per cent), for five to thirty years. The average follow-up was six years.

Preoperative Findings

Of the 162 dislocations, 142 (88 per cent) were complete recurrent anterior dislocations and twenty (12 per cent) were transient, in which the shoulder had always reduced spontaneously before roentgenograms could be made. Eight of the shoulders had been operated on previously but the dislocation had recurred. One hundred and forty (86 per cent) of the initial dislocations had been produced by a definite injury (the *traumatic* group) and twenty-two (14 per cent), by a natural movement of the arm (the *atraumatic* group). Gallie and LeMesurier, in their series, reported a 17 per cent incidence of atraumatic initial dislocations[24].

Family History

Information was available relative to a family history of recurrent dislocation for fifty-five of the 161 patients. Of these fifty-five, forty (73 per cent) denied any familial incidence and fifteen (27 per cent) gave a positive family history. This incidence was low compared with that in previous reports[13,31,36]

Hand Dominance

Of the 162 dislocated shoulders in 161 patients, eighty-three were on the right and seventy-nine, on the left side. Nineteen (12 per cent) of the patients had bilateral dislocation (an incidence comparable to the 10 per cent found by Moseley and Övergaard[36]), although only one had both shoulders repaired.

The hand dominance was known for 124 patients, of whom 106 (85 per cent) were right-handed; fifteen (13 per cent), left-handed; and three (2 per cent), ambidextrous.

Surgery was performed on fifty-two (49 per cent) right and fifty-four (51 per cent) left shoulders in the 106 right-handed patients; on eleven (73 per cent) right and four (27 per cent) left shoulders in the fifteen left-handed patients; and on one right and two left shoulders in the three ambidextrous patients. Thus, in the right-handed patients, there was no appreciable difference in the frequency of dislocation on the dominant and non-dominant sides, while in the left-handed patients, there was a sig-

nificantly increased incidence on the non-dominant side. Brav[9] reported an over-all increased incidence of dislocations on the weaker side.

Age at Surgery

Of the 161 patients, eighty-one were less than twenty-one years old and eighty were twenty-one years old or older. The youngest patient was fifteen years old and the oldest, forty-seven.

Causes of Initial Dislocations

Information relative to the specific mechanism of the initial dislocation was available on eighty-six patients. Forceful extension or abduction of the arm was responsible for the first dislocation in twenty-six shoulders (30 per cent); forceful elevation and external rotation, in twenty-one (24 per cent); a direct blow to the shoulder, in twenty-five (29 per cent); and a fall on the outstretched hand, in fourteen (16 per cent).

Our findings do not substantiate Bankart's theories[4] as to the mechanism of this injury, since 30 per cent of the recurrent dislocations in our series were caused initially by a forceful abduction or extension of the arm, a dislocation that Bankart claimed never recurs. Also, only 29 per cent of the recurrent dislocations were caused initially by a direct blow to the shoulder and elbow, an injury that Bankart thought was the sole cause of the recurrent dislocation. In our opinion, both the so-called ordinary (non-recurrent) and the recurrent dislocations of Bankart may produce the same lesion.

Surgical Technique

We employed the following technique in this series (Figs. 1-A, 1-B, and 1-C):

1. General anesthesia with endotracheal intubation is used.

2. The stability of the shoulder is tested after the patient is anesthetized. Two patients referred with a diagnosis of recurrent posterior dislocation were found to have anterior instability.

3. The patient is placed supine with a folded blanket under the arm rather than under the shoulder, so that the humeral head can be displaced posteriorly more easily during the procedure. We do not use the semi-sitting position so frequently described. The anesthetist is on the opposite side of the patient to allow more room at the head of the table.

4. Good exposure, adequate help, and proper instruments (Fig. 2) are essential.

5. A straight incision is made from the coracoid process to the axilla, a shorter incision being used in female patients (Fig. 1-A, *A*).

6. The deltopectoral interval is identified and developed down to the cephalic vein, which in the majority of instances is ligated proximally and distally and removed (Fig. 1-A, *B*). This eliminates oozing from the vein during the procedure. We have not found it necessary to separate the deltoid muscle from the clavicle since 1960.

7. The coracoid process is routinely osteotomized, allowing the coracobrachialis and the short head of the biceps to retract mesially (Fig. 1-A, *C*).

8. The arm, still at the side of the body, is then externally rotated, exposing the subscapularis muscle. The circumflex vessels along the inferior border of the muscle are ligated (Fig. 1-A, *C*).

9. Starting distally, the subscapularis muscle is carefully separated from the capsule *in toto* (Fig. 1-B, *D*). This is a very important step in the operation and can be effectively accomplished by holding the knife blade in the horizontal plane and separating the tendon from the capsule by sharp dissection. To avoid entering the joint, a small amount of tendon is left on the capsule. Once the tendon has been separated from the capsule (the attachment of the tendon usually extends over a distance of 2.5 centimeters in the medial-to-lateral direction), the muscle can be separated from the capsule by blunt dissection, using a wing-type periosteal elevator.

10. The arm is completely externally rotated before a vertical incision is made into the joint just lateral to the rim of the glenoid (Fig. 1-B, *E*). This gives an excellent exposure of the joint and the entire anterior rim and ensures that the lateral flap will be of proper length to permit adequate external rotation of the shoulder postoperatively (Fig. 1-B, *F*).

11. A humeral-head retractor (Fig. 2) is inserted into the joint and is used to displace the humeral head posterolaterally (Fig. 1-B, *H*). If the capsule is separated from the glenoid rim, a three-pronged retractor (Fig. 2) is inserted into the glenoid neck and used to retract the medial part of the capsule (Fig. 1-B, *H*).

12. The rim of the glenoid and the neck of the scapula can now be freshened with a small osteotome or curette. Three holes are made through the rim of the glenoid (at one, three, and five o'clock in the right shoulder and at eleven, nine, and seven o'clock in the left shoulder) using a small glenoid punch to initiate the holes and then a forceps with three-edged cutting points and a special awl to complete them (Fig. 1-B, *G* through *I*).

13. A double No. 0 cotton suture is passed through each hole, using a No. 5, one-half-taper Mayo needle. This tough little needle is perfectly curved for this purpose. Each double suture is passed through the edge of the lateral capsular flap (Fig. 1-C, *J*) and tied so as to hold the lateral flap securely against the freshened rim of the glenoid (Fig. 1-C, *K*). One limb of each of the top and bottom sutures (A and D in Fig. 1-C, *K*) is then cut off and the four remaining limbs of the sutures (A, B, C, and D in Fig. 1-C, *L*) are passed through the medial flap and tied to one another (A to B and C to D in Fig. 1-C, *N*). This procedure reinforces the capsule at the rim of the glenoid and along the neck of the scapula. The arm at this stage can be easily externally rotated 25 to 30 degrees beyond neutral.

14. Closure of the wound is accomplished by returning all tissues to their normal insertions. No staples, wires,

screws, or bone grafts are used. The subscapularis tendon is replaced in its original position on the lesser tuberosity and secured with interrupted sutures composed of double strands of No. 20 cotton or, rarely, one strand of No. 0 cotton in a heavily muscled individual. In this way the muscle is not shortened, overlapped, or transplanted. The coracoid process is reattached by making a single hole in the osteotomized fragment and in the base of the process, using a small scaphoid gouge, and then passing a double strand of No. 0 suture through these holes (Fig. 1-C, *P*); the strands are tied as a single suture, with the fragments held in proper position. A reinforcing suture passed through the attachment of the common tendon on the coracoid process and the coraco-acromial ligament then completes the fixation (Fig. 1-C, *P*). This method of fixation is simple and appears to be adequate, since no separation of the fragments was seen on any of the follow-up roentgenograms.

The average duration of surgery was two and a half hours. No patient in this series required blood replacement during or following operation.

Postoperative Routine

Until the early 1960's, we immobilized the shoulder for three to six weeks in a special shoulder sling, but during the last ten years most patients have used the sling for only two to three days, after which the arm has been completely free. During this time the patient can take showers and dress normally. Pendulum exercises as well as light activities are begun in the hospital. No formal physical therapy is used; instead, the patient is instructed to increase gradually the motion and function of the extremity, and is usually back at office work or school in two weeks. In six weeks, swimming or rowing is begun. By three months the patient should have regained 70 per cent of external rotation and elevation of the shoulder. Tennis, golf,

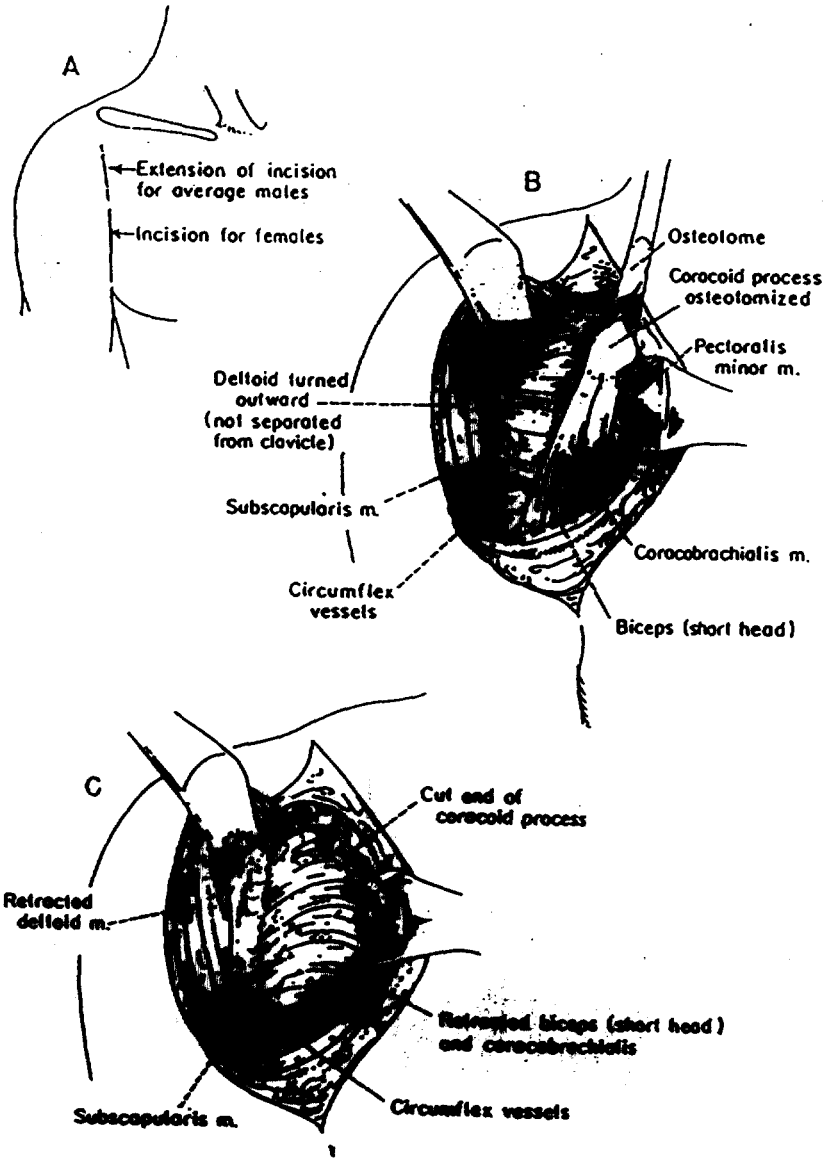


FIG. 1-A

and resistive exercises are then begun. At six months, the patient should have from 75 to 100 per cent of normal motion and strength in the shoulder, and be in condition to resume all activities including contact sports.

Operative Findings

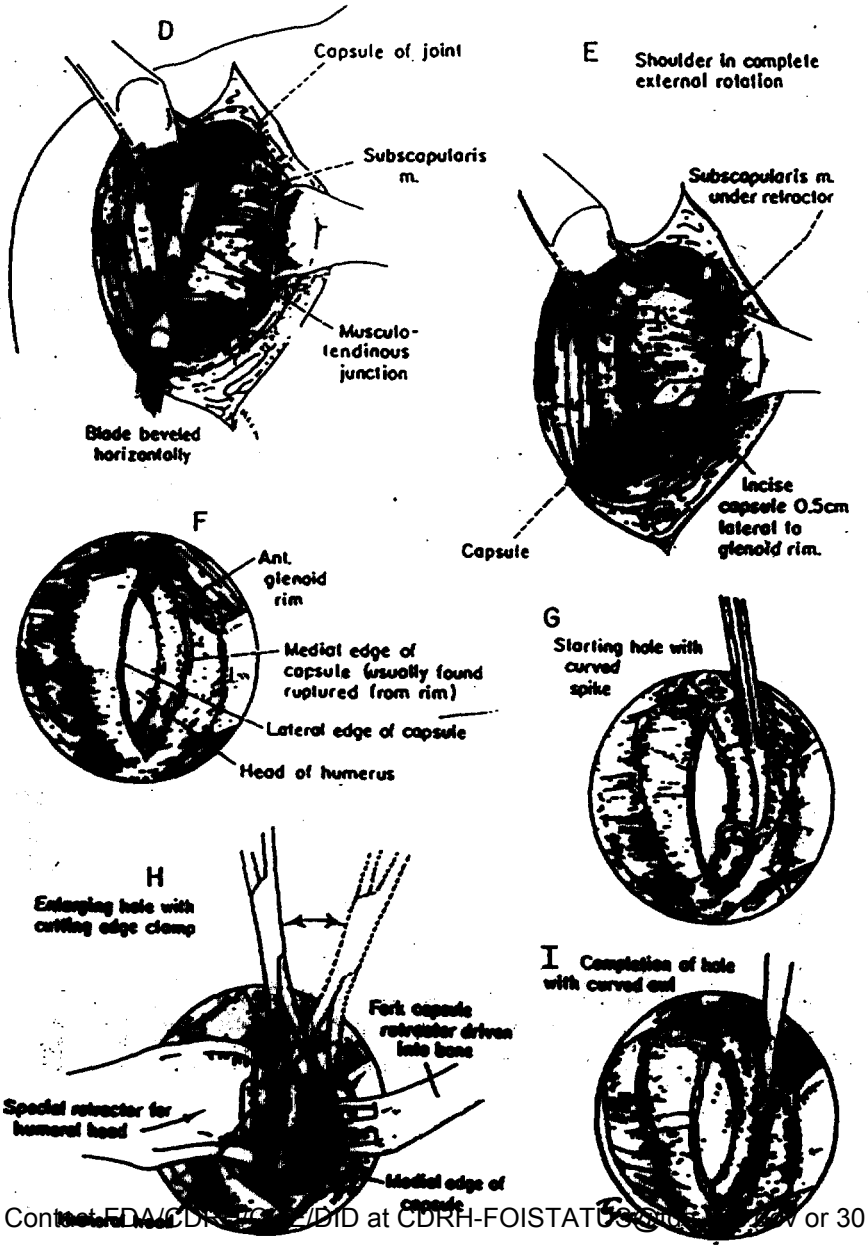
The operative findings were documented adequately in 158 of the 162 shoulders. Since the subscapularis muscle was not severed or divided while exposing the shoulder, but was carefully removed from its insertion and the capsule, the condition of the muscle and capsule could be assessed. The size, shape, and inclination of the glenoid fossa were not recorded except for obvious abnormalities, nor did we determine the degree of retrotorsion of the humeral head, as described by Saha[47] and by Debevoise and associates[14].

Muscles

Of the 161 patients, 130 (81 per cent) had normal muscle development, eighteen (11 per cent) were thin and of slight build, and thirteen (8 per cent) were definitely loose-jointed. In the 158 shoulders at surgery for which data were available, the subscapularis muscle appeared to be normal in 132 (83 per cent), "attenuated" or "inadequate" in fifteen (10 per cent), and definitely ruptured (within the muscle belly) in eleven (7 per cent) (Fig. 3). Of these ruptures, seven were in the lower half and four were in the upper half involving the junction of the subscapularis and supraspinatus muscles.

Capsule

The capsule was completely avulsed or separated



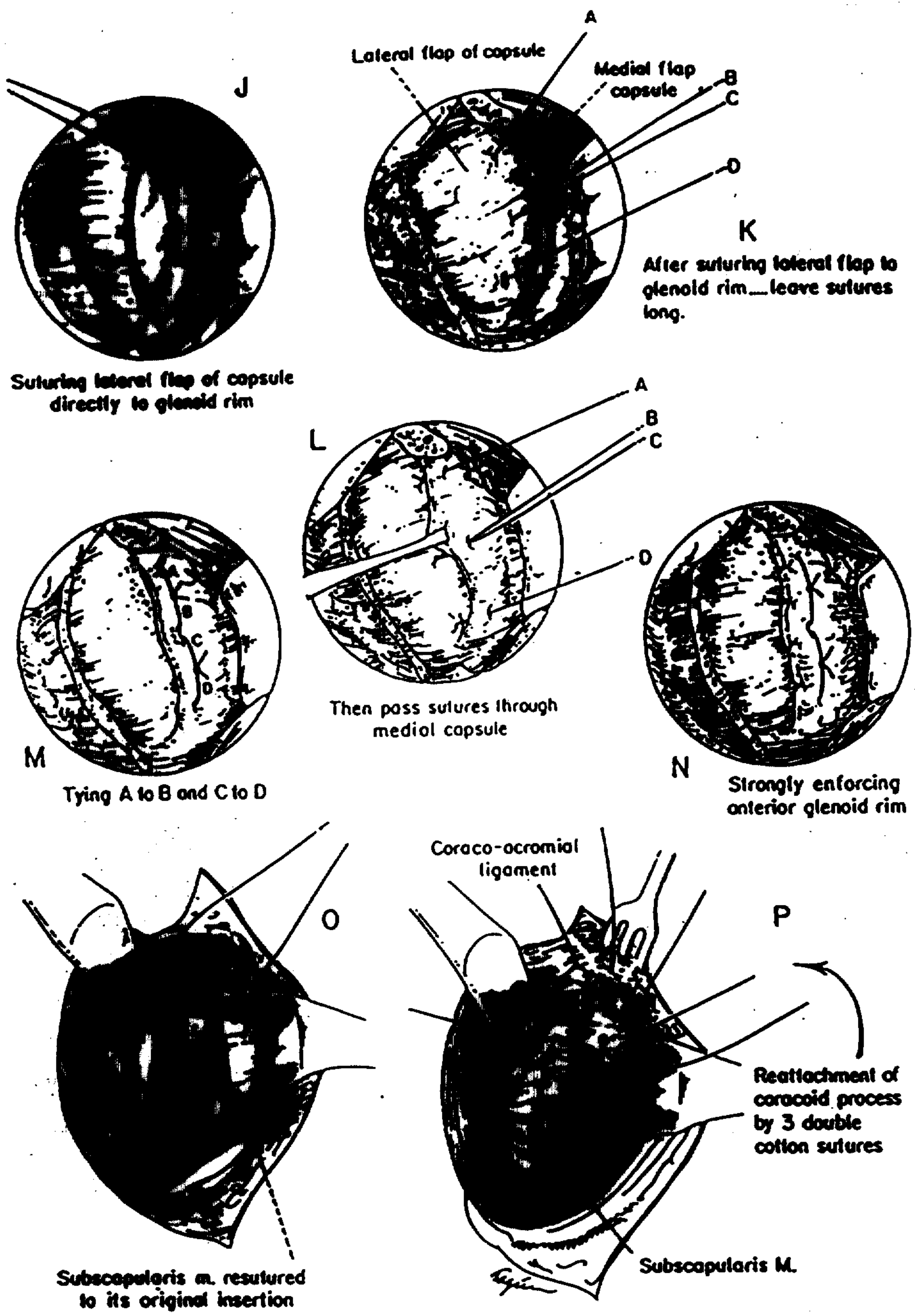


FIG. 1-C

from the anterior glenoid rim in 135 shoulders (Fig. 4), an incidence of 85 per cent, and was normally attached to the rim of the glenoid, with the labrum intact, in twenty-three shoulders (15 per cent). The incidences of an intact capsule ranged from 13 to 28 per cent in other series[1,8,13,17]. Considering all 158 shoulders, twenty-nine had a pouched, stretched, or redundant capsule, which was normally attached to the glenoid rim in thirteen, completely separated in twelve, and ruptured in four.

Labrum

The condition of the labrum at operation was adequately described in 118 shoulders. It was absent or completely destroyed in eighty-six (73 per cent), intact but separated from the rim in fifteen (13 per cent), and well developed but displaced into the joint across the glenoid (resembling a bucket-handle split of a meniscus in the knee) in seventeen (14 per cent) of the 118 shoulders (Fig. 5).

Glenoid Rim

Damage to the glenoid rim was present in 116 (73 per cent) and absent in forty-two of the 158 shoulders. Sixty-five (56 per cent) of the damaged rims were eburnated or eroded, three of them being in the atraumatic group, and fifty-one (44 per cent) were fractured. Of the fifty-one fractures, eighteen (35 per cent) involved one-sixth; twenty-six (51 per cent), one-quarter; and seven (14 per cent), one-third of the area of the joint surface.

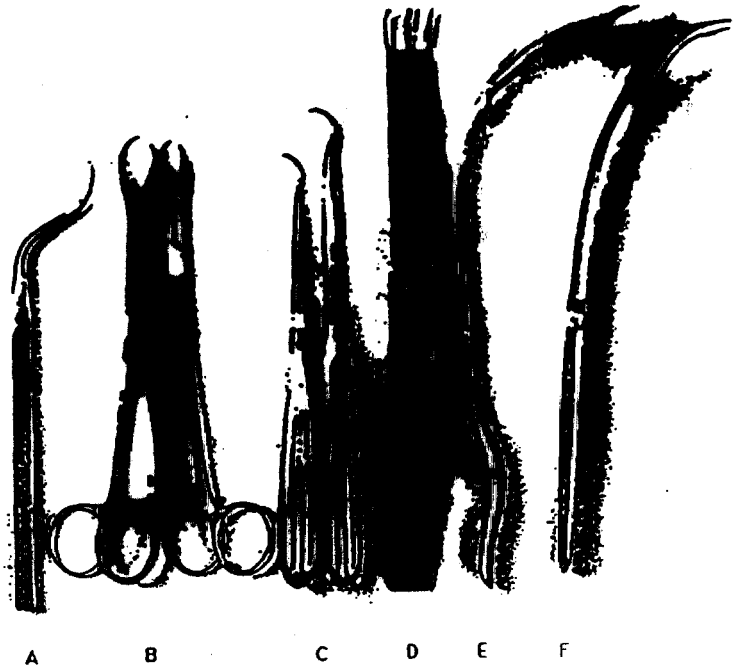


FIG. 2

Instruments used in the Bankart procedure. *A*, curved spike used to initiate holes in the glenoid rim; *B*, clamps with three-edged cutting points to enlarge the hole; *C*, curved awls used to complete the hole; *D*, retractor for the medial capsular flap; and *E* and *F*, two types of humeral-head retractor to fit different-sized heads and glenoid cavities.

Shoulders with No Bankart Lesion

In these twenty-three shoulders, the initial dislocation had been traumatic in nine and atraumatic in fourteen patients. The capsule of the shoulder was "herniated" or "redundant" in thirteen (57 per cent) and normal in ten. The subscapularis muscle was "deficient" in one of the twenty-three shoulders, while the glenoid fossa was described as deficient and shallow in two. A Hill-Sachs lesion of the humeral head, present in seven (30 per cent) of the twenty-three shoulders, was of moderate size in four; severe, in one; and mild, in two. None of these twenty-three shoulders showed separation of the capsule from the rim of the glenoid or evidence of trauma to the rim.

Humeral Head

Of the 162 shoulders, 142 had satisfactory anteroposterior preoperative and postoperative roentgenograms made with the arm in neutral position, in 60 degrees of internal rotation, and in 60 degrees of external rotation. The Hill-Sachs[27] head defect (a compression fracture of the humeral head due to impact against the anterior rim of the glenoid) was present in 110 (77 per cent) and absent in thirty-two (23 per cent). The defect was mild (Fig. 6-A) in thirty (27 per cent), moderately severe in sixty-four (58 per cent), and severe (Fig. 6-B) in sixteen (15 per cent). Of these 110 shoulders, 105 had had initial dislocations that were traumatic.

tiple loose bodies, an incidence of 8 per cent, which was comparable to the 9 per cent reported by Brav[9].

A bone cyst was present in the neck of the scapula

FIG. 3

Rupture (arrow) of the inferior half of the subscapularis muscle and

Other Lesions

FIG. 4

A typical Bankart lesion of the left shoulder with avulsion of the capsule from the anterior rim of the glenoid. The labrum is missing, apparently completely worn away.

FIG. 5

Intra-articular bucket-handle split of the labrum in the left shoulder.

prior to surgery in two patients, both lesions being just proximal to the articular surface. The cysts were not explored at surgery and no histological diagnosis was established. Clinically they appeared to be benign bone cysts. After operation one had disappeared, and the other was filling in at one year.

Muscle anomalies were seen in three shoulders. The pectoralis major was absent in one and the pectoralis minor inserted on the lesser tuberosity of the humerus in another, the second such anomaly seen by one of us (C. R. R.). The coracobrachialis and short head of the biceps muscle arose from the rotator cuff in one patient. In another patient, who had had a previous unsuccessful Bankart procedure, the coracoid process was found to be ununited at the second procedure.

Results

The results in the 145 shoulders evaluated were graded excellent, good, and poor using both the rating scale summarized in Table I and the patient's own evaluation of the shoulder. Based on the examining physician's evaluation, 108 (74 per cent) were graded excellent; thirty-three (23 per cent), good; and four (3 per cent), poor. The patients, however, rated their results as 120 (83 per cent) excellent, twenty-two (15 per cent) good, and three (2 per cent) poor. Thus, by the surgeon's rating there were 97 per cent excellent to good results and by the patients' evaluations, 98 per cent excellent to good results.

FIG. 6-A

Figs. 6-A and 6-B: Typical Hill-Sachs lesion.
Fig. 6-A: A mild lesion of the left shoulder.

FIG. 6-B

A severe lesion, before (left) and after (right) reduction of a dislocation. Note the compression fracture of the superolateral aspect of the humeral head.

Recurrences

There were five recurrences in our series of 145 shoulders, an incidence of 3.5 per cent. The recurrence rates following surgical repair in most series reported since 1948 are summarized in Table II. The recurrences in our series are described in the following case reports.

CASE 1. A twenty-year-old loose-jointed man dislocated the right shoulder initially without appreciable injury. In January in 1959, the capsule was partially separated from the glenoid rim and there was a moderate Hill-Sachs lesion. After the Bankart repair he had three recurrences within a year. He was then put on a program of specific resistive exercises, and during the ensuing ten years he had no recurrences.

CASE 2. An eighteen-year-old man who was loose-jointed had had an atraumatic dislocation of the left shoulder initially. Operation revealed a severe Hill-Sachs lesion and a redundant capsule that was separated from the rim of the glenoid. Two years after surgical repair the patient first noted a "popping-out" of the shoulder on forceful hyperextension of the arm; two nights later, while sleeping face down, the shoul-

der dislocated. This patient also was put on a program of resistive exercises for the shoulder muscles, and the dislocation had not recurred one year later.

These two patients, with very lax ligaments, would *not* be operated on at the present time unless they had failed to respond to a program of resistive exercises. We have found that this type of shoulder instability responds very well to exercises as the primary treatment, and that the results of surgical repair are unpredictable.

In the other three patients, the postoperative recurrences were caused by severe trauma, sufficient to produce a primary dislocation.

CASE 3. A twenty-two-year-old man had had a traumatic dislocation of the left shoulder initially, followed by many recurrences. At surgery, extensive damage to the capsule and glenoid rim was found but there was no Hill-Sachs lesion. Ten years after surgery, this man had one recurrence while roping a steer in a rodeo. However, during the next fifteen years he had no dislocations. He graded his result as excellent even though we had to grade it poor because the dislocation had recurred once following surgery.

CASE 4. A fifteen-year-old boy had had an initial traumatic dislocation of the left shoulder followed by many recurrences. Operation revealed a well developed Bankart lesion, a fracture of the glenoid rim, and a moderate-sized Hill-Sachs lesion. This boy was very belligerent and had two recurrences of the dislocation during violent fights within a few months after surgery. Several years later, he was killed in an automobile accident.

CASE 5. A thirty-four-year-old male epileptic who had had many dislocations of the right shoulder had a severe Hill-Sachs lesion and severe damage to the rim of the glenoid. After repair he sustained several dislocations during seizures within the first twelve months after surgery.

The results at follow-up in our series were correlated with several factors, including previous unsuccessful repair, absence of a Bankart lesion, fracture of the glenoid rim, a Hill-Sachs defect, external rotation of the shoulder, athletic activity, and epilepsy.

Results after Failed Surgery

Eight patients were referred to us because of recurrent dislocations after surgical repair. Three had had a Magnuson repair; two, a Putti-Platt procedure; two, a Bankart repair; and one, a Nicola repair. Seven had had a traumatic dislocation initially and one, an atraumatic dislocation. All had normal musculature; none were loose-jointed. In the three patients who had had a Magnuson repair, at reoperation the capsule was found to have been avulsed from the glenoid rim. One of the three had been a very promising collegiate basketball center, but was unable to play after the Magnuson repair because of recurrent dislocation of the non-dominant shoulder. At reoperation the subscapularis muscle was released from its transplanted position, revealing complete avulsion of the capsule from the rim of the glenoid. After Bankart repair of the type described, this patient again played basketball, and was named to the All-New England College Team during his senior year (Fig. 8). At follow-up, his shoulder had a full range of motion, was strong, and had not dislocated since operation. Of the other two patients who had had an unsuccessful Magnuson procedure prior to their Bankart operation, one had a good result one year later and the other was lost to follow-up.

In the two patients who had had a Putti-Platt repair, the capsule was found to be completely detached from the glenoid rim in one, while in the other it was lax and the subscapularis muscle was "deficient". After routine Bankart repair these two patients had had no recurrences, one and three years after operation.

In the two patients with failed Bankart repairs, the capsule was detached from the rim in one; a DuToit staple had pulled out in the other, exposing a fracture of the glenoid rim that involved approximately one-sixth of the glenoid fossa, and there was also a severe Hill-Sachs lesion of the humeral head. After routine Bankart procedures both patients returned to full activities, one with an excellent and the other with a good result.

The patient with the failed Nicola procedure had severe separation of the capsule from the glenoid rim but had an excellent result at follow-up, ten years after the Bankart repair.

Of these eight patients whose previous surgery had not been successful, three had excellent and four had good results after follow-ups ranging from one to ten years, and one was lost to follow-up. In each instance, reoperation disclosed adequate cause for failure.

Results in Shoulders without a Bankart Lesion

At operation in the twenty-three shoulders in which no Bankart lesion was found, holes were made through the rim at the base where the medial capsule was attached. Sutures were passed through these holes and into the lateral capsular flap and were used to attach the lateral flap securely to the glenoid rim. The medial flap of the capsule was then sutured over this as reinforcement. At follow-up examination after an average of seven years (range, one to twenty-five years), none had had a recurrence; thirteen were graded excellent and eight, good. The other two patients were lost to follow-up.

Results in Shoulders with Fracture of the Glenoid Rim

There were fifty-one shoulders with a fracture of the anterior glenoid rim. Of the eighteen with one-sixth of the glenoid fossa involved, ten were graded excellent, five were good, and three were lost to follow-up. None had recurrences.

Of the twenty-six with one-fourth of the glenoid fossa avulsed, fifteen had an excellent and eight, a good result, while one had a recurrence. The other two were lost to follow-up. Of the other seven shoulders with one-third of the glenoid fossa fractured off, five were graded excellent and two were lost to follow-up.

Of these fifty-one shoulders, forty-four were reexamined one to twenty-five years after repair (an average follow-up of ten years); forty-three (98 per cent) were rated excellent to good (69 per cent excellent and 29 per

cent good) and one had had a recurrence. Therefore, the rate of recurrence in this group was 2 per cent, which, surprisingly, was lower than the over-all recurrence rate of 3.5 per cent.

In these shoulders, no bone grafts or muscle transplants were used to reinforce the glenoid rim, and the fracture fragment was not replaced. Rather, it was either excised or left in the medial flap of the capsule, while the lateral flap was sutured in the usual way to the margin of the intact part of the glenoid fossa. A stable shoulder with an excellent range of motion and strength was obtained in twenty-two and good in eight after follow-up of one to twenty-six years (average, 6.3 years). In the sixty-four shoulders with a moderately severe Hill-Sachs lesion, there were three recurrences (4.7 per cent) and forty excellent, twenty-one good, and three poor results after an average follow-up of 5.3 years (range, one to twenty-three years). In the sixteen shoulders with severe Hill-Sachs lesions, there was one recurrence (6 per cent incidence). There were eleven excellent, four good, and one poor result after an average follow-up of three years (range, one to eight years).

TABLE II

PATHOLOGY, 1948 TO 1976

Series	Bankart Lesion (Per cent)	Abnormalities of Subscapularis (Per cent)	Hill-Sachs Lesion (Per cent)	Trauma to Anterior Glenoid Rim (Per cent)	Incidence of Recurrence (Per cent)
Adams[1] (1948)	87	None	82	"Unusual"	5.5
Bateman[3] (1972)					2.1
Boyd and Hunt[6] (1965)					4.1
Brav[9] (1955)	86		32		7.3
Connolly[11] (1969)			98		10.0
D'Angelo[12] (1970)	100	"Infrequent", occ. atrophy	100	"Extremely frequent"; fract., 31%	1.7
De Anquin[13] (1965)	72	None	100	Erosion, frequent; fract., 2%	0.7
DePalma[14] (1973)	45	"Lax" in 100%	75	Erosion, 46%; fract., 11%	8.7
Dickson and Devas[17,18] (1955 and 1957) (Bankart's own patients)	64				4.0
DuToit[20] (1976)	98		26	24	7.0
DuToit and Roux[21] (1955)	99		33	31	5.0
Eyre-Brook[22] (1948)	76		65		0
Gallie and LeMesurier[24] (1948)					4.0
Helfet[25] (1958)					7.0
Hermodsson[26] (1963)			100		
Lindholm[30] (1974)					4.0
Lombardo and associates[31] (1976)					2.0
May[35] (1970)					0
Morrey and Janes[36] (1976)	53		31		2.0 (1963) 11.0 (1975)
Moseley and Övergaard[38] (1962)	84	"Lax in all cases"	100		1.0
Osmond-Clarke[41] (1965)	90		89		1.4
Palmer and Widén[42] (1948)	45		100	Fract., 20%	7.0
Quigley and Freedman[44] (1973)	27			52	5.1
Rowe and associates (present series) (1976)	85	17	77	Erosion, 73%; fract., 44%	3.5
Saha[48] (1969)			25	2	
Symeonides[49] (1972)	62	"Lax in every case"	53	Fract., 18%	3.0
Vick and Bell[52] (1959)	80			51	2.6
Watson-Jones[53] (1948)	70				2.0

each instance after the lateral flap was sutured securely to the fractured margin of the glenoid and the medial flap was sutured over it as reinforcement.

Results in 110 Shoulders with Hill-Sachs Defects

In the thirty shoulders with a mild Hill-Sachs lesion [illegible]

Thus, there were four recurrences among the eighty shoulders with moderate to severe Hill-Sachs lesions, an incidence of 5 per cent, which would indicate that the presence of a sizable Hill-Sachs lesion is a more important factor causing instability after a Bankart procedure performed by the technique described than is a fracture of the

rate, compared with the over-all recurrence rate of 3.5 per cent, is an acceptable incidence.

Results in Shoulders with Complete External Rotation Restored

Of the 124 patients whose shoulders were evaluated by personal interview and examination, eighty-six (69 per cent) had complete elevation and external rotation compared with the opposite shoulder, and only two (2 per cent) of these eighty-six shoulders had redislocated after surgical repair. Another thirty (24 per cent) of the 124 shoulders had regained 75 per cent of normal external rotation and had had no recurrences. Thus, of the 116 shoulders with return of 75 to 100 per cent of normal external rotation, only two (1.7 per cent) had recurrent dislocation, while two of the other eight that had regained 50 per cent of external rotation or less had had a recurrence, an incidence of .25 per cent. The return of complete external rotation following surgery therefore was not associated with an increased incidence of instability or recurrent dislocation of the shoulder, but rather with a lower incidence.

Return to Athletic Activity

Seventy-seven of our 161 patients had been involved in athletics prior to their shoulder injury, which was on the dominant side in forty-six and on the non-dominant side in thirty-one. Of the forty-six patients whose dominant side was involved, thirty had engaged in throwing sports. Following surgical repair, ten (33 per cent) of the thirty were able to throw or pitch a baseball as hard and a football as far as they had before injury, and they could serve hard in tennis, swim hard with an overhead stroke, or "spike" (forcefully hit the ball downward over the net) while playing volleyball. The other twenty (67 per cent) could throw a football or softball hard and serve hard in tennis, but could not throw a baseball as hard as formerly. Some of these forty-six patients had become superior athletes after shoulder repair, including two college pitchers, two college catchers, one triple-letter man in college, one professional basketball player, one collegiate tennis champion, seven football players, and one backstroke swimming champion at the U.S. Naval Academy. One patient became a Marine and was in combat in Korea (Figs. 7-A, 7-B, and 7-C). Only one of the forty-six patients in whom the dominant shoulder was repaired failed to return to his original sports activities.

Of the thirty-one patients in whom the non-dominant shoulder was repaired, only one was not able to return to the sports activities in which he had participated before his injury. The other thirty had no limitations and in many instances were superior athletes, including ten college football players, eight three-letter men, five competitive swimmers, one hammer-thrower who placed third in the Olympic tryouts in the East, an All-New England basketball center (Fig. 8), a member of the U.S. Olympic Ski Team, a college hockey goal-tender, and two college weight-lifters.

These results compare favorably with those reported by other investigators. Of Lombardo and associates' twenty-seven patients with the dominant shoulder involved, none returned to their original level of performance after a modified Bristow procedure[31]. All of the patients of Gallie and LeMesurier[24] and 88 per cent of those of Palmer and Widén[41] returned to their normal activities, while in the series of Morrey and Janes[36] 5 per cent gave up sports and 22 per cent were forced to limit their athletic activities.

Results in Epileptics

There were four patients in our series whose initial dislocation and subsequent recurrences were caused by epileptic seizures. All had anterior dislocations (epileptics usually have posterior dislocations). Three had severe and one, a moderately severe Hill-Sachs lesion. All four had

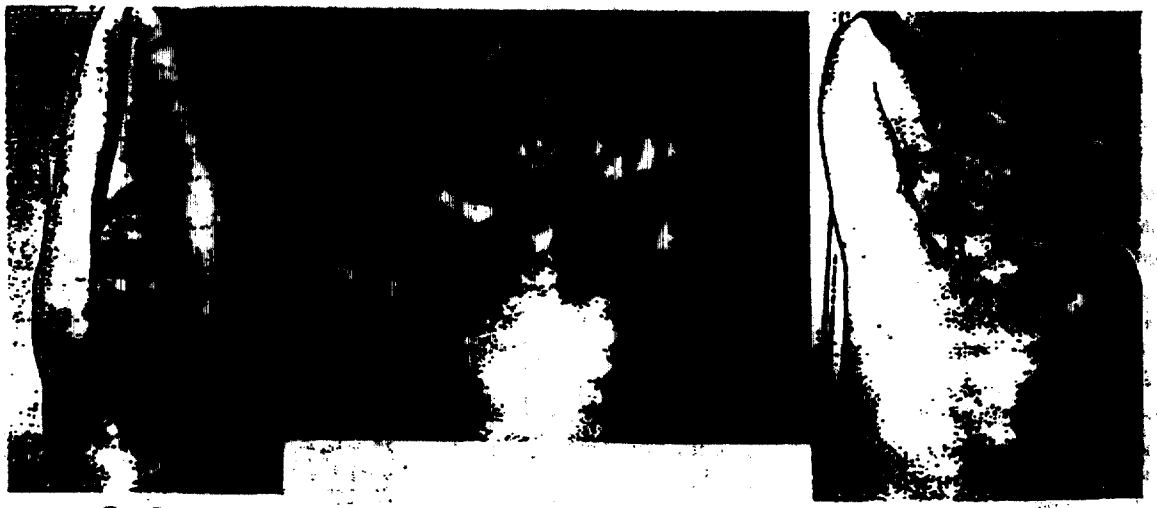


FIG. 7-A FIG. 7-B FIG. 7-C

Figs. 7-A, 7-B, and 7-C: Fifteen years following Bankart repair of the right (dominant) shoulder. Six months after surgery this patient joined the U.S. Marines and fought in combat in Korea. At present he is a competitive swimmer and tennis player and has full strength and motion. There have been no recurrences.

complete separation of the capsule from the glenoid rim, and one had a severe fracture of the anterior glenoid rim. After repair, two patients had had no recurrences and had good shoulder function at two and five years, despite continuing seizures; one (Case 5) had had recurrences; and one was lost to follow-up.

Late Roentgenographic Changes of the Glenohumeral Joint

In the 124 patients seen personally at follow-up, there was no evidence of late degenerative changes in the glenohumeral joint or of myositis ossificans. We believe

FIG. 8

One year after a Bankart procedure on the left (for a failed Magnuson procedure), this patient was elected All-New England center in college basketball.

that in the Bankart procedure used in this study, the soft tissues are not traumatized and stability does not depend on scar tissue. Surgical trauma is lessened because the holes in the glenoid rim are small in diameter and because the instruments are specially designed and smaller than those ordinarily used (Fig. 2). After Eden-Hybbinette repairs, Lindholm found that 8 per cent of the shoulders showed osteoarthritic changes of the glenohumeral joint and 4 per cent had myositis ossificans, but he did not indicate how long the patients were followed [30].

Complications

In one patient, a forty-seven-year-old carpenter who was operated on in 1953, two sinuses developed ten months after surgery. After removal of silk sutures the sinuses promptly closed up, and there had been no sign of deep sepsis or other sinuses during the ensuing twelve years while he continued full-time work as a carpenter. After this case we began to use cotton sutures routinely, and have seen no further reaction to suture material. One patient had a postoperative hematoma that necessitated evacuation and closure. His wound then healed uneventfully. This patient was found to have a qualitative platelet defect due to aspirin that he had taken preoperatively. Four other patients had mild postoperative hematomas which absorbed. One patient had thrombophlebitis of the cephalic vein which cleared up with warm compresses. Another had a weak deltoid muscle postoperatively, which gradually improved. Electromyograms confirmed that his axillary nerve was intact. There were no non-unions of the osteotomized coracoid process after repair by the method described.

Discussion

There was no evidence in this series that there is a single essential lesion responsible for recurrent dislocations of the shoulder. However, the commonest findings at surgery were separation of the capsule from the anterior glenoid rim (85 per cent), different degrees of the Hill-Sachs lesion of the humeral head (77 per cent), and damage to the anterior glenoid rim (73 per cent). In twenty-three (14.2 per cent) of the shoulders there was no evidence of the so-called Bankart lesion. In these patients, the capsule was redundant in nine, the subscapularis muscle was deficient in one, the glenoid fossa was deficient in two, and a Hill-Sachs lesion of the humeral head was present in seven. No findings other than absence of the Bankart lesion were noted in the remaining four shoulders.

The pathological lesions observed at operation for recurrent dislocation of the shoulder in twenty-eight series are summarized in Table II. The high incidence of pathological changes in the subscapularis muscle described by other authors [15,16,48] was not observed in this series. The towel-clip test for laxity of the subscapularis muscle employed by these investigators did not seem to be an accurate way to determine the functional state of the subscapularis muscle. In our series, obvious thinning and attenuation of the subscapularis was present in 10 per cent and direct rupture, in 7 per cent of the shoulders. Since in our patients this muscle was normal in most shoulders and at the close of the procedure it was returned to its original insertion without advancement or shortening, we doubt that abnormality of the subscapularis is an essential lesion. Adams [1] also found no abnormalities of the subscapularis, and noted that the capsule was stripped from the front of the glenoid neck but was otherwise normal. De Anquin [13], in his review of 150 operations for recurrent dislocations of the shoulder, also did not find sufficient lesions of the subscapularis muscle to account for the shoulder instability.

The labrum appears to be a variable structure. Town-

ley [49], Moseley and Övergaard [37,38], and DePalma [15,16] concluded that it is an extension of the capsular ligament along the rim of the glenoid. In our series, it was totally absent or destroyed in 73 per cent of the shoulders, well formed in 13 per cent, and displaced into the joint (resembling a bucket-handle tear of a meniscus in the knee) in 14 per cent (Fig. 5). Palmer and Widén [41] found a 3 per cent incidence of bucket-handle tears of the labrum in their series, and DuToit and Roux [21], an 11 per cent incidence. Watson-Jones [52], Bateman [5], and Brav [9] mentioned bucket-handle tears of the labrum, but did not give their incidence. We agree with D'Angelo [12] that the labrum *per se* plays a minor role in stability of the shoulder.

Separation of the capsule from the rim of the glenoid was the most significant and frequently found lesion in our series (85 per cent) (Fig. 4). However, Magnuson [33] concluded that the capsule of the shoulder has nothing whatever to do with holding the head of the humerus in the glenoid, and others [16,48] agreed with him. Conversely, the first line of defense against recurrent anterior dislocation was considered to be strong reinforcement of the capsule along the anterior rim of the glenoid by many other authors, whether by a bone block [13,22,28,41], fascial reinforcement [5,24], metal implants [37,38], bone-pedicle transplants [25,35], muscle and capsule reinforcement [1,2,9,39,40], or direct suture of the capsule to the rim of the glenoid or neck of the scapula [1-4,8,10,17,18,20,21,23,42,44-46,52].

The question is often asked, "Does shortening of the capsule account for the effectiveness of the Bankart procedure, rather than its reattachment to the glenoid rim?" Shortening undoubtedly is a factor, especially in patients in whom no Bankart lesion is found at surgery. In our series, we did not deliberately attempt to shorten the capsule or restrict external rotation of the shoulder. However, whenever the capsule is opened and repaired it must be shortened to some extent. To avoid restricting external rotation, as previously noted, the shoulder should be externally rotated completely before the vertical incision is made in the capsule just lateral to the glenoid rim (less than 0.5 centimeter). By doing this, the shoulder with the arm at the side could be rotated 25 to 30 degrees with ease at the end of the operative procedure in this series.

Although fractures of the anterior rim of the glenoid were noted by several investigators, their role in recurrent dislocation has not been established. D'Angelo [12] found a 31 per cent incidence of fractures of the anterior glenoid rim in his series, while the incidence found by Palmer and Widén [41] was 20 per cent; by Symeonides [48], 18 per cent; and by DePalma [15,16], 11 per cent. DePalma stated that unless the fractured glenoid fossa was built up by a bone graft, it "may be virtually impossible to restore muscle balance" [16], but this statement was not substantiated in our fifty-one patients who had fractures of the glenoid rim involving from one-sixth to one-third of the glenoid fossa. After direct suture of the capsule to the remaining glenoid rim with no bone grafts or transplants, only 2 per cent of these dislocations recurred, an incidence 1.5 per cent lower than in the whole series (3.5 per cent). Eighty-four per cent of these fifty-one patients also had a Hill-Sachs lesion of the humeral head. The effectiveness of the Bankart repair in patients with a fracture of the glenoid rim, which was a surprise to us, emphasizes the importance of reconstructing a stable capsular barrier to the humeral head along the anterior rim of the glenoid.

Opinions as to the effect of the Hill-Sachs lesion on the stability of the shoulder after Bankart repair vary. Palmer and Widén [41] stated that the Hill-Sachs defect was the essential lesion of recurrent anterior dislocation, and that when it is present, dislocation may recur even after the capsule and labrum have been repaired unless external rotation is restricted, preventing the defect from coming in contact with the glenoid rim. They recommended placing a bone graft at the glenoid rim (Hybbinette-Eden technique) to prevent the head defect from slipping over the rim. Connolly transplanted the tendon of the infraspinatus muscle into the head defect, using the procedure described by McLaughlin for recurrent posterior dislocations [11]. In our series, the size of the head defect did influence the incidence of recurrence since the recurrence rate was 4.7 per cent in the presence of a moderately severe defect and 6 per cent in the presence of a severe defect. These rates compare favorably with the recurrence rate of 7 per cent in Palmer and Widén's series [41] and the 10 per cent rate in Connolly's series [11].

Although it has been stated that return of complete external rotation of the shoulder following surgical repair is associated with an increased incidence of recurrence [6,16,41], only two (2 per cent) of our eighty-six patients with complete external rotation and a complete range of motion had recurrences, and none of the thirty patients with 75 per cent of normal external rotation had a recurrence. Conversely, in our eight patients whose external rotation was limited to less than 50 per cent of normal, two had recurrences, an incidence of 25 per cent. Therefore, in our series the return of maximum external rotation was associated with an increase rather than a decrease in stability. We found in this follow-up study that any restriction of external rotation can be a handicap in athletes who need complete elevation and external rotation in such above-the-shoulder activities as serving in tennis, pitching a baseball, throwing a football, making a lay-up in basketball, swimming, and gymnastics. Some types of work, such as plastering, painting, and paper-hanging, also require full shoulder motion.

A frequent question is, "What does one do when *no* Bankart lesion is found at surgery?" In the small group of twenty-three such patients in our series, the most consistent operative findings were a "herniated" or "redundant" capsule in 5 per cent and a Hill-Sachs lesion of the humeral head in 30 per cent. There were evidently other factors that we did not identify, such as neuromuscular imbalance (as emphasized by DePalma [15,16] and Symeonides [48]), and retrotorsion of the humerus (as described by Saha [47]). The most reasonable procedure to

carry out in this group, it seemed to us, was to reinforce the capsule along the anterior rim of the glenoid as already described. This evidently was effective, since after an average follow-up of eight years eighteen patients had had no recurrence. One had had recurrences and four were lost to follow-up.

Also asked is the question, "What have been the findings in shoulders in which no Hill-Sachs lesion was present, and how should they be treated?" In our series there were twenty-nine shoulders in which no Hill-Sachs lesion was found. Of these shoulders, twenty-three (72 per cent) did and nine (28 per cent) did not have a typical Bankart lesion. Therefore, a Bankart lesion was found more frequently in shoulders with no Hill-Sachs lesion (72 per cent) than a Hill-Sachs lesion was found in shoulders with no Bankart lesion (30 per cent). The recurrence rate in shoulders with no Hill-Sachs lesion was 4 per cent, almost as high as the rate in those with a Hill-Sachs lesion (5.4 per cent) and much higher than the rate in shoulders with no Bankart lesion (zero per cent).

Morrey and Janes [36] cautioned against a short-term follow-up study, pointing out that such a report from the Mayo Clinic in 1949 gave a recurrence rate of only 1.4 per cent, whereas a subsequent report from the same clinic, with long-term follow-up, showed a recurrence rate of 11 per cent. We agree that a short-term follow-up report can be misleading; however, in our series, which included forty-eight patients followed for five to thirty years, there were five recurrences: three within one year of surgery, one after two years, and one after ten years. Of the eight patients referred to us because of recurrence after repair, the recurrence had been sustained during the first postoperative year in three, within two years of surgery in three, and after five years in one (leaving one patient for whom no information was available). Therefore, of these eleven postoperative recurrences, nine (82 per cent) occurred within two years of surgery.

Morrey and Janes [36] suggested that a short period of postoperative immobilization may be a factor contributing to an increased recurrence rate. This, we think, would depend on the type of surgical repair employed. Procedures such as muscle and tendon transplants (Bristow and Magnuson operations) or bone-block operations (Hybbinette-Eden and De Anquin repairs) would require a period of immobilization long enough to ensure healing of the transplanted tendon or bone. With the technique used in our series, no postoperative immobilization was used in the second half of the series (eighty patients with an average follow-up of three years) and three to six weeks of immobilization was used in the first half (sixty-five patients with an average follow-up of 9.5 years). Of the five recurrences, two were in the former group and three, in the latter group.

Consequently, postoperative immobilization did not seem to be a significant factor.

Is the incidence of recurrence following surgical repair higher in patients with a family history of shoulder dislocations? Morrey and Janes [36] reported that 30 per cent of the postoperative recurrences in their series were in such patients. Information concerning family history was available in only one of our five patients with recurrence. In that instance, no one in the family had had a shoulder dislocation.

In our five patients whose shoulder dislocations recurred, there were several significant factors that appeared to contribute to the recurrence. Two of the five were loose-jointed and their initial dislocation and subsequent recurrences had been atraumatic or produced by minimum trauma. The experience of DuToit and Roux [20] was similar to ours, three of their seven recurrences being in patients with excessive ligament laxity. Our present approach to this type of shoulder instability is to start the patient on a schedule of specific resistive exercises to the shoulder. In the majority of our patients the shoulder instability was eliminated after muscle strength improved, and surgery was not needed.

The other three patients whose dislocations recurred had major trauma to the shoulder after repair, similar to that which produced the initial dislocation (roping a steer at a rodeo, an epileptic fit, and a violent fight). One of these patients had a single recurrence and after resistive exercises for the shoulder muscles he had no more recurrences during the ensuing fifteen years.

The lessons learned from this study, we believe, are that if the meticulous technique described is used, degenerative changes in the joint can be avoided, as well as myositis ossificans. In addition, the patient can regain a full range of shoulder motion and return to full participation in sports: (1) if the capsule is incised vertically just lateral to the glenoid rim while the shoulder is held in full external rotation, thereby ensuring that the repaired anterior capsule is not too tight; and (2) if the shoulder is not immobilized postoperatively, so that early resumption of motion and function is possible.

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LEGENDS

Figure 1. Photograph of the screws used in this study. A) 5.0 mm LactoSorb™ cancellous screw. B) 5.0 mm stainless steel cancellous screw. C) 3.5 mm LactoSorb™ cortical screw. D) 3.5 mm stainless steel cortical screw. E) 4.0 mm LactoSorb™ cancellous screw. F) 4.0 mm stainless steel cancellous screw.

Figure 2. Schematic diagrams showing placement of the diaphyseal and metaphyseal trephine osteotomies and lateral femoral condyle osteotomy.

Figure 3. Locations for the indentation testing, including four points on the bone plug surface and seven points on the surrounding metaphyseal bone surface.

Figure 4. The left lateral femoral condyle osteotomy was healed in two months.

Figure 5. A) Two months after the surgery, polymer screw material was seen in the screw track in this cortical trephine osteotomy, with callus around the screw head. B) By seventeen months, the screw track was filled with bone tissue and no evidence of any polymer material remained.

Figure 6. At two months in both the trephine metaphyseal and lateral Condyle osteotomy, polymer screw material was clearly seen in the screw tracks (A and D). For the nine month time period, polymer Screw material was still seen in the screw tracks but the amount was much less than that at two months (B and E). At fifteen or seventeen months, the screw tracks were still present but no evidence of any polymer material remained. The tracks had filled with fibrous and adipose connective tissue (C and F).

(b)(4) Test Data

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