



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Date: MAR 21 1997

From: Director, Office of Device Evaluation (HFZ-400)
Center for Devices and Radiological Health (CDRH)

Subject: Premarket Approval of Sulzer Orthopedics®, Inc.
Natural Knee® and Natural-Knee® II with CSTi™

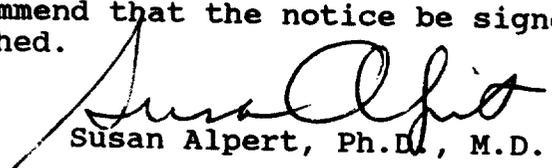
To: The Director, CDRH
ORA _____

ISSUE. Publication of a notice announcing approval of the subject PMA's.

FACTS. Tab A contains a FEDERAL REGISTER notice announcing:

- (1) premarket approval orders for the above referenced medical devices (Tab B); and
- (2) the availability of summaries of safety and effectiveness data for the devices (Tab C).

RECOMMENDATION. I recommend that the notice be signed and published.


Susan Alpert, Ph.D., M.D.

Attachments
Tab A - Notice
Tab B - Order
Tab C - S & E Summary

DECISION

Approved _____ Disapproved _____ Date _____

Prepared by Erin Keith, CDRH, HFZ-410, March 13, 1997, 594-2036

TABA

2

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

[DOCKET NO. _____]

Sulzer Orthopedics, Inc.; PREMARKET APPROVAL OF the Natural Knee® and Natural Knee® II with Cancellous Structured Titanium (CSTi™)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application submitted by Sulzer Orthopedics, Inc., Austin, TX, for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of the Natural Knee® and Natural Knee® II with Cancellous Structured Titanium (CSTi™).

After reviewing the recommendation of the Orthopedic and Rehabilitation Devices Panel, FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of March 21, 1997, of the approval of the application.

DATES: Petitions for administrative review by (insert date 30 days after date of publication in the FEDERAL REGISTER).

ADDRESSES: Written requests for copies of the summary of safety and effectiveness data and petitions for administrative review, to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857.

3

FOR FURTHER INFORMATION CONTACT:

Ms. Erin Keith,
Center for Devices and Radiological Health (HFZ-410),
Food and Drug Administration,
9200 Corporate Blvd.,
Rockville, MD 20850,
301-594-2036.

SUPPLEMENTARY INFORMATION: On April 27, 1995, Sulzer Orthopedics, Inc., Austin, TX 78717, submitted to CDRH an application for premarket approval of the Natural Knee[®] and Natural Knee[®] II with CSTi[™]. These devices are biologically fixed total knee prostheses and are indicated for uncemented use in skeletally mature individuals with intact medial and lateral collateral ligaments undergoing primary surgery for rehabilitating knees damaged as a result of Noninflammatory Degenerative Joint Disease or Inflammatory Joint Disease.

On June 12, 1995, the Orthopedics and Rehabilitation Devices Panel of the Medical Devices Advisory Committee, an FDA advisory committee, reviewed and recommended approval of the application.

On March 21, 1997, CDRH approved the application by a letter to the applicant from the Director of the Office of Device Evaluation, CDRH.

A summary of the safety and effectiveness data on which CDRH based its approval is on file in the Dockets Management Branch (address above) and is available from that office upon written request.

4

Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

Opportunity For Administrative Review

Section 515(d)(3) of the act, (21 U.S.C. 360e(d)(3)) authorizes any interested person to petition, under section 515(g) of the act, for administrative review of CDRH's decision to approve this application. A petitioner may request either a formal hearing under part 12 (21 CFR part 12) of FDA's administrative practices and procedures regulations or a review of the application and CDRH's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration under 21 CFR 10.33(b). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and information showing that there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish a notice of its decision in the FEDERAL REGISTER. If FDA grants the petition, the notice will state the issue to be reviewed, the form of the review to be used, the persons who may participate in the review, the time and place where the review will occur, and other details.

Petitioners may, at any time on or before (insert date 30 days after date of publication in the FEDERAL REGISTER), file with the Dockets Management Branch (address above) two copies of

U
B
TAP



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Jacquelyn Hughes
Manager, Regulatory Affairs
Sulzer Orthopedics®, Inc.
9900 Spectrum Drive
Austin, Texas 78717

MAR 21 1997

Re: P940002
Natural-Knee® and Natural-Knee® II with CSTi™
Filed: April 27, 1995
Amended: May 16 and 25, July 27 and December 11, 1995;
January 22, March 25 and 29, April 19, May 17 and 23,
June 14, August 23, September 12, 16, 18 and 20, and
November 13 and 29, 1996; January 30, February 6 and 7,
and March 6, 1997

Dear Ms. Hughes:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your premarket approval application (PMA) for the Natural-Knee® and Natural Knee® II with CSTi™. These devices are indicated for uncemented use in skeletally mature individuals with intact medial and lateral collateral ligaments undergoing primary surgery for rehabilitating knees damaged as a result of Noninflammatory Degenerative Joint Disease (NIDJD) or Inflammatory Joint Disease (IJD). We are pleased to inform you that the PMA is approved subject to the conditions described below and in the "Conditions of Approval" (enclosed), and the condition that the postmarket study proposed on page 61 of Exhibit 5 of your March 25, 1996 amendment be completed. You may begin commercial distribution of the device upon receipt of this letter.

The sale, distribution, and use of this device are restricted to prescription use in accordance with 21 CFR 801.109 within the meaning of section 520(e) of the Federal Food, Drug, and Cosmetic Act (the act) under the authority of section 515(d)(1)(B)(ii) of the act. FDA has also determined that to

8

ensure the safe and effective use of the device that the device is further restricted within the meaning of section 520(e) under the authority of section 515(d)(1)(B)(ii) insofar as the sale, distribution, and use must not violate sections 502(q) and (r) of the act.

In addition to the postapproval requirements in the enclosure, the postapproval reports must include the results of a postapproval study to be performed as outlined in the Amendment of March 25, 1996. The specific purpose of the postapproval study is to evaluate the nine-year survivorship of the device. A complete description of the postapproval study protocol must be submitted in the form of a PMA Supplement and approved before the study begins. A summary of the survivorship data and patient accounting should be provided in annual progress reports until the study is completed. The results of the long term data must be reflected in the labeling (via a Supplement) when the postapproval study is completed.

CDRH will publish a notice of its decision to approve your PMA in the FEDERAL REGISTER. The notice will state that a summary of the safety and effectiveness data upon which the approval is based is available to the public upon request. Within 30 days of publication of the notice of approval in the FEDERAL REGISTER, any interested person may seek review of this decision by requesting an opportunity for administrative review, either through a hearing or review by an independent advisory committee, under section 515(g) of the Federal Food, Drug, and Cosmetic Act (the act).

Failure to comply with the conditions of approval invalidates this approval order. Commercial distribution of a device that is not in compliance with these conditions is a violation of the act.

You are reminded that, as soon as possible and before commercial distribution of your device, you must submit an amendment to this PMA submission with copies of all approved labeling in final printed form.

9

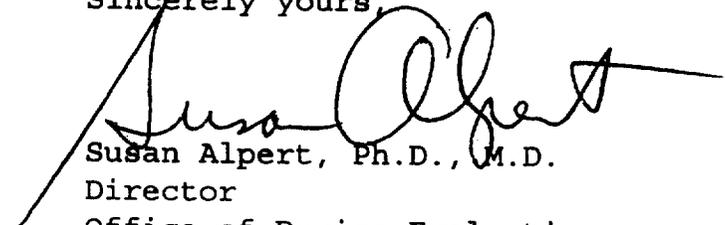
Page 3 - Ms. Jacqueline Hughes

All required documents should be submitted in triplicate, unless otherwise specified, to the address below and should reference the above PMA number to facilitate processing.

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

If you have any questions concerning this approval order, please contact Ms. Erin Keith at (301) 594-2036.

Sincerely yours,



Susan Alpert, Ph.D., M.D.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

10

CONDITIONS OF APPROVAL

APPROVED LABELING. As soon as possible, and before commercial distribution of your device, submit three copies of an amendment to this PMA submission with copies of all approved labeling in final printed form to the PMA Document Mail Center (HFZ-401), Center for Devices and Radiological Health, Food and Drug Administration (FDA), 9200 Corporate Blvd., Rockville, Maryland 20850.

ADVERTISEMENT. No advertisement or other descriptive printed material issued by the applicant or private label distributor with respect to this device shall recommend or imply that the device may be used for any use that is not included in the FDA approved labeling for the device. If the FDA approval order has restricted the sale, distribution and use of the device to prescription use in accordance with 21 CFR 801.109 and specified that this restriction is being imposed in accordance with the provisions of section 520(e) of the act under the authority of section 515(d)(1)(B)(ii) of the act, all advertisements and other descriptive printed material issued by the applicant or distributor with respect to the device shall include a brief statement of the intended uses of the device and relevant warnings, precautions, side effects and contraindications.

PREMARKET APPROVAL APPLICATION (PMA) SUPPLEMENT. Before making any change affecting the safety or effectiveness of the device, submit a PMA supplement for review and approval by FDA unless the change is of a type for which a "Special PMA Supplement-Changes Being Effected" is permitted under 21 CFR 814.39(d) or an alternate submission is permitted in accordance with 21 CFR 814.39(e). A PMA supplement or alternate submission shall comply with applicable requirements under 21 CFR 814.39 of the final rule for Premarket Approval of Medical Devices.

All situations which require a PMA supplement cannot be briefly summarized, please consult the PMA regulation for further guidance. The guidance provided below is only for several key instances.

A PMA supplement must be submitted when unanticipated adverse effects, increases in the incidence of anticipated adverse effects, or device failures necessitate a labeling, manufacturing, or device modification.

A PMA supplement must be submitted if the device is to be modified and the modified device should be subjected to animal or laboratory or clinical testing designed to determine if the modified device remains safe and effective.

A "Special PMA Supplement - Changes Being Effected" is limited to the labeling, quality control and manufacturing process changes specified under 21 CFR 814.39(d)(2). It allows for the addition of, but not the replacement of previously approved, quality control specifications and test methods. These changes may be implemented before FDA approval upon acknowledgment by FDA that the submission is being processed as a "Special PMA Supplement - Changes Being Effected." This acknowledgment is in addition to that issued by the PMA Document Mail Center for all PMA supplements submitted. This procedure is not applicable to changes in device design, composition, specifications, circuitry, software or energy source.

Alternate submissions permitted under 21 CFR 814.39(e) apply to changes that otherwise require approval of a PMA supplement before implementation of the change and include the use of a 30-day PMA supplement or annual postapproval report. FDA must have previously indicated in an advisory opinion to the affected industry or in correspondence with the applicant that the alternate submission is permitted for the change. Before such can occur, FDA and the PMA applicant(s) involved must agree upon any needed testing protocol, test results, reporting format, information to be reported, and the alternate submission to be used.

POSTAPPROVAL REPORTS. Continued approval of this PMA is contingent upon the submission of postapproval reports required under 21 CFR 814.84 at intervals of 1 year from the date of approval of the original PMA. Postapproval reports for supplements approved under the original PMA, if applicable, are to be included in the next and subsequent annual reports for the original PMA unless specified otherwise in the approval order for the PMA supplement. Two copies identified as "Annual Report" and bearing the applicable PMA reference number are to be submitted to the PMA Document Mail Center (HFZ-401), Center for Devices and Radiological Health, Food and Drug Administration, 9200 Corporate Blvd., Rockville, Maryland 20850. The postapproval report shall indicate the beginning and ending date of the period covered by the report and shall include the following information required by 21 CFR 814.84:

- (1) Identification of changes described in 21 CFR 814.39(a) and changes required to be reported to FDA under 21 CFR 814.39(b).
- (2) Bibliography and summary of the following information not previously submitted as part of the PMA and that is known to or reasonably should be known to the applicant:
 - (a) unpublished reports of data from any clinical investigations or nonclinical laboratory studies involving the device or related devices ("related" devices include devices which are the same or substantially similar to the applicant's device); and

- (b) reports in the scientific literature concerning the device.

If, after reviewing the bibliography and summary, FDA concludes that agency review of one or more of the above reports is required, the applicant shall submit two copies of each identified report when so notified by FDA.

ADVERSE REACTION AND DEVICE DEFECT REPORTING. As provided by 21 CFR 814.82(a)(9), FDA has determined that in order to provide continued reasonable assurance of the safety and effectiveness of the device, the applicant shall submit 3 copies of a written report identified, as applicable, as an "Adverse Reaction Report" or "Device Defect Report" to the PMA Document Mail Center (HFZ-401), Center for Devices and Radiological Health, Food and Drug Administration, 9200 Corporate Blvd., Rockville, Maryland 20850 within 10 days after the applicant receives or has knowledge of information concerning:

- (1) A mixup of the device or its labeling with another article.
- (2) Any adverse reaction, side effect, injury, toxicity, or sensitivity reaction that is attributable to the device and
 - (a) has not been addressed by the device's labeling or
 - (b) has been addressed by the device's labeling, but is occurring with unexpected severity or frequency.
- (3) Any significant chemical, physical or other change or deterioration in the device or any failure of the device to meet the specifications established in the approved PMA that could not cause or contribute to death or serious injury but are not correctable by adjustments or other maintenance procedures described in the approved labeling. The report shall include a discussion of the applicant's assessment of the change, deterioration or failure and any proposed or implemented corrective action by the applicant. When such events are correctable by adjustments or other maintenance procedures described in the approved labeling, all such events known to the applicant shall be included in the Annual Report described under "Postapproval Reports" above unless specified otherwise in the conditions of approval to this PMA. This postapproval report shall appropriately categorize these events and include the number of reported and otherwise known instances of each category during the reporting period. Additional information regarding the events discussed above shall be submitted by the applicant when determined by FDA to be necessary to provide continued reasonable assurance of the safety and effectiveness of the device for its intended use.

REPORTING UNDER THE MEDICAL DEVICE REPORTING (MDR) REGULATION. The Medical Device Reporting (MDR) Regulation became effective on December 13, 1984, and requires that all manufacturers and importers of medical devices, including in vitro diagnostic devices, report to FDA whenever they receive or otherwise become aware of information that reasonably suggests that one of its marketed devices

- (1) may have caused or contributed to a death or serious injury or
- (2) has malfunctioned and that the device or any other device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

The same events subject to reporting under the MDR Regulation may also be subject to the above "Adverse Reaction and Device Defect Reporting" requirements in the "Conditions of Approval" for this PMA. FDA has determined that such duplicative reporting is unnecessary. Whenever an event involving a device is subject to reporting under both the MDR Regulation and the "Conditions of Approval" for this PMA, you shall submit the appropriate reports required by the MDR Regulation and identified with the PMA reference number to the following office:

Division of Surveillance Systems (HFZ-531)
Center for Devices and Radiological Health
Food and Drug Administration
1350 Piccard Drive, Room 240
Rockville, Maryland 20850
Telephone (301) 594-2735

Events included in periodic reports to the PMA that have also been reported under the MDR Regulation must be so identified in the periodic report to the PMA to prevent duplicative entry into FDA information systems.

Copies of the MDR Regulation and an FDA publication entitled, "An Overview of the Medical Device Reporting Regulation," are available by written request to the address below or by telephoning 1-800-638-2041.

Division of Small Manufacturers Assistance (HFZ-220)
Center for Devices and Radiological Health
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

TAB C

SUMMARY OF SAFETY AND EFFECTIVENESS DATA

I. GENERAL INFORMATION

Device Generic Name: Biologically Fixed Total Knee Prostheses

Device Trade Name: Natural-Knee® and Natural-Knee® II with CSTi™

Applicant's Name and Address:

Sulzer Orthopedics® Inc.
9900 Spectrum Drive
Austin, TX 78717

Premarket Approval (PMA) Number: P940002

Date of Panel Recommendation: June 12, 1995

Date of Good Manufacturing Practice Inspection: March 8, 1996

Date of Notice of Approval to Applicant: March 21, 1997

II. INDICATIONS FOR USE

The Natural-Knee and Natural-Knee II with Cancellous Structured Titanium (CSTi™) are indicated for uncemented use in skeletally mature individuals with intact medial and lateral collateral ligaments undergoing primary surgery for rehabilitating knees damaged as a result of Noninflammatory Degenerative Joint Disease (NIDJD) or Inflammatory Joint Disease (IJD).

III. DEVICE DESCRIPTION

The Sulzer Orthopedics Natural-Knee and Natural-Knee II Systems are semi-constrained total knee prostheses, each consist of three anatomically designed components: the femoral, tibial and patellar prostheses.

The femoral components are anatomically designed with left and right components. The femoral components have an anterior patellar flange and a centrally located groove that conforms to the geometry of the patellar prosthesis. The distal area of the interior box of the femoral components have two smooth pegs to provide medial-lateral stability. Both components are manufactured from cast cobalt chromium (CoCr) conforming to ASTM F75. The interior box surfaces are coated with CSTi porous-coating. The Natural-Knee femoral component is available in 6 sizes while the Natural-Knee II femoral component is

16

available in 7 sizes. The Natural-Knee II femoral component has a narrowed intercondylar notch compared to the Natural-Knee. The medial and lateral condyle widths of the Natural-Knee II are wider than the Natural-Knee femoral components. The radii between the intercondylar notch of the femoral component and tibial insert of the Natural-Knee II are more closely matched than the Natural-Knee.

The cruciate ligament retaining tibial component for the Natural-Knee and Natural-Knee II consists of two parts, a metal tray (baseplate) and a fixed polyethylene bearing insert, which are assembled at the time of surgery. The metal tray component is recessed to allow encapsulation of polyethylene inserts using a snap-lock mechanism. The baseplate is available in both resurfacing and stemmed options. The resurfacing option is constructed from wrought titanium alloy (Ti-6Al-4V) and the stemmed option is constructed from cast Ti-6Al-4V conforming to ASTM F136 and F1108, respectively. The baseplates are partially coated with CSTi at the bone/implant interfaces. Two baseplate screw holes accept 6.5mm titanium cancellous type bone screws (ASTM F136) for fixation and stability of the tibial baseplate. The Natural-Knee tibial baseplate component features a central screw hole for supplemental fixation of the insert to the tray. The supplemental insert fixation screw is made of Ti-6Al-4V (ASTM F136). Natural-Knee tibial baseplates incorporate both an anterior and posterior notch and are available in 6 sizes (0-5).

Natural-Knee II tibial baseplates are available in 7 sizes (00-5). The locking mechanism of the Natural-Knee II baseplate features full containment of the insert to the baseplate and does not have a central screw for supplemental insert fixation. The Natural-Knee II component does not have an anterior notch and the posterior notch is 2mm deeper to provide greater clearance for the posterior cruciate ligament.

The tibial inserts for both knees are manufactured from ultra high molecular weight polyethylene (UHMWPE) conforming to ASTM F648 and form the bearing surface for tibiofemoral articulations. Both congruent and ultracongruent tibial insert options are available. The ultracongruent inserts feature reduced radii of curvature and heightened anterior and posterior. Natural-Knee tibial insert components feature a central screw hole for supplemental fixation of the insert to the tray. Natural-Knee congruent tibial inserts are available in 5 thicknesses (9-19mm) while the ultracongruent option is available in 6 thicknesses (9-22mm). Natural-Knee II congruent and ultracongruent tibial inserts are available in 6 thicknesses (9-22mm). The 9mm sized inserts have a minimum thickness of 6mm underneath the condyles.

The metal-backed patellar component for both the Natural-Knee and the Natural-Knee II has a radially symmetric UHMWPE (ASTM F648) dome attached to a circular Ti-6Al-4V (ASTM F136 or F1108) baseplate. The baseplate has three smooth pegs and is partially coated with CSTi on the inferior surface. The bearing surface conforms to the patellar groove on the anterior flange of the femoral component. Patellas are available in four sizes (0-3).

The bone-contacting surfaces of all three metallic components of both the Natural-Knee

and Natural-Knee II devices are partially coated with CSTi. The CSTi is metallurgically bonded to the prosthesis by a proprietary sintering process. This provides a surface coating consisting of interconnected three-dimensional pores into which bone or fibrous tissue can grow.

IV. CONTRAINDICATIONS, WARNINGS, AND PRECAUTIONS

A. Contraindications

The uncemented use of the Natural-Knee and Natural-Knee II Systems with CSTi is contraindicated for the following:

- Patients with active infection; and
- Patients with physical conditions that would eliminate or limit adequate implant support or prevent the use of an appropriately sized implant e.g., insufficient quality or quantity of bone stock in the affected limb to render the procedure unjustifiable or such that successful uncemented fixation is unlikely.

If, at the time of surgery, one or more the following becomes apparent, uncemented implantation of the involved prosthetic component(s) is contraindicated, and the component(s) should be fixed with cement:

- Vascular deficiency at the bone site;
- Inadequate bone stock to assure both a firm press fit and close apposition of the cut bone surfaces to the prosthesis;
- Inadequate bone quality (e.g., severe osteoporosis);
- The inability to make bone cuts so as to assure both correct component position and intimate apposition of bone and prosthetic surfaces; or
- Lack of stability of the implanted components throughout a full range of motion.

B. Warnings

1. Preoperative

- Thorough familiarity with the surgical technique is essential. The use of certain surgical instruments is suggested in the performance of this surgery. Review of the use and handling of these instruments is important. The alignment and cutting jigs should be checked prior to surgery. Bent or damaged instruments may lead to improper implant position and

result in implant failure. A surgical technique brochure fully describing the procedure is available from Sulzer Orthopedics, Inc.

- X-ray templates should be used to estimate implant sizes, placement and joint alignment. An adequate inventory of implant sizes should be available at the time of surgery, including sizes larger and smaller than those expected to be used. Extra implant components are recommended. All packages and implants should be thoroughly inspected prior to surgery for possible damage (see "Sterilization" section).
- Do not alter implants prior to use. Only new implants may be used. A surgical implant must not be reused under any circumstances. Once implanted and subsequently removed, an implant should be discarded. Even though the implant appears undamaged, it may have small defects and internal stress patterns which may lead to failure.

2. Intraoperative

- Correct selection of the implant size and type is extremely important. Consideration of the anatomical and biomechanical factors including patient age, activity level, weight, bone and muscle conditions should be made prior to selection of the implant .
- Failure to use the optimum size implant, adequately seat the component on bone, and ensure that the component is stable through the whole range of motion may result in loosening, dislocation, subsidence or fracture of the components. In particular, it is necessary that there be a close bone/prosthesis interface.
- The components, instruments, and non implanted trial prostheses of the Natural-Knee and Natural-Knee II Systems with CSTi should not be used with those of another manufacturer. Because dimensional compatibility cannot be assured, adverse outcomes can result from the use of components from different manufacturers. With the exception of the patellar component, Natural-Knee and Natural-Knee II components are not to be interchanged between systems.
- The patellar component has the smallest bearing and fixation surfaces, therefore it more vulnerable to subluxation and loosening/dislocation. Particular attention during surgery to patellar tacking is necessary for fully successful uncemented application of the device.
- The tibial component should be seated so there is adequate coverage of the cortical bone in all directions (Medial-Lateral and Anterior-Posterior).

- Proper cleaning and preparation of the tibial surfaces are important in enhancing prosthesis fixation. Bone excision should be limited to the amount necessary to accommodate the implants. Excessive bone removal may result in mechanical disturbances and bone resorption with subsequent failure of the procedure due to loosening or deformation of the implant. When preparing and positioning tibial components, proper tibial alignment must be ensured.
- Prior to closure, the surgical site should be thoroughly cleansed of bone chips, ectopic bone, bone cement, etc. Foreign particles at the metal/plastic articular interface may cause excessive wear and/or friction. Ectopic bone and/or bone spurs may lead to dislocation or painful and restricted motion. Range of motion should be thoroughly checked for early contact or instability.

C. Precautions

1. Preoperative

- When total knee replacement is being considered, particularly for the young and the active patient, the surgeon should discuss all aspects of the surgery and the implant with the patient before surgery. The discussion should include the limitations of joint reconstruction, limitations particular to the patient, the possible consequences resulting from these limitations and, therefore, the necessity of following the physician's preoperative instructions.
- Allergies and other reactions to implant materials, although rare, have been reported in the literature and therefore should be considered and ruled out preoperatively.
- The correct handling of the implant is extremely important. The Natural-Knee and Natural-Knee II with CSTi porous coated devices should not be allowed to contact any metallic or other hard surface prior to implantation. Natural-Knee and Natural-Knee II should be used without nicks, scratches, or other alterations; these can produce defects and stresses which may become the focal point for eventual failure of the implant.
- CSTi should not be allowed to contact cloth or other fibers releasing materials prior to implantation. Conventional cleaning techniques cannot be relied upon to remove lint, dirt or body tissue from CSTi.
- Polyethylene inserts, once snapped in place, should not be removed and reinserted.

- The safety and effectiveness of the use of this device in bilateral applications have not been established.

2. Intraoperative

- In the event the device is not stable during manipulation or reduction, while the patient is under general anesthesia, the device should be fixed with cement.

3. Postoperative

Postoperative care is important. The patient should be instructed on the limitations of this device and should be cautioned regarding the load-bearing, range of motion, and activity levels permissible. Early load-bearing should be carefully controlled.

- Early postoperative care should be carefully structured to maintain range of motion, and to prevent dislocation or thromboembolism.
- Postoperative therapies, patient handling (e.g., changing dressings, placing on bedpans, etc.) and patient activities should be structured to prevent excessive loading of the operative knee. Surgical procedure chosen, patient's age and/or bone quality may necessitate extending the period of limited weight bearing.
- Periodic X-rays are recommended for close comparison with immediate postoperative X-rays to detect evidence or progressive changes in implant position or loosening, evidence of bending, cracking of component, and/or disassembly of components.
- The patient should be encouraged to promptly report any unusual changes in the operative extremity to his physician.

V. ALTERNATIVE PRACTICES OR PROCEDURES

Depending on the severity of the patient's condition, alternative treatments may consist of conservative medical or lifestyle management, such as medication and/or weight and activity reduction. Surgical alternatives would include such procedures as debridement, osteotomy, and arthrodesis. If prosthetic intervention is necessary, other commercially available porous-coated or nonporous-coated knee joint prostheses intended for cemented or uncemented use may be used as alternatives to the Natural-Knee and Natural-Knee II Systems.

VI. MARKETING HISTORY

Natural-Knee and Natural-Knee II are distributed and marketed in a variety of countries for both cemented and uncemented applications. The following table outlines the marketing and distribution history of the devices. To date, these products have not been withdrawn from any market for any reason related to the safety or effectiveness of the device.

Marketing History of Natural-Knee and Natural-Knee II		
Region	Natural-Knee (Initial Marketing Date)	Natural-Knee II (Initial Marketing Date)
USA	cemented (1990)	cemented (1995)
Europe	surgeon discretion* (1992)	surgeon discretion (1997)
Middle East	surgeon discretion (1996)	not currently marketed
Japan	physicians discretion* (1994)	not currently marketed
Australia	physicians discretion (1993)	not currently marketed
Canada	cemented and uncemented (1992)	cemented and uncemented (1996)

* Labeling language allows for either cemented or uncemented fixation.

VII. POTENTIAL ADVERSE EFFECTS OF THE DEVICE ON HEALTH

With at least five year postoperative data on patients, the most frequently reported operative-site and systemic complications reported are described in the following tables.

Most Frequently Reported Operative-site Complications		
Complication	Percentage	No. / Total Implants
adhesion or decreased range of motion	8.6	26/304
revision of the patellar component	5.0	17/343
removal of the tibial bearing insert	4.6	16/346
knee effusion	3.3	10/304
knee pain	2.3	7/304
revision of tibial base plate component	2.3	8/346

Most Frequently Reported Operative-site Complications		
subluxation	2.3	7/304
polyethylene wear	1.3	4/304
bursitis	1.3	4/304
deep infection	1.0	3/304
fractured patella	1.0	3/304
knee instability	1.0	3/304
hematoma	0.7	2/304
knee tendinitis	0.7	2/304
patella polyethylene wear	0.7	2/304

Most Frequently Reported Systemic Complications		
Complication	Percentage	No./Total Patients
cardiac disorder	11.5	30/261
hip problems	7.7	20/261
cancer	7.3	19/261
spinal/back problems	7.3	19/261
contralateral osteoarthritis	7.3	19/261
foot/ankle problems	6.9	18/261
shoulder problems	6.5	17/261
contralateral knee problems	6.5	17/261
hand/wrist/elbow problems	5.8	15/261
cerebrovascular accident	4.6	12/261
digestive system problems	3.5	9/261
pulmonary embolism	2.3	6/261
deep vein thrombosis	2.3	6/261

In addition to the adverse events noted in the clinical study there are other potential adverse events associated with prostheses for total knee replacement. These events commonly include:

- Cardiovascular disorders, including damage to blood vessels, wound hematoma, venous thrombosis, pulmonary embolism and myocardial infarction.
- Pulmonary disorders including pneumonia and atelectasis.

- Temporary or permanent neuropathies.
- Fractures of the tibia or femur. Postoperative fractures are usually stress fractures. Fractures are usually evidence of defects in the cortex due to prior screw holes and misdirected reaming and/or inadequate maldistributed bone cement. Intraoperative fractures are usually associated with revision surgery deformity and/or severe osteoporosis.
- Urological complications, especially urinary retention and infection.
- Complications associated with general surgery, drugs, ancillary devices used, blood, etc.
- Changing position of the prosthesis (bending, fracture and/or disassembly of components) with or without loosening or clinical symptoms.
- Subluxation, dislocation, decreased range of motion and shortening or lengthening of the extremity.
- Ectopic ossification.
- Early or late infection.
- Aggravated conditions in other joints or back due to intraoperative trauma, leg length discrepancy, femoral medialization, or muscular deficiencies.
- Excessive wear of the tibial component from damage to mating wear surfaces or debris particles.
- Tissue reactions and allergies to corrosion or wear products.
- Aseptic loosening.
- Possible detachment of CSTi coating could be associated with increased metal debris.

VIII. SUMMARY OF PRECLINICAL STUDIES

Preclinical testing characterized the device design and CSTi coating. The preclinical testing provided by the applicant evaluated the mechanical and material properties of the CSTi coating on Ti-6Al-4V and CoCr; characterized the UHMWPE; characterized the device design; and demonstrated tissue ingrowth into the CSTi coating in animal and human studies.

A. Preclinical Laboratory Studies

The primary objective of the laboratory studies was to define the characteristics of the porous-coating that provide the biological fixation surfaces of the device. Testing was conducted to determine the characteristics of the polyethylene (PE) used in the patellar and tibial components. Mechanical testing was also performed to evaluate the performance of the finished knee components.

1. Mechanical Properties of CSTi on Ti-6Al-4V (baseplate and patella)

The mechanical characteristics of the bond between the porous-coating and the Ti-6Al-4V prosthesis surface were determined under static and fatigue loading conditions. The results of these tests demonstrate the CSTi coating to have adequate mechanical bond characteristics for the application of cementless fixation of a total knee replacement device. The test results are as follows.

The fatigue strength of the Ti-6Al-4V base material after the porous-coating process has been determined by the Rotating Beam Method to be 70 ksi in a nonporous-coated region, and 29 ksi in a porous-coated region. The average ultimate and yield strengths were 151 ksi and 143 ksi, respectively. The CSTi coating has been evaluated for static strength of attachment with results indicating a coating/substrate shear strength average of 7570 psi and tensile strength averaging 6689 psi.

Characterization of tensile and shear fatigue strengths of CSTi on Ti-6Al-4V was performed. Loads of 1700 psi and 2600 psi for 10^7 cycles were applied and all samples ran out at the specified stress levels after 10^7 cycle.

Abrasion testing revealed no detectable particles produced at 445N (100 lbs.) of load. Higher loads ranging from 890N (200 lbs.) to 2780N (625 lbs.) exhibited an increasing amount of material removed until half the coating thickness was removed at 2780N of load.

2. Mechanical Properties of CSTi on CoCr (femoral components)

Under static and fatigue loading conditions the mechanical characteristics of the bond between the porous-coating and the CoCr femoral prosthesis surface were determined. The results of these tests demonstrate the CSTi coating to have adequate mechanical bond characteristics for the application of cementless fixation of a total knee replacement device. The test results are as follows.

The fatigue strength of the CoCr base material after the porous-coating process has been determined by the Rotating Beam Method to be 49.6 ksi in a nonporous-coated region, and 37.2 ksi in a porous-coated region. The average ultimate and yield strengths were 95 ksi and 65 ksi, respectively.

The CSTi coating has been evaluated for static strength of attachment with results indicating a coating/substrate shear strength average of 7139 psi and tensile strength averaging 5903 psi.

Analysis on the characterization of tensile and shear fatigue strengths of CSTi on CoCr was performed. Loads of 1700 psi and 2600 psi for 10^7 cycles were applied and all samples ran out at the specified stress levels after 10^7 cycle.

Compression testing was conducted that resulted in compression yield strength of 12,075 psi.

Abrasion testing performed revealed no detectable particles produced at 445N (100 lbs.) of load. Higher loads ranging from 890N (200 lbs.) to 2780N (625 lbs.) exhibited an increasing amount of material removed until half the coating thickness was removed at 2780N of load.

3. Material Properties of CSTi Coating

The pore sizes measured for the CSTi coating were found to be within the range that allow for adequate biological fixation. See the preclinical results sections VIII B1-B2 for further discussion of animal and human implant studies.

a. Ti-6Al-4V substrate

The CSTi coating pore size ranges between 444 and 530 microns using a linear intercept method. The average coating pore size is 487 microns and the average percent porosity is 49%.

Specimens of CSTi sintered onto Ti-6Al-4V substrate were analyzed for corrosion properties. This testing showed that the corrosion scans have a similar form to those for commercially pure titanium beads on a Ti-6Al-4V substrate.

b. CoCr Substrate

The CSTi coating pore size ranges between 443 and 539 microns using a linear intercept method. The average coating pore size is 491 microns and the average percent porosity is 52%.

Specimens of CSTi sintered onto CoCr substrate were analyzed for corrosion properties. This testing showed that the corrosion scans have a similar form to those for CoCr beads on CoCr substrate.

4. Characterization of UHMWPE

UHMWPE components are available in standard packaged form and oxygenless packaged form. Testing was conducted on both forms to determine the following characteristics; tensile strength, yield strength, percent elongation, Shore hardness, percentage crystallinity, Izod impact strength, crystallization temperature and melting temperature. These data were comparable to data provided for other marketed devices with components constructed from UHMWPE.

5. Component Testing

a. Baseplate/Insert Attachment Strength

Mechanical tests were performed to determine the static loads necessary to separate the UHMWPE insert from the tibial tray. The baseplate/insert attachment strength was tested in shear by applying a uniform load until insert disattachment. The Natural-Knee has a posterior to anterior (P/A) shear strength of 74 lbs. and an anterior to posterior (A/P) strength of 72 lbs. The Natural-Knee II has a posterior to anterior (P/A) shear strength of 287 lbs. and an anterior to posterior (A/P) strength of 110 lbs. The Natural-Knee and Natural-Knee II P/A and A/P results are comparable to other commercially available total knee systems and surpass expected physiologic loading.

b. Contact Area

The contact areas for the Natural-Knee were measured at flexion angles of 0, 30, 60, and 90 degrees under a compressive load of 500 lbs. The average contact area at these flexion angles is 0.221, 0.187, 0.170 and 0.144 in², respectively. The contact areas for the Natural-Knee II were measured at 0 degrees flexion and 296 kgf compressive load, 60 degrees flexion and 370 kgf, and 90 degrees and 333 kgf and the average contact area at these flexion angles is 0.357, 0.352, and 0.267 in², respectively. These results are comparable to other commercially available total knee systems.

c. Constraint Test

The amount of constraint in anterior-posterior, medio-lateral and rotary-laxity conditions between the femoral and tibial components under minimum loading conditions at varying levels of flexion was determined for the Natural-Knee and Natural-Knee II prostheses. The constraint values were comparable to or higher than other commercially available total knee systems.

d. Static Pull-Out Test of Patella

The locking mechanisms of six non-sterilized metal-backed patellas were tested under axial loading conditions to determine the tensile pull-out strength. The average load to disengage the plastic at a rate of 2 in/min was 81 lbs. This value is comparable to those of other commercially available total knee systems and surpass expected physiologic loading.

e. Lateral Shear Fatigue Testing of the Metal Backed Patella

The locking mechanism of the Natural-Knee Metal Backed Patella was tested in shear using maximum expected lateral *in vivo* load of 70 lbs (R=0.1, 15 Hz). All components survived 10^7 cycles with no failures (e.g., separation of dome from base). These results are comparable to other commercially available total knee systems and surpass expected physiologic loading.

f. Patella-Femoral Contact Area and Stability

Contact area and lateral subluxation testing were performed on the patellar component at 15 degrees flexion and 423 N compressive load, 45 degrees flexion and 1758 N, and 90 degrees flexion and 2127 N. For the Natural-Knee, the average subluxation force is 110.5 N, 379.7 N, and 622.3 N, respectively. For the Natural-Knee II, the average subluxation is 375.3 N, 1498.2 N, and 1794.8 N, respectively. For the Natural-Knee, the average contact area is 34.5, 62.3, and 72.1 mm², respectively. For the Natural-Knee II, the average contact area is 28.4, 93.7, and 87.3 mm², respectively. These results are comparable to other commercially available total knee systems.

B. Preclinical *In Vivo* Studies

The objectives of the preclinical *in vivo* studies were to characterize the attachment of the prosthesis via bone ingrowth.

1. Animal Studies

In an effort to determine the effectiveness of CSTi porous-coating as a bone ingrowth material, adult canines were used in two separate transcortical plug studies: one study was 24 weeks in duration, the other, 12 weeks in duration.

Transcortical plugs 6mm in diameter and 18mm long were coated with CSTi. The plugs were placed perpendicular to the long axis of the femur and the dogs were allowed full weight bearing until sacrifice. Dogs were sacrificed at various intervals in order to evaluate pushout shear strength. Histological sections were also sampled to determine the type and extent of biological

ingrowth.

Ultimate shear strength for the CSTi porous material-bone interface was measured at 3, 6 and 12 week intervals for one study and at 24 weeks for the other study (Table 1).

Histology was performed in each of the transcortical plug studies to determine the type and extent of bone ingrowth. A comparison of the histologies of both studies was performed (Table 2).

Additional quantitative analysis of the bone volume in the first study revealed that an average of 69.5% of the pore volume was filled with bone tissue. This result is comparable with other coatings used on devices that have been legally marketed for biological fixation.

No adverse tissue reactions or other evidence of rejection of implants have been noted in the transcortical plug studies with CSTi.

2. Human Evaluation

Hofmann et al.¹⁵ inserted "plug-type" implants in the condyles of human knees. Four types of implants were evaluated: CSTi with a 300-500 micron pore size, CSTi with a 450-800 micron pore size, hydroxylapatite(HA)/CSTi with a 450-800 micron pore size, and CoCr beads with a 425 micron pore size. CSTi with a 300-500 micron pore size was used as a control. One control and one of the above plugs were implanted in each side of the condylar surface of a human knee. A total of 56 plugs were implanted in 28 patients. The implants were followed for up to 42 weeks. Thirty implants were harvested for evaluation. There was a 0.7% bone ingrowth difference between the two control plugs. The larger pore size CSTi samples showed an 8.1% increase and the HA coated sample showed an 11.3% increase. Lastly, the CoCr beaded implants had 34.7% less bone growth than the control plugs. The study showed bone ingrowth into the CSTi coating was superior to the CoCr beaded coating.

Bloebaum et al.² studied five retrieved Sulzer Orthopedics APR[®] total hip prostheses. Data obtained from these retrievals has some applicability to this PMA as the CSTi porous-coating used on the APR hip stem is the same as that used on the Natural-Knee and Natural-Knee II Systems. The age of the patients ranged from 19-50 years old with an average age of 32 years. The duration of implantation ranged from three weeks to 48 months.

At three weeks the implant showed sparse woven bone at the implant/bone interface. At three months the implant showed immature woven bone that interdigitated with the outer layer of the porous-coating. Indications of maturing bone were observed. The sample at 11 months showed close

approximation of bone to the implant in the porous-coated region. Penetration of mature bone was seen to the level of the substrate.

The stems retrieved at 24 months and at 48 months showed maturation and mineralization on ingrown bone continuing up to 48 months for the APR hip.

3. Additional Studies

A theoretical mathematical model was used in conjunction with finite element analysis (FEA) to estimate the worst case (cantilever loading on the largest sized component) fatigue strengths of the resurfacing (unstemmed) and stemmed tibial baseplate components of the Natural-Knee and Natural-Knee II systems. Using a method validated with fatigue testing on baseplates of similar designs (Krevolin et al: An Innovative Method for Analyzing Fatigue Failure of Tibial Baseplates; Fifth World Biomaterials Congress, Toronto, Canada, May 29-June 2, 1996), the worst case fatigue strengths of the resurfacing and stemmed Natural-Knee baseplates was calculated to be 118 lbs. and 161 lbs., respectively. The worst case fatigue strengths of the resurfacing and stemmed Natural-Knee II baseplates was 150 lbs. and 180 lbs., respectively. These results are comparable to other commercially available total knee replacement devices.

C. Conclusions of Preclinical Studies

Tensile and shear static and fatigue testing of the bond between the CSTi porous-coating and the Ti-6Al-4V and CoCr substrate materials indicate that the coating bond strength should be adequate for the intended use of the device. In addition, *in-vivo* studies show that the interface between the bone and porous-coating exhibited increased strength over time. Mechanical bench-testing of the components demonstrates that the strength and design of the knee prosthesis should support a stable, functioning knee joint.

IX. SUMMARY OF CLINICAL STUDIES

The objective of the clinical studies was to demonstrate use of the three component Natural-Knee in patients resulted in a safe and effective uncemented total knee arthroplasty.

A. Evolution of Device Designs

The Natural-Knee and Natural-Knee II devices described in the sections I-VIII of this document were not studied in the clinical trial described in the following sections of this document. The sponsor utilized an earlier version of the Natural-Knee device in the clinical study. For purposes of clarity the "Natural-Knee" device described in sections I-VIII will be designated as Natural-Knee I and the device used in the

clinical study will be designated as Natural-Knee in sections IX-XII and the attached data tables.

The Natural-Knee was cleared for marketing in the USA for fixation with bone cement, through the premarket notification process (510(k)) in K853991. Natural-Knee I and Natural-Knee II designs were also cleared for marketing in the USA for use with bone cement, under K934695 and K936159. All three versions of the Natural-Knee device incorporate the identical CSTi coating, similar implant/implant interface designs and similar bone/CSTi interface designs.

The clinical study described in the following sections was designed to evaluate the uncemented fixation of the Natural-Knee with CSTi coating. Given the preclinical data provided for the Natural-Knee, Natural-Knee I and Natural-Knee II, and the similarities in the CSTi/bone interface design between the Natural-Knee, Natural-Knee I and Natural-Knee II designs additional clinical data on the Natural-Knee I and Natural-Knee-II designs was not necessary to establish the safety and effectiveness of the uncemented (biological) fixation of these two designs.

The modifications made to the Natural-Knee which resulted in the Natural-Knee I, and those to the Natural-Knee I resulting in Natural-Knee II are outlined in the following tables. In addition to the modifications, the tables: provide the 510(k) numbers under which these changes were made to the cemented version of the device; describe rationale or validation testing for the modification; and state the effect of the change(s) on the implant/implant and CSTi/bone interfaces.

Natural-Knee I FEATURES WHICH DIFFER FROM THE Natural-Knee			
MODIFICATION	510(K) FOR DESIGN CHANGE ON CEMENTED VERSION	DESIGN RATIONALE/TESTING	EFFECT OF MODIFICATION ON IMPLANT/IMPLANT AND CSTI/BONE INTERFACES
Femoral component constructed from CoCr alloy instead of Ti alloy	K902335(N-K I)	Ti alloy has proven to have insufficient wear characteristics and CoCr alloy has superior wear characteristics for this application as evidenced by literature ^{41,42,43,44,45,46} . The FDA draft guidance document for total knee devices recommends the use of CoCr for the articulating surfaces of a total knee device	This change was made in response to FDA and its advisory panel concern over Ti alloy's wear characteristics. CoCr has been shown to be an acceptable and widely used implant material ^{41,42,43,44,45,46} . This change affects the articulating surface not the CSTi/bone interface.
Increased tibial insert polyethylene thickness	K912663	Literature has shown thin tibial inserts wear excessively. ⁴⁸ FDA guidance on minimum polyethylene (PE) thickness; suggests a minimum thickness under the condyle of 6mm or provide long term wear data on thinner tibial inserts	Evidence of PE wear occurred during the clinical study. The modification was made to increase the wear through life of the component. This is a change in minimum PE thickness only not the CSTi/bone interface.

31

Natural-Knee I FEATURES WHICH DIFFER FROM THE Natural-Knee			
Polyethylene tibial insert modified to include a central hole for supplemental screw fixation	K912663	Accommodates supplemental screw fixation to tibial baseplate. Baseplate/Insert Attachment strength testing (Section VIII A5a) verifies the appropriate nature of this design modification	This is a change in the insert/baseplate locking feature not the CSTi/bone interface
Congruent and Ultracongruent tibial insert options	K912663 K931651	Provides added femoral congruency and contact area, thus reducing the contact stress. Wear is a function of contact stress and other variables. A reduction in contact stress leads to a reduction in wear. The contact area analysis(Section VIII A5b) verifies the increase in contact area	This modification was made to decrease the contact stress and overall wear of the device. This is a change in articulating interface not the CSTi/bone interface.
Tibial baseplate thickness increased from 0.235" to 0.247"	K934695	Increases resistance of the component to fatigue failure as verified by Finite Element Analysis (FEA) and bench testing (Section VIII B3)	Evidence of baseplate failure occurred during the clinical study. The design change was intended to increase the component's resistance to failure. This is a change to thickness only not the CSTi/bone interface
Tibial baseplate modified to allow supplemental screw fixation	K934695	Tibial baseplate was modified to allow supplemental screw fixation of the tibial insert to the baseplate. This change increases the detachment strength of the tibial insert, as demonstrated in Baseplate/Insert Attachment testing (Section VIII A5a)	This is a change in the insert/baseplate locking feature not the CSTi/bone interface.

Natural-Knee II FEATURES WHICH DIFFER FROM THE Natural-Knee I			
MODIFICATIONS	510(K) FOR DESIGN CHANGE ON CEMENTED VERSION	DESIGN RATIONALE/TESTING	EFFECT OF MODIFICATION ON IMPLANT/IMPLANT AND CSTI/BONE INTERFACES
Tibial baseplate insert locking mechanism modified	K936159	Allows for full containment of insert in the baseplate. Attachment testing verifies an increase of detachment strength for the device (section VIII A5a)	Modification was made to increase the component resistance to detachment, enhancing the stability of the component. This was a change in insert/baseplate locking feature not the implant/bone interface
Smoother finish on inner metal tray (tibial baseplate)	K936159	Reduces potential for wear due to micromotion at the baseplate/insert interface and enhances the insert/baseplate locking mechanism. Baseplate/insert attachment test results (section VIII A5a) show this design modification does not impact negatively on the attachment strength of the device	This modification was made to reduce the potential for overall PE wear. This was a change in insert/baseplate locking feature not the CSTi/bone interface
Tibial baseplate tray thickness increased from 0.247" to 0.288"	K936159	Increases the baseplate resistance to fatigue failure as demonstrated by FEA and bench testing (section VIII B3)	Evidence of baseplate failure occurred during the clinical study. Modification was made to increase the component resistance to failure. This is a change in baseplate thickness only not the CSTi/bone interface

Natural-Knee II FEATURES WHICH DIFFER FROM THE Natural-Knee I			
Additional 22mm size congruent tibial insert	K936159	A larger size increases the contact area (section VIII A5b) and minimizes the contact stresses	Additional size allows for further reduction in contact stresses in cases where patient anatomy warrants its use. This is only an added thickness not a change to the CSTi/bone interface
Femoral and tibial components available in one additional size	K936159	The additional size allows for more accurate fit of differing patient anatomy	This is only an added size not a change to the CSTi/bone interface
Straighter and narrower femoral intercondylar notch	K936159	Reduces the potential for subluxation by increasing the contact area. An increase in contact area will result in a decrease in contact stress and wear of the component. Contact area analysis (section VIII A5b) verifies the increase in contact area	Incidences of subluxation occurred in the clinical study. This modification was made to increase stability of the device and reduce overall wear of the device. This is a change in articulating interface not the CSTi/bone interface
Wider femoral medial and lateral condyle	K936159	Minimizes patellar stresses and increases contact area, thereby decreasing contact stress and wear of the component. Contact area analysis (section VIII A5b) verifies the increase in contact area	Evidence of wear of the tibial insert occurred during the clinical study. This modification aids in reducing contact stress and wear of the tibial insert. This is a change in articulating interface not the CSTi/bone interface
More closely matched medial and lateral radii between intercondylar notch of femoral component and tibial insert	K936159	Increases contact area, thereby decreasing contact stress and wear of the component. Contact area analysis (section VIII A5b) verifies the increase in contact area	Evidence of wear of the tibial insert occurred during the clinical study. This modification aids in reducing contact stress and wear of the tibial insert. This is a change in articulating interface not the CSTi/bone interface
3mm increase in height of the anterior flange of the femoral component	K936159	Provides slightly more anterior coverage of the bone	There was no change in the actual implant/bone interface with respect to porous materials used
Edge chamfer added to the lateral anterior flange of the femoral component	K936159	Provides less soft tissue irritation than if rubbing against a sharper edge	This is a design enhancement to minimize the possibility of tissue irritation not a change in the CSTi/bone interface
Reduced lateral flange distal to the anterior chamfer flange of the femoral component	K936159	Provides less soft tissue irritation than if rubbing against a sharper edge	This is a design enhancement to minimize the possibility of tissue irritation not a change in the CSTi/bone interface
Femoral ribs placed subsurface (e.g., they were shortened beneath the surface of the porous coating)	K936159	Provides a slightly more complete interface between porous coating and bone	This modification slightly increases the surface area of the CSTi coating/bone interface, potentially increasing the area available for tissue ingrowth
Tibial baseplate anterior notch removed	K936159	Increases anterior tibial rim coverage, thus strengthening the baseplate. The increase in fatigue strength of the baseplate was verified by FEA and bench testing (section VIII B3)	Evidence of baseplate failure occurred during the clinical study. This modification was made to strengthen the component. This modification also slightly increase the amount of CSTi possibly increasing the surface area of the bone/coating interface
Posterior cruciate ligament notch deepened by 2mm in the tibial baseplate	K936159	Provides greater clearance. FEA results show this design modification does not impact negatively on the fatigue strength of the baseplate (section VIII B3)	This is a design enhancement to minimize the possibility of tissue irritation not a change in the CSTi/bone interface.

*

Modification effects the CSTi surface area and therefore the CSTi/Bone interface.

B. Study Design

The multi-center prospective investigation of the Natural-Knee System with CSTi, for uncemented (biological) fixation, at 13 US investigational sites, received FDA approval on September 2, 1987. The clinical investigation involved longitudinal follow-up and was conducted under a common protocol with defined inclusion/exclusion criteria and carefully monitored for compliance. Standard data collection forms and measures were used throughout the study. The length and degree of follow-up (pre-operative and postoperative at 3 months, 6 months, 1 and 2 years) is adequate to assess the short-term follow-up typically presented for similar orthopedic implant approvals and also shows the performance over a longer period of time (follow-up going on the eighth year). The number of implants (326) is sufficient to draw reasonable conclusions pertaining to the safety and effectiveness of the implant, when intended for uncemented fixation.

To address the question of potential bias in patients selected to enter the study at a site in the absence of randomization, the applicant showed where possible that entry into the study was sequential with exceptions to entry being those patients excluded by the inclusion/exclusion criteria of the study protocol.

Data were analyzed for effectiveness parameters including pain, function, and range of motion. Radiographs were assessed for the extent of prosthesis to bone contact and alignment of the device. Safety was evaluated by documenting, tabulating, and analyzing all systemic and operative-site complications, device removal events, and patients withdrawn from the study. Data from this single protocol, multi center clinical investigation were pooled and compared to individual literature-based historical control populations implanted with commercially available cemented total knee devices and approved total knee devices implanted without cement.

The broad range of literature comparisons presented in the initial PMA submission demonstrated the performance of the Natural-Knee relative to the performance of the wide array of marketed devices, both cemented and uncemented (Table 3). In that respect and given that there was no concurrent control these comparisons do provide useful information using the best available scientific data to assess the Natural-Knee. Although not as specifically defined as the Natural-Knee study population, the patient populations represented in the literature controls are drawn from the same broad population of patients requiring total knee arthroplasty.

Because of concerns with potential bias from using the broad-based controls, the applicant was asked to identify and provide those comparisons in which the control group was demonstrably more similar to the NIDJD Cohort (e.g., control groups should not include IJD patients, revision patients, or posterior stabilized or fully constrained prostheses). Thus a comparative analysis using a reduced number of controls with characteristics most similar to the NIDJD Cohort was performed (Table 4), including a reanalysis of some literature and new literature not originally available.

C. Methodology

Patients who met the following inclusion criteria were implanted with the uncemented Natural-Knee total knee replacement:

- Medical conditions of osteoarthritis, rheumatoid arthritis, avascular necrosis, and arthritis secondary to a variety of diseases and anomalies.
- Skeletal maturity.
- Adequate quantity and quality of bone stock.
- Valgus-varus deformity and moderate flexion contracture, if correctable.
- Failed previous surgery where pain, deformity or dysfunction persists.

Patients were to be excluded from the study under the following conditions:

- Physical conditions that would tend to eliminate adequate implant support or prevent use of an appropriately sized implant, e.g., insufficient quality or quantity of bone (resulting from conditions such as cancer, congenital dislocation or osteoporosis), neuromuscular compromise, obesity, vascular deficiency in the affected limb, absence of musculoligamentous supporting structures, and joint neuropathy.
- Active infection of the knee; older or remote infection.
- Severe instability secondary to advanced loss of osteochondral structure or the absence of collateral integrity.

Intimate contact between bone and device components is critical and initial mechanical stability must be achieved during surgery to allow normal postoperative rehabilitation in uncemented knee systems. As a result, the component(s) were cemented into place if there was inadequate bone stock, poor bone quality, or instability on trial reduction, based on the surgeon's evaluation at the time of implantation. This accounts for the small number of hybrid knees (i.e., some components cemented, some not cemented) in this study.

D. Definition of Terms/Evaluations Used in the Clinical Summary

Clinical effectiveness was evaluated using the MHSS scoring system. The Hospital for Special Surgery (HSS) scoring system¹⁹ is based on assessments and rating of pain, function, performance, and deformity in the following categories: pain at rest, pain on walking, walking distance, ability to climb stairs, ability to rise from a chair, range of motion, muscle strength, flexion deformity, instability, extension lag and varus or valgus deformity. The same categories are used for the MHSS with minor modifications (Table 5). The complete MHSS score is the sum of scores of the individual categories (components). The MHSS scores are grouped into rating levels as follows: 85-100 = excellent, 70-84 = good, 60-69 = fair, and < 60 = poor.

Radiographs were taken at all evaluation visits. Radiolucencies were evaluated as a measure of bone contact with the prosthesis, the smaller the radiolucency the greater the bone contact. Radiolucent lines were categorized by width as < 1mm, 1-2mm, or > 2mm. Proportions of implants with no radiolucencies and of each width category were determined for each zone and follow-up visit.

Percent occurrence of operative-site (based on number of implants) and systemic (based on number of patients) complications was computed. Device removal events were categorized as revisions when tibial, femoral and/or patellar components were removed. Replacement of the polyethylene insert was categorized as a reoperation. Revisions where at least one component of the study device remained and reoperations contributed to clinical effectiveness analyses.

Implant survivorship was estimated by the cohort life-table (actuarial) method. The life-table method computes survival probabilities from the yearly survival rates for grouped data accounting for implants entering the study at different times and for patients who die or are lost to follow-up. Survivorships were computed based on failure defined as any device removal event (i.e., revision or reoperation). Survival probabilities, based on failure defined as any device removal event, were compared to cemented and uncemented literature controls. The normal distribution z-statistic with continuity adjustment was used to test for differences in two-year, three-year, and four-year survival probabilities.

E. The Patient Population

Of 346 Natural-Knee devices implanted in 300 patients, there were 326 devices implanted according to study protocol. In 17 cases one or two of the components were implanted with cement and in three cases no patellar component was implanted. These 20 cases were summarized separately and excluded from comparisons with control groups. The remainder of this discussion concerns only the 326 total uncemented Natural-Knee implants.

The diagnosis of NIDJD was associated with 304 of the 326 implants (Table 6), with osteoarthritis accounted for 96% of the NIDJD diagnoses. The diagnosis of IJD was associated with the other 22 implants (Table 6), with rheumatoid arthritis accounted for 91% of the IJD diagnoses. No revision cases were entered into the study.

Of the NIDJD implants, 47% (143) were in male patients and 53% (161) were in female patients (Table 7), a ratio reflective of the underlying distribution of patients receiving total knee prostheses. The age of patients with NIDJD ranged from 35 to 86 years (mean = 68 years). Of the IJD implants, 59% (13) were in male patients and 41% (9) were in female patients. The age of patients with IJD ranged from 37 to 82 years (mean = 59 years).

The individual literature control populations consisted of both NIDJD and IJD patients without stratification. Control patients ranged in age from 19 to 91 years, with the mean age anywhere from 51 to 76 years. The percentage of female patients in the controls ranged from 48 to 83%. Table 3 outlines these and other parameters for all the individual literature controls. Table 4 outlines the demographics of the controls on whom MHSS knee scores, where reported.

The NIDJD (or PMA) cohort was comprised of 304 implants in 261 patients who had their devices implanted according to protocol. This group was the primary focus of the PMA and the one to which literature controls were compared.

Of the 304 NIDJD Cohort knees implanted 271 received a two-year evaluation. Five implants were lost due to death and two to revision so 91% of the implants available (297) at the two-year evaluation provided clinical information. The numbers of implants evaluated at 3, 4, 5, and 6-years were 263 (90%), 251 (88%), 218 (82%), and 193 (78%), respectively. Life table analyses were performed and are provided in the clinical effectiveness results section. Of the LJD patients 20 (91%) implanted received a two-year evaluation. Three implants were lost due to death after two years. The numbers of implants evaluated at 3, 4, 5, and 6 years were 19 (100%), 16 (84%), 14 (74%), and 13 (68%), respectively.

F. Effectiveness

Efficacy of the NIDJD Cohort was evaluated using the MHSS score and the individual components of the score. The mean MHSS scores, pain scores, function scores, and average range of motion for the 2-year through 6-year follow-up evaluations are summarized in Table 8. The distribution of implants in the four rating groups (Excellent 85-100, Good 70-84, Fair 60-69, and Poor <60) is summarized in Table 9.

As part of the determination of clinical effectiveness of the Natural-Knee, clinical evaluation results were compared to HSS scores and component distributions described in published studies of cemented and uncemented knees^{6,10,14,18,20,24,30,31,32,35,37}. Comparisons were made for the two-year, three-year or latest follow-up visit (two-year minimum) depending on the data provided by the literature-based control. The number of literature-based controls became much more limited when the comparisons were limited to those studies where results were presented for NIDJD patients only. Based on this criterion there were four articles with data on six devices for which some types of comparisons could be made (Table 10).

The two-year and three-year mean MHSS for the NIDJD Cohort were statistically significantly greater ($p < 0.001$, t-test) than the mean for all three of the control devices in the NIDJD-restricted literature controls that reported these mean scores (Table 11.) The distribution of ratings for the Natural-Knee showed better or statistically equivalent results at two years, three years, and latest follow-up when compared with the broader range of literature controls^{14,18,20,30,31,37} (Table 12).

The distribution of pain ratings, distance walked, rising from chair, and climbing stairs at two years was compared to one NIDJD-restricted literature control using the Wilcoxon statistical test (Table 13). A greater proportion of Natural-Knee patients were able to rise without support, with a statistical significance of $p < 0.01$. The distributions of the other components were not found significantly different. Other two-year and latest follow-up comparisons of MHSS components with more general literature controls also found the Natural-Knee was either significantly better than or not statistically significantly difference than the control (Table 14).

Radiographs of the Natural-Knee were taken in the immediate postoperative period, and at all follow up evaluations. The percent of Natural-Knee implants and individual components with radiolucency at the two-year through six-year evaluations is shown in Table 15. The width of most reported radiolucencies was <1mm. The proportion of devices and each component part with any radiolucency were statistically compared using Fisher's exact test with the proportions reported in several literature control populations of both cemented and uncemented knees. None of these literature control populations were strictly NIDJD. The Natural-Knee and its component parts demonstrated superior results than almost all cemented and uncemented literature-control knees^{6,9,20,1,31,33,37} in terms of the proportion of implants with radiolucency at both the two-year evaluation and at the latest follow-up (Table 16).

To establish the efficacy of the Natural-Knee system for use in the IJD population a comparison between the IJD and NIDJD patients was performed. There was no statistically significant difference in preoperative or three-year overall MHSS scores, pain scores, function scores, range of motion scores, radiolucency frequency or survivorship between the IJD and NIDJD group, therefore the populations were comparable. This indicates IJD outcomes are comparable to the literature controls. The only statistically significant difference in complication rates was found in humeral fracture and thigh pain: both were significantly higher in the IJD group compared to the NIDJD group, $p=0.006$. These fractures were the result of patient falls.

G. Safety

All complications, both systemic (general) and operative-site, were tabulated for all implants entered into the study and for the NIDJD Cohort. There were 97 overall operative-site complications, 93 where in the NIDJD Cohort. The operative site complications for the Cohort, IJD and NIDJD patients are detailed in Tables 17A, 17B and 17C.

There were 292 systemic (or general) complications in the NIDJD Cohort with patients entering the seventh year of follow-up. There were 34 patient deaths unrelated to the device involving 42 implants. The systemic complications for the Cohort, IJD and NIDJD patients are detailed in Tables 18A, 18B and 18C.

Incidence of complications for the NIDJD Cohort were compared with complication rates reported in fifteen literature-control cemented and uncemented knees using Fisher's exact test. The comparisons showed a statistically significant ($p<0.05$) lower incidence of urinary tract infection and phlebitis or phlebitis with cellulitis compared with three of the controls, and a lower incidence of allergic reaction compared with one of the controls. No other systemic complications reported in the literature were significantly different from the NIDJD Cohort (Table 19).

Statistical comparisons of the operative-site complications reported in the NIDJD Cohort and literature control studies showed a statistically significant ($p<0.05$) lower incidence of loosening, deep infection, patella fractures and adhesions/decreased range of motion for the NIDJD Cohort, in most cases. Subluxation and knee pain were statistically significantly less in two cemented literature control studies than in the NIDJD Cohort (Table 20). Four

operative-site complications were reported in the IJD group (Table 17B). Though the number of patients in the IJD group is low, the number of operative site complications reported is supportive of the safety of this device for rheumatoid patients. The reported complications for the IJD group were comparable to those in the NIDJD group.

There were 23 systemic complications reported for IJD patients. Complications reported more than once are given in Table 18B. None of these complications were unanticipated and the incidence rate was not significantly higher than that reported for the NIDJD group.

H. Device Revisions

Table 21 shows the life table for the NIDJD Cohort using as an endpoint any device removal event for any reason. The cumulative survival estimate at five years was 95.3% (92.8% - 97.8%, 95% confidence interval). Cumulative survival estimates through four years for the NIDJD Cohort and six literature-control devices implanted in NIDJD patients are shown in Table 22. Statistical comparisons were made for comparisons with cumulative two-year, three-year, and four-year survival estimates provided for 15 more general literature-control devices (Table 23). No literature-control implant survival probability was significantly greater than that of the Natural-Knee at two, three, or four years of follow-up. Natural-Knee survival was significantly greater than that of four of the cemented devices and one of the uncemented devices. Resulting updated five-year and six-year cumulative survival probabilities (Tables 24 and 25) were similar to those reported for the two-year through four-year survival comparisons.

Seventeen of the 343 patellar components implanted in the total study group were revised. Seven of these revisions were due to wear-through of the PE of the patellar component, 2 were revised due to infection, and 8 other were revised for reasons not specific only to the patellar component. Of these last 8, 4 had wear and/or cracking of the PE.

Eight of the 346 tibial baseplate components implanted in the total study group were revised. One fractured baseplate was revealed by x-ray at the six-year evaluation. Another baseplate was revised due to knee pain that was uncertain in relation to the device. Two baseplates were removed for infection. The other reasons for revision were: subluxation and instability, effusion, subluxation following a 12 ft. fall, and synovitis with no tissue ingrowth.

Sixteen of the 346 tibial bearing insert components implanted in the total study group were revised. Eight of those involved replacement of the insert without removal of the tibial baseplate. These removals were for wear and/or instability.

Two patients in the IJD group have undergone revision of one or more components in the study. One patient had the patella, femoral component and tibial insert removed after 1727 days (4.7 years) due to patellar-femoral wear. A second patient underwent replacement of the patella, femoral component and tibial insert due to wear of the patella, femoral component and polyethylene insert 2349 days (6.4 years) after surgery.

I. Additional Clinical Studies

Because of the well-documented relatively high failure rates of some metal-backed patella designs, the applicant was requested to provide either clinical data or fatigue test data on the long-term survivorship of the metal-backed Natural-Knee patellar component. The applicant provided long-term data from a single investigator's use of the Natural-Knee device. Dr. Aaron Hofman, a developer of the device, performed 302 consecutive uncemented total knee arthroplasties utilizing the metal-backed Natural-Knee patellar component. Fifty-nine patients have died and 31 are lost to follow-up, leaving 212 implants available for evaluation at 6-10 years, with a mean follow-up of 7 years 7 months. Eleven patients (5%, n=212) underwent revision of the metal-backed patellar component: 2 (0.9%) for infection; 7 (3.3%) removed for cold flow wear diagnosed during procedures to replace tibial insert components; 1 (0.5%) for isolated wear (71 months); and 1 (0.5%) for patellar maltracking. Although, the metal backed patellar component did not experience a higher failure rate in this study when compared to other all-polyethylene patellar designs, the interlock of the polyethylene and metal back components of the patellar were improved as described previously in section IX A.

X. CONCLUSIONS DRAWN FROM THE CLINICAL INVESTIGATIONS

The results of this investigation show that statistical comparison of the Modified Hospital for Special Surgery (MHSS) scores and the pain and function components between the Natural-Knee NIDJD Cohort and the literature-based control groups demonstrated that, within the first three years, the Natural-Knee with CSTi performed overall as well as or better than the controls. The percentage of implants receiving good or excellent MHSS ratings was greater for the Cohort than for the literature-control devices. In comparison with the literature-control devices, the Natural-Knee Cohort showed significantly better results in the distribution for five of eight components, and no significant differences for the other three components.

Statistical comparisons of operative site and systemic complications reported in the Natural-Knee Cohort and literature control studies showed statistically lower or similar incidences of complications for the Natural-Knee Cohort in most cases.

Efficacy, radiographic and safety information of the IJD group parallels the results provided by the NIDJD Cohort. The mean three year postoperative MHSS scores were not significantly different between the two groups (93 IJD ; 91 NIDJD). In addition there were no significant differences between the two groups for the pain component score, function and range of motion. Ten percent of the IJD implants had one or more radiolucencies compared with 14% of NIDJD implants which compared favorably to radiolucencies reported in the literature. There was no indication of increased or unusual complications associated with the IJD group compared to the NIDJD group. Five-year survival for the IJD group (93.5%) was not significantly different from that of the NIDJD group (95.3%)

Overall, the Natural-Knee IJD group results compare favorably with results of the NIDJD group, which performed as well or better than the controls. Other studies of the use of cemented and cementless knee arthroplasty in osteoarthritis and/or rheumatoid arthritis patients also reports no significant differences in

success rates between rheumatoid and osteoarthritic patients.⁴⁷

Data from one investigator's consecutive series indicate that the long-term clinical performance of the uncemented use of the metal-backed patellar component of the Natural-Knee is similar to the performance of other cemented polyethylene patellar components.

In summary, the above clinical information demonstrates the safety and effectiveness of the uncemented use of the Natural-Knee with CSTi, relative to commercially available cemented and uncemented knee prostheses used for total knee arthroplasty. No additional risks were identified for these patients other than the risks normally associated with total knee arthroplasty. Histological analyses indicate that CSTi implants are fixed by tissue ingrowth. Furthermore, the uncemented use of the Natural-Knee with CSTi provides the potential benefits of not using cement. The recognized side effects of cement, e.g., thermal destruction of local bone tissue, exposure to the toxic effects of polymethylmethacrylate and fracture of the bone cement, are avoided.

Therefore, it is reasonable to conclude that the benefits of the use of the Natural-Knee with CSTi for the target population outweigh the risk of injury when used as indicated in accordance with the directions for use. Additionally FDA feels the results of clinical study can also be applied the modified version of the Natural-Knee and Natural-Knee II, and expects for both designs the benefits of the use of the device for the target population outweigh the risk of injury when used as indicated in accordance with the directions for use. This conclusion is based the results of preclinical bench testing and the fact these changes do not impact on the bone/CSTi interface and therefore do not impact on the method of fixation.

XI. PANEL RECOMMENDATION

At an advisory meeting held on June 12, 1995, the Orthopedic and Rehabilitation Devices Advisory Committee recommended that Sulzer Orthopedics' PMA for the Natural-Knee with CSTi be approved subject to submission to, and approval by, the Center for Devices and Radiological Health (CDRH) of the following:

- An update on the clinical study;
- A protocol for a post-approval study;
- Either removal of IJD from the indications statement or data statistically comparing the NIDJD and IJD results, with the power reported;
- Data on the Natural-Knee I CoCr femoral component (the IDE study had a titanium alloy femoral component);
- Data on patients who received cemented prostheses from the investigators to support the long-term performance of the device;
- Fatigue data on the stemmed and unstemmed tibial component; and
- Fatigue testing of the patellar component that produces a failure mechanism that is seen clinically.

XII. CDRH DECISION

The applicant informed FDA in 1995 that the Natural-Knee had undergone a design modification after the

clinical trial was initiated in 1987, and was not seeking approval of the original design of the device intended for biological/uncemented fixation (bone or fibrous tissue ingrowth into the CSTi coating). Instead, the applicant would seek approval for the modified version of the device, Natural-Knee I. (See section IX A. Evolution of Device Designs of this document for an explanation of the design modification.) The CSTi porous-coating, intended for biological/uncemented fixation and CSTi/bone interface were unchanged.

In concurrence with the June 12 , 1995 Orthopedic and Restorative Devices Panel the FDA requested test data on the fatigue strength of the patellar and tibial components, data justifying IJD diagnosis, and modifications to the labeling to place the PMA in approvable form. The applicant amended the PMA to adequately address the deficiencies.

At the applicant's request, a meeting between the applicant and FDA was held. The applicant informed FDA the applicant was also seeking to approval of another version of the device, the Natural-Knee II (See section III. Device Description and IX A. Evolution of Device Designs of this document for an explanation of Natural-Knee II design). FDA informed the applicant that FDA would consider including the Natural-Knee II in the PMA if data on the device description, manufacturing, and preclinical data were submitted in an amendment demonstrating the changes were safe and effective without adversely impacting on the CSTi/bone interface.

The issue of fixation, of an uncemented total knee replacement device by tissue (bone or fibrous) ingrowth into the CSTi coating, was the focus of the FDA request for clinical data for the Natural-Knee device and the submission of the PMA. The changes resulting in the Natural-Knee I and Natural-Knee II designs did not alter the method of device fixation, biological/uncemented fixation (bone or fibrous tissue ingrowth into the CSTi coating). FDA determined the issue of biological/uncemented fixation was adequately addressed by the Natural-Knee clinical data, therefore, additional clinical data was not necessary for the Natural-Knee I and Natural-Knee II designs. Thus , the safety and effectiveness of the Natural-Knee I and Natural-Knee II were based on preclinical data, the Natural-Knee clinical results and the marketing determinations made for the device modifications made under the 510(k) process.

As stated above the applicant will not market the Natural-Knee design used in the clinical study. In its place the applicant will market the modified versions Natural-Knee I and the Natural-Knee II, described in section III. Device Description of this document. Natural-Knee I is now redesignated Natural-Knee, the name the device will be marketed under.

XIII. APPROVAL SPECIFICATIONS

- Directions for use: See the labeling (Attachment 1).
- Hazards to Health from Use of the Device: See Indications, Contraindications, Warnings, Precautions, and Adverse Events in the labeling (Attachment 1).
- Postapproval Requirements and Restrictions: See approval order (Attachment 2).

Table 1 Static shear strength of CSTi porous material-bone interface.

STUDY COMPLETION DATE	<u>STATIC SHEAR STRENGTH</u>			
	<u>3 WK.</u>	<u>6 WK.</u>	<u>12 WK.</u>	<u>24 WK.</u>
1983	-	-	-	21.9 MP (21 samples)
1985	7.75 MP (14 samples)	12.60 MP (14 samples)	18.15 MP (16 samples)	-

1/13

Table 2 Qualitative histological examination of bone ingrowth.

<u>TIME</u> <u>IN-SITU</u>	<u>1983 STUDY</u>	<u>1985 STUDY</u>
3 Weeks	"Regionally non-uniform ingrowth of woven bone callus"..ingrown bone was in the process of mineralizing" "Ca/P ratio roughly 80% of that of the bulk cortical bone"	"Extensive ingrowth of woven bone callus".. "ingrown bone was in the process of mineralizing"
6 Weeks	Not obtained	Similar findings to 3 week data with greater mineralization present
12 Weeks	Not obtained	"Mineralization comparable to 24 week sections with a transformation to a more organized bone with mature haversian systems and extensive vascularity"
24 Weeks	"Extent of the ingrowth was greatly increased.." "Mature haversian systems and numerous freely anasto-observed throughout the (CSTi) pore structure" in titanium surface	Not obtained

44

Table 3 Literature-control study devices with cemented (c) or uncemented (u) fixation used for comparison with results for the Natural-Knee.

Device	Ref.	Year	Fixation	No. of Knees	Follow-up (Yr.)		Patient Age (Yr.)		Diagnosis*		Gender	Used for Comparisons of			
					Mean	Range	Mean	Range	OA%	RA%	% Females	Clin.	Surv.	Radio.	Safety
Attenborough	21	1988	c	172	6.4	4-10	65	32-89	44	56	67		x		
Duo-condylar	30	1976	c	109	3	2-4	65	25-72	25	75	83	x		x	x
Freeman, Sheehan, Manchester	39	1982	c	365	-	-	-	-	-	-	-		x		
Kinematic	9	1989	c	1069	2.0	1-7.5	67	-	48	47	77			x	x
Kinematic	10	1984	c	142	2.2	2-4	76	25-86	41	54	68	x		x	x
Kinematic II, PCA	34	1988	c	110	-	2-3	70	52-88	84	16	-				x
			u	50	-	2-3	59	22-82	88	12	-			x	
Kinematic stabilizer	14	1988	c	79	3.1	2.0-5.8	65	27-83	47	46	56	x			x
LCS	3	1986	c	93	3.7	2-7	66	36-91	61	29	68				x
LCS (bicruciate, rotating platform, posterior cruciate)	5	1990	c	64	-	12 max	64	33-88	-	-	83			x	
			u	147	-	6 max	66	31-88	-	-	85			x	
LCS (uni, bicruciate, rotating platform, posterior cruciate revision)	4	1989	c	107	7.5	2.2-10.4	64.1	20-88	57	40	62				x
			u	170	4.4	2-7.5	59.9	21-86	69	23	60				x
Miller-Galante	35	1990	c	139	3.6	3-6	70	31-97	81	14	57	x			x

* OA = Osteoarthritis
RA = Rheumatoid arthritis

30

Table 3, continued.

Device	Ref.	Year	Fixation	No. of Knees	Follow-up (Yr.)		Patient Age (Yr.)		Diagnosis*		Gender	Used for Comparisons of				
					Mean	Range	Mean	Range	OA%	RA%	% Females	Clin.	Surv.	Radio.	Safety	
Mixture (Hinge, Total condylar, Kinematic I and II, Rotating Kinematic, AGC, G-PAC, P-PAC II)	11	1991	c	1000	-	1-14	-	19-91	86	9	-					x
Oxford	12	1986	c	125	4.1	2-5	64.6	45-83	59	41	80			x		
PCA	6	1991	c	25	3.0	2-5	65.6	46-81	48	40	-	x			x	x
			u	26	3.0	2-5	65.5	29-81	48	40	-	x			x	x
PCA	8	1988	u	142	-	1.1-4.4	66.9	26-86	69	27	68				x	
PCA	28	1991	u	108	5.3	3.2-7.8	51	19-69	32	68	57			x		
PCA	32	1987	u	30	2	2	57	28-76	-	-	58	x				
Posterior cruciate condylar	33	1981	c	73	2	2	-	-	64	29	-					x
Posterior stabilized condylar	37	1988	c	119	5.1	2-8	66.9	22-84	74	18	61 *	x	x	x	x	x

31

W

Table 3, continued.

Device	Ref.	Year	Fixation	No. of Knees	Follow-up (Yr.)		Patient Age (Yr.)		Diagnosis*		Gender	Used for Comparisons of			
					Mean	Range	Mean	Range	OA%	RA%	% Females	Clin.	Surv.	Radio.	Safety
Posterior stabilized condylar, Total condylar	18	1982	c	118	-	2-4	66	36-84	91	9	71	x		x	x
Press fit condylar	31	1991	c	59	2.7	-	66	-	81	13	48	x		x	x
Press fit condylar	40	1990	c (Uncemented femurs)	114	2.8	2-4.4	65	22-84	68	29	70			x	
Stanmore	13	1984	c	103	5.7	3.2-9.2	68	37-84	46	54	86		x		
Stanmore	27	1991	c	194	-	1-15	-	-	-	-	-		x		
Total condylar	1	1984	c	37	5	5-7	65	50-74	84	16	-			x	x
Total condylar	20	1979	c	461	-	3-5	64	30-85	73	27	80	x		x	x
Total condylar, Posterior stabilized condylar	38	1989	c	1430	-	15 max	67	20-87	78	13	69		x		
Tricon-M	24	1988	u	96	2.3	2.1-3.2	-	-	44	56	-	x		x	
Two- and three-compartment knees	22	1986	c	3604	-	1-6	-	18-91	46	54	-		x		

^a Provides two-year data.

^b Gives two-year radiographic data.

^c All postoperative evaluations were done at two years.

W

Table 4 Baseline demographic characteristics for studies that report MHSS knee scores. Unless otherwise specified, demographic information includes all patients with diagnosis of osteoarthritis and rheumatoid arthritis.

Demographic Characteristic	Device						
	PMA Cohort*	PCA	Kinematic ³⁴ II ³⁴	Tricon-M ²⁴	Total Condylar ²⁰	Duocondylar ¹	Geometric ¹⁹
No. Implants with Osteoarthritis	304	44	92	42	139	18	16
No. Implants with Rheumatoid Arthritis	-	6	18	54	81	42	34
Age (Range)	68 (35-86)	59 (22-82)	70 (52-88)	61**	64 (30-85)	62	62
Weight (Range) lbs.	184 (118-280)	190	170	-	-	-	-
Female (%)	53	60	60	-	81	-	-

* All patients with a diagnosis of NIDJD.

** Age being reported is that of patients with osteoarthritis.

48

Table 5 Hospital for Special Surgery (HSS) scoring system¹⁹ and the Modified Hospital for Special Surgery (MHSS) scoring system.

Component Assessed (maximum score possible)			
HSS		MHSS	
Rating Categories	Points	Rating Categories	Points
Pain (30)		Pain (30)	
Pain on Walking (15)-		Pain on Weight Bearing (15)	
None	15	None	15
Mild	10	Slight	10
Moderate	5	Mild	8
Severe	0	Moderate	5
		Marked	0
		Continuous bed/chair status	0
Pain at Rest (15)		Pain at Rest (15)	
None	15	None	15
Mild	10	Trivial	10
Moderate	5	Moderate	5
Severe	0	Severe	0
Function (22)		Function (22)	
Distance Walked (12)		Distance Walked (12)	
Walking and standing unlimited	12	Unlimited	12
Walking 5-10 blocks and standing ability intermittent (<0.5 hour)	10	6 blocks	10
Walking 1-5 blocks and standing ability up to 0.5 hour	8	2-3 blocks	8
Walking less than 1 block	4		
Cannot walk	0	Indoors only	4
		Unable to walk	0
Stairs (5)		Stairs (5)	
Climbing stairs	5	Normally	5
Climbing stairs with support	2	Normally with railing	2
		Any method	1
		Not able	0
Transfer Activity (5)		Rising from Chair (5)	
Transfer activity	5	Normally	5
Transfer activity with support	2	Easily rise with 1 or 2 arms	3
		Difficult, using 2 arms	2
		Needs assistance	1
		Unable	0
Other Assessments (48)		Other Assessments (48)	
Range of Motion (18)		Range of Motion (18)	
1 point for each 8 degrees of arc of motion to a maximum of 18 points	18	1 point for each 8 degrees of arc of motion to a maximum of 18 points (passive)	18
Muscle Strength (10)		Muscle Strength (10)	
Excellent: cannot break the quadriceps power	10	Cannot overcome quadriceps	10
Good: can break the quadriceps power	8	Can overcome quadriceps	4
Fair: moves through the arc of motion	4		
Poor: cannot move through the arc of motion	0		
Flexion Deformity (10)		Flexion Deformity (10)	
No deformity	10	No deformity	10
Less than 5 degrees	8	1-4 degrees	8
5-10 degrees	5	5-10 degrees	5
More than 10 degrees	0	>10 degrees	0
Instability (10)		Stability (10)	
None	10	Medial-lateral (8)	
Mild: 0-5 degrees	8	Stable	8
Moderate: 5-15 degrees	5	Moderate instability	5
Severe: >15 degrees	0	Marked instability	0
		Anterior-posterior (2)	
		Stable	2
		Unstable	0
Subtractions		Subtractions	

Table 5, continued.

Component Assessed (maximum score possible)

HSS		MHSS	
Rating Categories	Points	Rating Categories	Points
Support		Support	
None	0	None	0
One cane	-1	One cane, long walks	-1
One crutch	-2	One cane, full time	-1
Two crutches	-3	Two canes	-2
		One crutch	-2
		Two crutches	-3
		Walker	-3
Extension Lag		Extension Lag	
Extension lag of 5 degrees	-2	5-9 degrees	-2
Extension lag of 10 degrees	-3	10-14 degrees	-3
Extension lag of 15 degrees	-5	≥15 degrees	-5
Varus or Valgus Deformity		Varus or Valgus Deformity	
Each 5 degrees of varus	-1	Each 5 degrees of varus	-1
Each 5 degrees of valgus	-1	Each 5 degrees of valgus	-1

Table 6 Diagnoses and diagnostic categories for the total uncemented Natural-Knee implants/patients.

	Implants		Patients	
	N	%	N	%
Noninflammatory Joint Disease (NIDJD)				
Osteoarthritis	291	95.7	249	95.4
Post Traumatic Arthritis	12	3.9	12	4.6
Post Hepatitis	1	0.3	1	0.4
Total	304		261*	
Inflammatory Joint Disease (IID)				
Rheumatoid Arthritis	20	90.9	18	90.0
Gout	1	4.5	1	5.0
Monarticular Sero-Negative Inflammatory Arthritis	1	4.5	1	5.0
Total	22		20	7.3

* One bilateral patient with diagnosis of osteoarthritis in left knee, post hepatitis arthritis in right knee. Percent based on number of patients.

Table 7 Age and sex distribution of patients receiving the total uncemented Natural-Knee implant.

Age	NIDJD						IJD					
	Male		Female		Total		Male		Female		Total	
	N	%	N	%	N	%	N	%	N	%	N	%
30-39	1	0.7	-	-	1	-	-	-	2	22.2	2	9.1
40-49	1	0.7	1	0.6	2	-	1	7.7	5	55.6	6	27.3
50-59	16	11.2	21	13.0	37	12.8	1	7.7	1	11.1	2	9.1
60-69	53	37.1	74	46.0	127	40.9	5	38.5	-	-	5	22.7
70-79	59	41.2	57	35.4	116	38.4	6	46.2	-	-	6	27.3
80-89	13	9.1	8	5.0	21	7.8	-	-	1	11.1	1	4.5
Total	143	100	161	100	304	100	13	100	9	100	22	100
Minimum	35		40		35		40		37		37	
Maximum	86		84		86		79		82		82	
Mean	69		67		68		68		47		59	
Std Dev	8.0		8.1		8.1		10.6		13.9		15.8	

Table 8 Mean MHSS scores, mean pain and function component scores, and mean range of motion (degrees of flexion) scores for Natural-Knee Cohort implants. Standard deviations given in parenthesis. Sample size (n) is the number of implants with complete MHSS scores.

Component	Evaluation				
	2-year (n=266)	3-year (n=258)	4-year (n=242)	5-year (n=210)	6-year (n=177)
MHSS	90.7 (6.7)	90.6 (8.0)	91.2 (7.3)	90.0 (8.6)	90.3 (8.9)
Pain	28.2 (3.5)	27.7 (4.7)	27.9 (4.6)	27.9 (4.5)	27.7 (4.9)
Function	19.6 (3.3)	19.8 (3.1)	19.5 (3.7)	19.1 (3.7)	19.2 (4.0)
Range of Motion (°)	117.0 (12.5)	117.7 (13.6)	118.3 (12.7)	117.9 (12.3)	117.6 (13.1)

Table 9 Distribution of MHSS rating categories for the Natural-Knee Cohort.

Rating	Evaluation									
	2-year		3-year		4-year		5-year		6-year	
	N	%	N	%	N	%	N	%	N	%
Excellent	219	82	214	83	207	86	173	82	150	85
Good	46	17	37	14	31	13	30	14	20	11
Fair	0	0	4	2	3	1	5	2	4	2
Poor	1	1	3	1	1	<1	2	1	3	2
Total	266		258		242		210		177	

Table 10 Baseline demographic characteristics for studies that report MHSS knee scores for NIDJD implants. Unless otherwise specified, age, weight, and sex information includes all patients with diagnosis of osteoarthritis and rheumatoid arthritis.

Demographic Characteristic	Device						
	PMA Cohort*	PCA	Kinematic ³⁴ II ³⁴	Tricon-M ²⁴	Total Condylar ²⁰	Duocondylar ¹	Geometric ¹⁹
No. Implants with Osteoarthritis	304	44	92	42	139	18	16
No. Implants with Rheumatoid Arthritis	-	6	18	54	81	42	34
Age (Range)	68 (35-86)	59 (22-82)	70 (52-88)	61**	64 (30-85)	62	62
Weight (Range) lbs.	184 (118-280)	190	170	-	-	-	-
Female (%)	53	60	60	-	81	-	-

* All patients with a diagnosis of NIDJD.

** Age being reported is that of patients with osteoarthritis.

Table 11 MHSS scores and rating category for the Natural-Knee Cohort and literature-control devices. Data for literature-control devices include only patients diagnosed with osteoarthritis.

MHSS Score/Category	Device						
	PMA Cohort	PCA	Kinematic II ³⁴	Tricon-M ²⁴	Total Condylar ^{14,20}	Ducocondylar ¹	Geometric ¹⁹
Two Year MHSS (SD)	90.7 (6.7)	81	87	81	-	-	-
N	266	44	92	42	-	-	-
p-value ¹		p<0.0001	p<0.0001	p<0.0001			
Three Year MHSS (SD)	90.6 (8.0)	-	-	-	85	74	71
N	258	-	-	-	139	18	16
p-value ¹					p<0.0001	p<0.0001	p<0.0001
40 Three Year MHSS Component							
% Excellent	83				68	45	19
% Good	14				25	22	63
% Fair	2				3	22	6
% Poor	1				4	11	12
p-value ²					p=0.0006	p=0.0001	p<0.0001

Table 12 Distribution (%) of MHSS rating categories for the Natural-Knee Cohort and comparable ratings for literature-control cemented knees.

Rating	Two-Year		Three-Year		Latest Follow-up (Two-Year Minimum)					
	Natural-Knee n=266	Posterior Stabilized Condylar ³⁷ n=119	Natural-Knee n=258	Posterior Stabilized Condylar ³⁷ n=105	Natural-Knee n=277	Kinematic ¹⁴ n=26	Duo-Condylar ³⁰ n=88	Total Condylar ²⁰ n=220	Posterior Stabilized Condylar ¹⁸ n=118	Press Fit Condylar ³¹ n=59
Excellent	82.3	83.2	82.9	83.8	83.0	53.8	37.5	62.3	88.2	67.8
Good	17.3	15.1	14.3	14.3	14.5	38.5	37.5	27.7	8.5	22.0
Fair	0.0	0.0	1.6	0.0	1.8	3.8	15.9	4.6	0.8	8.5
Poor	0.4	1.7	1.2	1.9	0.7	3.8	9.1	5.4	2.5	1.7
P-value	0.8857		0.8285		0.0006		<0.0001	<0.0001	0.2303	0.0044

14

Table 13 Two-year Pain and Function knee-rating categories for the Natural-Knee Cohort and an osteoarthritic group of patients implanted with the Tricon-M knee²⁴.

MHSS Category	PMA Cohort		Tricon-M	
	N	%	N	%
Pain				
Weight Bearing				
None	215	79	33	79
Mild/Slight	54	20	6	14
Moderate	2	1	2	5
Marked	0	0	1	2
p-value ¹				
				p=0.7645
Resting				
None	242	89	42	95
Trivial	24	9	2	5
Moderate	5	2	0	0
Severe	0	0	0	0
p-value ¹				
				p=0.2461
Distance Walked				
Unlimited	225	83	36	86
6 Blocks	17	6	5	12
2-3 Blocks	23	9	0	0
Indoors Only	6	2	1	2
Unable to Walk	0	0	0	0
p-value ¹				
				p=0.5247
Rising from Chair				
Normal	200	74	22	52
With Support	71	26	20	48
p-value ¹				
				p=0.0061
Climbing Stairs				
Normal	165	61	23	55
Requiring Assistance	106	39	19	45
p-value ¹				
				p=0.4997

¹ Wilcoxon test comparing the distribution of the ratings between the Cohort and the Tricon-M device.

Table 14

Distribution (%) of Hospital for Special Surgery (MHSS or HSS) function components for the Natural-Knee Cohort and one uncemented and one cemented (Duo-Condylar) literature-control knee.

Component	Evaluation			
	Two-Year		Latest Follow-up (Two Year Minimum)	
	Natural-Knee	PCA ³²	Natural-Knee	Duo-Condylar ³⁰
Distance Walked				
n	271	23	289	88
Unlimited	83.0	73.9	81.0	28.4
6 blocks	6.3	4.3	6.6	28.4
2-3 blocks	8.5	17.4	8.0	31.8
Indoors only	2.2	4.3	3.8	10.2
Unable to walk	0.0	0.0	0.7	1.1
p-value		0.2388		<0.0001
Rising from a Chair				
n	271	-	290	88
Normal rise	73.8	-	75.9	44.3
With support	26.2	-	24.1	48.5
Unable	0.0	-	0.0	7.2
p-value				<0.0001
Climbing Stairs				
n	271	23	290	88
Normally	60.9	52.2	63.1	27.3
Normally w/rail	32.5	47.8	31.4	60.2
Any method	6.3	0.0	3.4	0.0
Not able	0.4	0.0	2.1	12.5
p-value		0.6367		<0.0001

Table 15 Number and percentage of Cohort implants with reported radiolucencies by component.

Follow-up	Radiolucency	Component							
		Tibia		Femur		Patella		Total Knee	
		N	%	N	%	N	%	N	%
2-year	None	240	90.6	234	90.0	256	97.3	216	80.9
	<1 mm	23	8.7	24	9.2	7	2.7	47	17.6
	1-2 mm	2	0.8	2	0.8	0	0.0	4	1.5
	Total	265		260		263		267	
3-year	None	238	91.9	240	93.8	250	97.3	225	85.9
	<1 mm	20	7.7	16	6.3	7	2.7	36	13.7
	1-2 mm	1	0.4	0	0.0	0	0.0	1	0.4
	Total	259		256		257		262	
4-year	None	224	91.4	233	95.9	240	98.0	217	87.5
	<1 mm	21	8.6	8	3.3	4	1.6	28	11.3
	1-2 mm	0	0.0	2	0.8	1	0.4	3	1.2
	Total	245		243		245		248	
5-year	None	200	93.5	195	93.3	209	98.6	188	87.4
	<1 mm	13	6.1	13	6.2	3	1.4	25	11.6
	1-2 mm	1	0.5	1	0.5	0	0.0	2	0.9
	Total	214		209		212		215	
6-year	None	173	96.1	172	97.7	174	97.8	170	93.4
	<1 mm	6	3.3	3	1.7	4	2.2	10	5.5
	1-2 mm	0	0.0	1	0.6	0	0.0	1	0.5
	>2 mm	1	0.6	0	0.0	0	0.0	1	0.5
	Total	180		176		178		182	

Table 16 Percentage of devices in the Natural-Knee Cohort with radiolucency and comparison with literature-control studies of cemented (c) and uncemented (u) knee implants.

Device	Fixation	Follow-up	Control		Natural-Knee		P-Value
			N	% with Radiolucency	N	% with Radiolucency	
Femur							
Kinematic ⁹	c	Two-Year	822	12.8	267	9.7	0.1960
Posterior Cruciate Condylar ³³	c	Two-Year	73	34.2	267	9.7	<0.0001
Kinematic ¹⁰	c	Latest	123	15.4	284	4.2	0.0003
Press Fit Condylar ³¹	c	Latest	59	33.9	284	4.2	<0.0001
Duo-Condylar ³⁰	c	Latest	94	25.5	284	4.2	<0.0001
PCA ⁶	c	Latest	25	0.0	284	4.2	0.6080
PCA ⁶	u	Latest	26	0.0	284	4.2	0.6080
Patella							
Posterior Cruciate Condylar ³³	c	Two-Year	73	2.7	267	2.6	1.0000
Press Fit Condylar ³¹	c	Latest	59	13.6	284	1.1	<0.0001
Press Fit Condylar ⁴⁰	c	Latest	114	22.8	284	1.1	<0.0001
PCA ⁶	c	Latest	25	4.0	284	1.1	0.2880
PCA ⁶	u	Latest	26	23.1	284	1.1	<0.0001

Table 16, continued.

Device	Fixation	Follow-up	Control		Natural-Knee		P-Value
			N	% with Radiolucency	N	% with Radiolucency	
Tibia							
Kinematic ⁹	c	Two-Year	822	26.6	267	9.4	<0.0001
Posterior Cruciate Condylar ³³	c	Two-Year	73	21.9	267	9.4	0.0072
Total Condylar ¹	c	Two-Year	33	66.7	267	9.4	<0.0001
Tricon-M ²⁴	u	Two-Year	96	11.5	267	9.4	0.5540
Kinematic ¹⁰	c	Latest	123	17.9	284	8.8	0.0111
Posterior Stabilized Condylar ¹⁸	c	Latest	118	32.2	284	8.8	<0.0001
Press Fit Condylar ³¹	c	Latest	59	61.0	284	8.8	<0.0001
Press Fit Condylar ⁴⁰	c	Latest	114	29.8	284	8.8	<0.0001
Duo-Condylar ³⁰	c	Latest	94	75.5	284	8.8	<0.0001
PCA Keel ⁸	u	Latest	42	35.7	284	8.8	<0.0001
PCA Peg/Screws ⁸	u	Latest	30	40.0	284	8.8	<0.0001
PCA ⁶	c	Latest	25	12.0	284	8.8	0.4840
PCA ⁶	u	Latest	26	23.1	284	8.8	0.0330

46

101

Table 16, continued.

Device	Fixation	Follow-up	Control		Natural-Knee		P-Value
			N	% with Radiolucency	N	% with Radiolucency	
Knee							
Posterior Stabilized Condylar ³⁷	c	Two-Year	119	87.4	267	19.1	<0.0001
Total Condylar ²⁰	c	Latest	220	21.8	284	12.7	0.0078
PCA ⁶	c	Latest	25	12.0	284	12.7	1.0000
PCA ⁶	u	Latest	26	46.2	284	12.7	<0.0001

Table 17A Incidence of Operative-site complications for the Natural-Knee Cohort (NIDJD Patients)

Complication	Overall Incidence	
	N	%
Adhesion, Decreased R.O.M.	26	8.6
Effusion ^a	10	3.3
Knee Pain	7	2.3
Subluxation	7	2.3
Poly Wear	4	1.3
Bursitis - Knee ^b	4	1.3
Deep Infection ^c	3	1.0
Fractured Patella	3	1.0
Knee Instability	3	1.0
Hematoma	2	0.7
Knee Tendinitis	2	0.7
Patella Polyethylene Wear	2	0.7
Device Failure	2	0.7
Ankylosis	1	0.3
Femoral Wear/Patella Breakdown	1	0.3
Sepsis	1	0.3
Necrosis of Skin	1	0.3
Knee Bursitis/Tendinitis	1	0.3
Hemarthrosis	1	0.3
Knee Sprain	1	0.3
Tibial Bone Cyst	1	0.3
Knee Swelling	1	0.3
Wound Drainage	1	0.3
Knee Contusion	1	0.3
Knee Ecchymosis	1	0.3
Patellar tendon calcification	1	0.3
Wound Slough	1	0.3
Ruptured Quadriceps Mechanism	1	0.3
Loose Component	1	0.3
Stitch Abscess	1	0.3
Synovitis - Knee	1	0.3

^a Minimum 2+ effusion.

^b Five reports were received: one patient reported Knee Bursitis twice. Only four reports are counted to compute percent incidence.

^c Four reports were received; the same ongoing infection was reported twice for one patient. Only three reports are counted to compute percent incidence.

Table 17B Incidence of Operative-site complications for the Natural-Knee IJD Patients

Complication	Overall Incidence	
	N	%
Adhesion, Decreased R.O.M.	1	4.5
Knee Pain	1	4.5
Polyethylene wear	1	4.5
Femoral wear/Patella breackdown	1	4.5

Table 17C

Incidence of Operative Site Complications for the Natural-Knee (NIDJD and IJD Patients)

Complication	Overall Incidence*	
	N	%
Adhesion, Decreased R.O.M.	27	8.3
Effusion ^a	10	3.1
Knee Pain	8	2.4
Subluxation	7	2.2
Poly Wear	4	1.2
Bursitis - Knee ^b	4	1.2
Knee Instability	3	1.0
Deep Infection ^c	3	1.0
Fractured Patella	3	1.0
Femoral Wear/Patella Breakdown	2	0.6
Device Failure	2	0.6
Patella Polyethylene Wear	2	0.6
Hematoma	2	0.6
Knee Tendonitis	2	0.6
Ankylosis	1	0.3
Wear of Patella/Femur/Poly Insert	1	0.3
Sepsis	1	0.3
Wound Slough	1	0.3
Patellar tendon calcification	1	0.3
Ruptured Quadriceps Mechanism	1	0.3
Loose Component	1	0.3
Synovitis - Knee	1	0.3
Stitch Abscess	1	0.3
Knee Ecchymosis	1	0.3
Knee Contusion	1	0.3
Knee Bursitis/Tendonitis	1	0.3
Necrosis of Skin	1	0.3
Hemarthrosis	1	0.3
Knee Sprain	1	0.3
Wound Drainage	1	0.3
Knee Swelling	1	0.3
Tibial Bone Cyst	1	0.3

^a Minimum 2+ effusion.

^b Four reports were received; one patient reported Knee Bursitis twice. Only three reports are counted to compute percent incidence.

^c Four reports were received; the same ongoing infection was reported twice for one patient. Only three reports are counted to compute percent incidence.

* The patients were evaluated at an average time point of 63 months and with a maximum time point of 88 months.

Table 18A Incidence of systemic complications for the Natural-Knee Cohort (261 NIDJD patients). Systemic incidents in bilateral patients are counted once. Multiple incidents of the same complication reported by the same patient are counted only once.

Complication	Cohort Patients		Complication	Cohort Patients	
	N	%		N	%
Cardiac Disorder	30	11.5	Parkinson's Disease	2	0.8
Hip Problems	20	7.7	Phlebitis	2	0.8
Cancer	19	7.3	Allergic Reaction [†]	2	0.8
Spinal/Back Problems	19	7.3	Vascular Occlusion	1	0.8
Contralateral Osteoarthritis	19	7.3	Hypertension	1	0.4
Foot/Ankle Problems	18	6.9	Leg/Hip Pain	1	0.4
Shoulder Problems	17	6.5	Ulcer	1	0.4
Contralateral Knee Problems	17	6.5	Gout	1	0.4
Hand/Wrist/Elbow Problems	15	5.8	General Inflammatory Arthritis	1	0.4
Cerebrovascular Accident	12	4.6	Hernia	1	0.4
Digestive System Problems	9	3.5	Sinus Infection	1	0.4
Pulmonary Embolus	6	2.3	Chest Pain	1	0.4
Deep Vein Thrombosis	6	2.3	Skin Rash	1	0.4
Fall	5	1.9	Leg Pain	1	0.4
Sciatica	5	1.9	Yeast Infection	1	0.4
Diabetes Mellitus	5	1.9	Sebaceous Cyst	1	0.4
Respiratory Problems	5	1.9	Sepsis	1	0.4
Urinary Tract Infection	5	1.9	Sore Pelvis and Knees	1	0.4
Other Urinary Problems	5	1.9	Anemia	1	0.4
Cranial/Head Problems	4	1.5	Ataxia	1	0.4
Multiple Injuries/MVA	2	0.8	Chest Muscle Strain	1	0.4

[†] Allergic reactions were the result of surgery or medications not a reaction to the implant itself.

Table 18B

Incidence of Systemic complications for the Natural-Knee IJD Patients

Complication	Overall Incidence	
	N	%
Hip problems	3	13.6
Contralateral knee problems	2	9.0
Foot/ankle problems	2	9.0
Humeral fracture	2	9.0
Thigh pain	2	9.0



Table 18C Incidence of Systemic Complications for the Natural-Knee (NIDJD and IDJ Patients)

Complication	Cohort and IJD Patients*		Complication	Cohort and IJD Patients*	
	N	%		N	%
Cardiac Disorder	31	11.0	Parkinson's Disease	2	0.7
Hip Problems	23	8.2	Humeral Fracture	1	0.4
Spinal/Back Problems	20	7.1	Respiratory Infections	1	0.4
Foot/Ankle Problems	20	7.1	Leg/Hip Pain	1	0.4
Contralateral Osteoarthritis	19	6.8	Hypertension	1	0.4
Cancer	19	6.8	Brow Ptosis	1	0.4
Contralateral Knee Problems	19	6.8	Gout	1	0.4
Shoulder Problems	18	6.4	Ulcer	1	0.4
Hand/Wrist/Elbow Problems	15	5.3	General Inflammatory Arthritis	1	0.4
Cerebrovascular Accident	13	4.6	Hernia	1	0.4
Digestive System Problems	9	3.2	Sinus Infection	1	0.4
Pulmonary Embolus	6	2.1	Chest Pain	1	0.4
Other Urinary Problems	6	2.1	Vascular Occlusion	1	0.4
Deep Vein Thrombosis	6	2.1	Skin Rash	1	0.4
Fall	5	1.8	Leg Pain	1	0.4
Respiratory Problems	5	1.8	Sepsis	1	0.4
Diabetes Mellitus	5	1.8	Sebaceous Cyst	1	0.4
Sciatica	5	1.8	Yeast Infection	1	0.4
Urinary Tract Infection	5	1.8	Sore Pelvis and Knees	1	0.4
Cranial/Head Problems	4	1.4	Ataxia	1	0.4
Thigh Pain	2	0.7	Tractor Accident	1	0.4
Multiple Injuries/MVA	2	0.7	Chest Muscle Strain	1	0.4
Allergic Reaction†	2	0.7	Prostatitis	1	0.4
Phlebitis	2	0.7	Retinal Detachment	1	0.4
Anemia	2	0.7	Ear Infection	1	0.4

* The patients were evaluated at an average time point of 63 months and with a maximum time point of 88 months.

† Allergic reactions were the result of surgery or medications not a reaction to the implant itself.

Table 19 Incidence of systemic complications reported in the Natural-Knee Cohort and one or more literature-control studies of cemented (c) and uncemented (u) knee implants.

Complication	Study															
	Natural-Knee n=261		Duo-Condylar ³⁰ (c) n=88		Posterior Stabilized Condylar ³⁷ (c) n=80		Kinematic ⁹ (c) n=798		Kinematic ¹⁰ (c) n=91		Kinematic ¹⁴ (c) n=66		LCS ³ (c) n=97		LCS ⁴ (u) n=208	
	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%
Cardiac disorder	15	5.8	4	4.5	1	1.3	-	-	1	1.1	-	-	-	-	-	-
Pulmonary embolism	6	2.3	1	1.1	1	1.3	-	-	-	-	-	-	2	2.1	2	1.0
Spinal/back Problems	7	2.7	-	-	-	-	-	-	-	-	-	-	-	-	1	0.5
Deep venous thrombosis	5	1.9	-	-	-	-	-	-	-	-	1	1.5	-	-	-	-
Urinary tract infection	4	1.5	20	22.7***	-	-	-	-	3	3.3	2	3.0	-	-	-	-
Other urinary problems	2	0.8	-	-	2	2.5	-	-	1	1.1	-	-	-	-	-	-
Allergic reaction †	2	0.8	6	6.8**	-	-	-	-	1	1.1	-	-	1	1.0	0	0
Pneumonia	2	0.8	2	2.3	-	-	-	-	3	3.3	-	-	-	-	-	-
Cholecystitis	2	0.8	1	1.1	-	-	-	-	-	-	-	-	-	-	-	-
Phlebitis/ & Cellulitis	1	0.4	9	10.2***	-	-	1	0.1	1	1.1	-	-	3	3.1	5	2.4
GI bleed	1	0.4	-	-	1	1.3	-	-	2	2.2	-	-	-	-	-	-

* p<0.05

** p<0.01

*** p<0.001

† Allergic reactions were the result of surgery or medications not a reaction to the implant itself.

Table 19, continued.

Complication	Study																	
	Natural-Knee n=261		LCS ⁴ (c) n=149		PCA ⁶ (u) n=26		PCA ⁶ (c) n=25		Posterior Stabilized Condylar ¹⁸ (c) n=91		Press Fit Condylar ³¹ (c) n=52		Mixture ¹¹ (c) n=792		Total Condylar ¹ (c) n=29		Total Condylar ²⁰ (c) n=183	
	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%
Cardiac disorder	15	5.8	-	-	-	-	-	-	3	3.3	-	-	27	3.4	-	-	-	-
Pulmonary embolism	6	2.3	4	2.7	-	-	0	0	1	1.1	-	-	7	0.9	1	3.4	-	-
Spinal/back problems	7	2.7	1	0.7	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Deep venous thrombosis	5	1.9	-	-	2	7.7	2	8.0	-	-	2	3.8	10	1.3	2	6.9	-	-
Urinary tract infection	4	1.5	-	-	-	-	-	-	14	15.4***	-	-	34	4.3*	-	-	-	-
Other urinary problems	2	0.8	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Allergic reaction [†]	2	0.8	1	0.7	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Pneumonia	2	0.8	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Cholecystitis	2	0.8	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Phlebitis/ & Cellulitis	1	0.4	6	4.0*	-	-	-	-	-	-	-	-	-	-	-	-	7	3.8**
GI bleed	1	0.4	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

* p<0.05

** p<0.01

*** p<0.001

† Allergic reactions were the result of surgery or medications not a reaction to the implant itself.

55

96

Table 20 Incidence of operative-site complications in the Natural-Knee Cohort and one or more literature-control studies of cemented (c) and uncemented (u) knee implants.

Complication	Study													
	Natural-Knee n=304		Posterior Stabilized Condylar ³⁷ (c) n=119		Kinematic ⁹ (c) n=1069		Kinematic ¹⁰ (c) n=124		Kinematic ¹⁴ (c) n=79		Kinematic ³ (c) n=110		LCS ³ (c) n=123	
	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%
Adhesions/Decreased ROM	26	8.6	13	10.9	-	-	34	27.4***	5	6.3	-	-	15	12.2
Subluxation	7	2.3	-	-	5	0.5	-	-	3	3.8	6	5.5	-	-
Pain	5	1.6	-	-	1	0.1	-	-	-	-	-	-	-	-
Instability	3	1.0	-	-	-	-	-	-	3	3.8	-	-	-	-
Fracture patella	3	1.0	6	5.0*	2	0.2	-	-	2	2.5	2	1.8	-	-
Deep infection	3	1.0	2	1.7	11	1.0	-	-	3	3.8	1	0.9	5	4.1*
Bursitis	2	0.7	-	-	-	-	-	-	-	-	-	-	3	2.4
Wound drainage	1	0.3	-	-	6	0.6	-	-	5	6.3* *	-	-	-	-
Wound slough	1	0.3	-	-	-	-	-	-	-	-	-	-	1	0.8
Sepsis	1	0.3	-	-	-	-	-	-	-	-	-	-	-	-
Ruptured Quadriceps Mechanism	1	0.3	-	-	-	-	-	-	3	3.8*	1	0.9	-	-
Necrosis of skin	1	0.3	-	-	4	0.4	2	1.6	3	3.8*	-	-	-	-

56

16

Table 20, continued.

Complication	Study													
	Natural-Knee n=304		Miller-Galante ³⁵ (c) n=139		LCS ⁴ (u) n=208		LCS ⁴ (c) n=149		PCA ⁶ (u) n=26		PCA ⁶ (c) n=25		PCA ³⁴ (u) n=50	
	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%
Adhesions/Decreased ROM	26	8.6	-	-	65	31.3*	20	13.4	-	-	0	0.0	4	8.0
Subluxation	7	2.3	-	-	-	-	-	-	-	-	-	-	3	6.0
Pain	5	1.6	3	2.2	-	-	-	-	1	3.8	0	0.0	-	-
Instability	3	1.0	2	1.4	1	0.5	1	0.7	-	-	-	-	-	-
Fracture patella	3	1.0	-	-	1	0.5	0	0.0	-	-	-	-	-	-
Deep infection	3	1.0	-	-	3	1.4	14	9.4**	0	0.0	0	0.0	-	-
Bursitis	2	0.7	-	-	5	2.4	4	2.7	-	-	-	-	-	-
Wound drainage	1	0.3	-	-	-	-	-	-	-	-	-	-	-	-
Wound slough	1	0.3	2	1.4	3	1.4	3	2.0	-	-	-	-	-	-
Sepsis	1	0.3	1	0.7	-	-	-	-	-	-	-	-	-	-
Ruptured Quadriceps Mechanism	1	0.3	1	0.7	0	0.0	1	0.7	0	0.0	1	4.0	-	-
Necrosis of skin	1	0.3	-	-	-	-	-	-	-	-	-	-	-	-
Loose component	1	0.3	-	-	2	1.0	3	2.0	-	-	-	-	2	4.0*
Hematoma	1	0.3	-	-	2	1.0	6	4.0**	-	-	-	-	-	-
Hemarthrosis	1	0.3	-	-	-	-	-	-	-	-	-	-	-	-

* Incidence rate significantly larger than the Natural-Knee Cohort (p < 0.05)

† Incidence rate significantly smaller than the Natural-Knee Cohort (p < 0.05)

57

Table 20, continued.

Complication	Study											
	Natural-Knee n=304		Posterior Stabilized Condylar ¹⁸ (c) n=118		Press Fit Condylar ³¹ (c) n=59		Mixture ¹¹ (c) n=1000		Total Condylar ¹ (c) n=33		Total Condy- lar ²⁰ (c) n=220	
	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%
Adhesions/Decreased ROM	26	8.6	-	-	2	3.4	12	1.2	7	21.2*	78	35.5* **
Subluxation	7	2.3	2	1.7	-	-	5	0.5	-	-	4	1.8
Pain	5	1.6	-	-	-	-	-	-	-	-	-	-
Instability	3	1.0	-	-	-	-	-	-	-	-	-	-
Fracture patella	3	1.0	10	8.5**	1	1.7	1	0.1	-	-	-	-
Deep infection	3	1.0	1	0.8	1	1.7	15	1.5	-	-	3	1.4
Bursitis	2	0.7	-	-	-	-	-	-	-	-	-	-
Wound drainage	1	0.3	9	7.6** *	-	-	-	-	2	6.1*	42	19.1* **
Wound slough	1	0.3	-	-	-	-	-	-	-	-	-	-
Sepsis	1	0.3	-	-	-	-	-	-	-	-	-	-
Ruptured Quadriceps Mechanism	1	0.3	-	-	-	-	2	0.2	-	-	-	-
Necrosis of skin	1	0.3	4	3.4*	-	-	-	-	2	6.1*	1	0.5
Loose component	1	0.3	2	1.7	1	1.7	-	-	2	6.1*	2	0.9
Hematoma	1	0.3	6	5.1**	-	-	24	2.4*	-	-	-	-

58

19

Table 21 Natural-Knee Cohort life table. Endpoint is revision or reoperation.

Interval Since Surgery (Yr)	No. Entered Interval	No. With-drawn	No. at Risk	No. Revised Interval	Proportion			Std. Error Cumulative Survival	95% CI Cumulative Survival	
					Revised Interval	Survival Interval	Cumulative Survival		Lower	Upper
0-1	304	6	301.0	4	0.0133	0.9867	1.0000	0.0000	1.0000	1.0000
1-2	294	4	292.0	1	0.0034	0.9966	0.9867	0.0066	0.9737	0.9996
2-3	289	11	283.5	1	0.0035	0.9965	0.9833	0.0073	0.9688	0.9978
3-4	277	18	268.0	3	0.0112	0.9888	0.9798	0.0081	0.9639	0.9958
4-5	256	15	248.5	4	0.0161	0.9839	0.9688	0.0102	0.9488	0.9889
5-6	237	46	214.0	3	0.0140	0.9860	0.9532	0.0126	0.9284	0.9781
6-7	188	166	105.0	0	0.0000	1.0000	0.9399	0.0146	0.9111	0.9686
7-8	22	22	11.0	0	0.0000	1.0000	0.9399	0.0146	0.9111	0.9686

59

nd

Table 22 The cumulative survival rate estimates through four years for the Natural-Knee Cohort and for osteoarthritic knees in literature-control studies.

Interval	Natural-Knee Cohort (N=304)	Total Condylar ³⁸ (N=N/A*)	Total Condylar ²⁹ (N=50)	Total Condylar ^{22**} (N=281)	PCA ²⁸ (N=35)	Townley ^{22**} (N=431)	Geomedic ^{22**} (N=151)
0 - 1	98.7	99.4	100	97.0	100	96.5	99.3
1 - 2	98.3	98.7	100	96.1	100	94.2	93.5
2 - 3	98.0	97.9	100	95.4	100	92.7	93.0
3 - 4	96.9	97.9	100	95.4	88.0	90.5	93.0

* The number at risk for osteoarthritis is not given. The number of implants for all diagnosis was 224.
 ** Survival estimates were read from a figure in the article providing cumulative survival rates for the device.

Table 23 Comparison of the Natural-Knee Cohort cumulative survival probabilities with literature source controls. Failure in the Cohort is defined as reoperation or revision.

Device	N	Cumulative Two-Year Survival	Standard Error	Z-Statistic	P-Value	Cumulative Three-Year Survival	Standard Error	Z-Statistic	P-Value
Natural-Knee (Cohort)	304	0.9833	0.0074	-	-	0.9798	0.0082	-	-
LCS ⁵ (Bicruciate-Retaining)	25	1.0000	0.0000	0.67	0.5045	1.0000	0.0000	0.18	0.8594
LCS ⁵ (Rotating-Platform)	65	0.9813	0.0185	0.37	0.7127	0.9813	0.0185	0.39	0.6983
LCS ⁵ (Posterior Cruciate Retaining)	57	0.9789	0.0211	0.27	0.7878	0.9789	0.0211	0.42	0.6739
PCA ²⁸	108	0.9910	0.0092	0.12	0.9039	0.9530	0.0205	0.93	0.3522
Cemented									
LCS ⁵ (Bicruciate-Retaining)	21	1.0000	0.0000	1.18	0.2374	0.9091	0.0867	0.52	0.6033
LCS ⁵ (Rotating-Platform)	43	0.9753	0.0244	0.21	0.8361	0.9753	0.0244	0.34	0.7331
Posterior Stabilized Condylar ³⁷	917	0.9936	0.0029	1.02	0.3081	0.9912	0.0038	1.03	0.3050
Posterior Stabilized Condylar ³⁶	137	1.0000	0.0000	1.54	0.1237	0.9901	0.0099	0.39	0.6964
Total Condylar ³⁸	224	0.9846	0.0088	0.22	0.8232	0.9787	0.0106	0.21	0.8355
Freeman, Sheehan, and Manchester ³⁸	365	0.9683	0.0099	0.97	0.3324	0.9057	0.0182	3.56	0.0003
Two and Three compartment knees ²²	3604	0.9481	0.0042	3.93	<0.000	0.9279	0.0052	5.17	<0.000
Stanmore ²⁷	194	0.9515	0.0158	1.58	0.1140	0.9340	0.0184	2.07	0.0388
Stanmore ¹³	103	1.0000	0.0000	1.38	0.1686	0.9532	0.0228	0.83	0.4065
Attenborough ²¹	172	0.9278	0.0201	2.38	0.0173	0.8651	0.0268	3.93	<0.000
Oxford ¹²	153	0.9821	0.0125	0.25	0.7995	0.9581	0.0207	0.75	0.4505

Table 23, continued.

Device	N	Cumulative Four-Year Survival	Standard Error	Z-Statistic	P-Value
Cementless					
Natural-Knee (Cohort)	304	0.9686	0.0103	-	-
LCS ⁵ (Bicruciate-Retaining)	25	1.0000	0.0000	0.947	0.3435
LCS ⁵ (Rotating-Platform)	65	0.9813	0.0185	0.758	0.8738
LCS ⁵ (Posterior Cruciate Retaining)	57	0.9789	0.0208	0.005	0.9960
PCA ²⁸	108	0.8780	0.0331	2.433	0.0089
Cemented					
LCS ⁵ (Bicruciate-Retaining)	21	0.9091	0.0866	0.389	0.6965
LCS ⁵ (Rotating-Platform)	43	0.9753	0.0243	0.248	0.8040
Posterior Stabilized Condylar ³⁸	917	0.9874	0.0052	1.439	0.1499
Posterior Stabilized Condylar ³⁷	137	0.9627	0.0105	0.025	0.9795
Total Condylar ³⁸	224	0.9787	0.0213	0.421	0.6737
Freeman, Sheehan, and Manchester ³⁹	365	0.8487	0.0243	4.428	<0.0001
Two and Three compartment knees ²²	3604	0.9077	0.0064	4.875	<0.0001
Stanmore ²⁷	194	0.9089	0.0217	2.309	0.0209
Stanmore ¹³	103	0.9120	0.0318	1.498	0.1339
Attenborough ²¹	172	0.8388	0.0290	4.069	<0.0001
Oxford ¹²	153	0.9375	0.0287	0.858	0.3904

Table 24 Five-year cumulative survival of the Cohort and historical controls. Failure is defined as the reoperation or revision of the knee implant.

Device	Effective Sample Size ^a	Cumulative Survival	Standard Error
Cohort	214.0	0.953	0.0363
Posterior Stabilized Condylar ³⁸	69.0	0.987	0.0052
Total Condylar ³⁸	120.5	0.979	0.0105
Freeman, Sheehan, and Manchester ³⁹	57.5	0.776 ^b	0.0322
2-3 Compartment Knees (OA) ²²	162.0	0.878 ^b	0.0124
2-3 Compartment Knees (RA) ²²	280.0	0.911 ^c	0.0088
Stanmore ²⁷	120.0	0.889 ^c	0.0242
Attenborough ²¹	67.0	0.792 ^b	0.0331
PCA ²⁸	83.0	0.842 ^b	0.0363

^a Effective sample size is given as the number of implants without the failure event at the start of the 5- year interval minus half of the implants that were censored during the year. The assumption is that each of the censored implants were followed for half of the interval.

^b Survival is significantly lower compared to the Natural-Knee Cohort survival ($p < 0.01$).

^c Survival is significantly lower compared to the Natural-Knee Cohort survival ($p < 0.05$).

Table 25 Six-year cumulative survival of the Cohort and historical controls. Failure is defined as the reoperation or revision of the knee implant.

Device	Effective Sample Size ^a	Cumulative Survival	Standard Error
Cohort	106.5	0.940	0.0373
Total Condylar ³⁸	105.5	0.962	0.0154
2 or 3 Compartment Knees (OA) ²²	55.5	0.867 ^b	0.0144
2 or 3 Compartment Knees (RA) ²²	96.5	0.901	0.0104
Stanmore ²⁷	106.5	0.874	0.0260
PCA ²⁸	82.0	0.832 ^c	0.0373

^a Effective sample size is given as the number of implants without the failure event at the start of the 6-year interval minus half of the implants that were censored during the year. The assumption is that each of the censored implants were followed for half of the interval.

^b Survival is significantly lower compared to the Natural-Knee Cohort survival ($p < 0.01$).

^c Survival is significantly lower compared to the Natural-Knee Cohort survival ($p < 0.05$).

Table 26 Patient Follow-Up for the Natural-Knee

	Evaluation						
	1-yr	2-yr	3-yr	4-yr	5-yr	6-yr	7-yr
Theoretically Due ^a	326	326	326	326	326	314	52
Death	2	3	7 ^b	7 ^c	15 ^d	8 ^e	3
Revision/Reoperation	2/3	0/1	0/1	2/1	1/4	1/2	0/1
Implants Expected ^f	322	319	312	303	285	268 ^g	43 ^h
Implants Evaluated	301	291	282	267	232	206	27
MHSS Evaluation							
Complete	297	285	276	257	224	188	23
Partial	4	6	5	10	8	18	4
X-ray only	0	0	1	0	0	0	0
Radiographic Evaluation							
Complete	280	258	246	243	208	175	23
Partial	18	29	34	21	21	19	3
No X-rays taken	3	4	2	3	3	12	1
% Theoretical Follow-up ⁱ	91.1	87.4	84.7	78.8	68.7	57.7	44.2
% Expected Follow-up ^j	93.5	91.2	90.4	88.1	81.4	77.4	62.8

^a Theoretically Due is defined as the number of implants that would have been examined if all patients had returned on the exact anniversary of their respective surgery dates.

^b Five patient deaths involving seven study implants (two bilateral patients died).

^c Five patient deaths involving seven study implants (two bilateral patients died).

^d Twelve patient deaths involving 15 study implants (three bilateral patients died).

^e Seven patient deaths involving eight study implants (two bilateral patients died; however, the "death" of one patient's first implant occurred and is counted in the 7-year interval).

^f Implants Expected is defined as theoretically due minus cumulative deaths and revisions.

^g Forty-six of the 48 cumulative deaths and revisions were theoretically due for a 6-year evaluation.

^h Nine of the 51 cumulative deaths and revisions were theoretically due for a 7-year evaluation.

ⁱ Computed as complete MHSS evaluations divided by theoretically due.

^j Computed as implants evaluated divided by implants expected.

REFERENCES

- 1 Aglietti, P, E Rinonapoli: Total Condylar Knee arthroplasty: A five-year follow-up study of 33 knees. *Clinical Orthopaedics and Related Research* 186:104-111, 1984.
- 2 Bloebaum, RD, MH Rubman, LD Dorr: Bone maturation and mineralization at the implant interface of retrieved porous coated femoral hip components. *Clinical Orthopaedics and Related Research* manuscript submitted.
- 3 Buechel, FF, MJ Pappas: The New Jersey Low-Contact-Stress Knee Replacement System: Biomechanical rationale and review of the first 123 cemented cases. *Archives of Orthopaedic and Traumatic Surgery* 105:197-204, 1986.
- 4 Buechel, FF, MJ Pappas: New Jersey Low Contact Stress Knee Replacement System: Ten-year evaluation of meniscal bearings. *Orthopedic Clinics of North America* 20:147-177, 1989.
- 5 Buechel, FF, MJ Pappas: Long-term survivorship analysis of cruciate-sparing versus cruciate-sacrificing knee prostheses using meniscal bearings. *Clinical Orthopaedics and Related Research* 260:162-169, 1990.
- 6 Collins, DN, SA Heim, CL Nelson, PC Smith, III: Porous-Coated Anatomic total knee arthroplasty: A prospective analysis comparing cemented and cementless fixation. *Clinical Orthopaedics and Related Research* 267:128-136, 1991.
- 7 Dodd, CAF, DS Hungerford, KA Krackow: Total knee arthroplasty fixation: Comparison of the early results of paired cemented versus uncemented Porous Coated Anatomic knee prostheses. *Clinical Orthopaedics and Related Research* 260:66-70, 1990.
- 8 Engh, GA, JD Bobyn, TL Petersen: Radiographic and histologic study of porous coated tibial component fixation in cementless total knee arthroplasty. *Orthopedics* 11:725-731, 1988.
- 9 Ewald, FC, HP Hsu, PS Walker: Is Kinematic total knee replacement better than total hip replacement? *Orthopedic Clinics of North America* 20:79-88, 1989.
- 10 Ewald, FC, MA Jacobs, RE Miegel, PS Walker, R Poss, C.B. Sledge: Kinematic total knee replacement. *The Journal of Bone and Joint Surgery* 66-A:1032-1040, 1984.
- 11 Gill, GS, DM Mills: Long-term follow-up evaluation of 1000 consecutive cemented total knee arthroplasties. *Clinical Orthopaedics and Related Research* 273:66-76, 1991.
- 12 Goodfellow, JW, J O'Connor: Clinical results of the Oxford knee: Surface arthroplasty of the tibiofemoral joint with a meniscal bearing prosthesis. *Clinical Orthopaedics and Related Research* 205:21-42, 1986.
- 13 Grimer, RJ, MRK Karpinski, AN Edwards: The long-term results of Stanmore total knee replacements. *The Journal of Bone and Joint Surgery* 66-B:55-62, 1984.
- 14 Hanssen, AD, J.A. Rand: A comparison of primary and revision total knee arthroplasty using the Kinematic Stabilizer prosthesis. *The Journal of Bone and Joint Surgery* 70-A:491-499, 1988.



- 15 Hofmann, AA, KN Bachus, AU Daniels, LA Dauterman: Quantitative analysis of bone ingrowth into porous coated metal test plugs implanted into human cancellous bone. Presented at the Society for Biomaterials Symposium on Retrieval and Analysis of Surgical Implants and Biomaterials, Snowbird, Utah, 1988.
- 16 Hungerford, DS, RV Kenna: Preliminary experience with a total knee prosthesis with porous coating used without cement. *Clinical Orthopaedics and Related Research* 176:95-107, 1983.
- 17 Hungerford, DS, KA Krackow, RV Kenna: Two-to-five year experience with a cementless porous-coated total knee prosthesis. In: Rand, JA, LD Dorr, editors, *Total Arthroplasty of the Knee. Proceedings of the Knee Society, 1985 and 1986*, pp. 215-235. Rockville, Maryland: Aspen, 1987.
- 18 Insall, JN, PF Lachiewicz, AH Burstein: The Posterior Stabilized Condylar prosthesis: A modification of the Total Condylar design (two to four-year clinical experience). *The Journal of Bone and Joint Surgery* 64-A:1317-1323, 1982.
- 19 Insall, JN, CS Ranawat, P Aglietti, J Shine: A comparison of four models of total knee-replacement prostheses. *The Journal of Bone and Joint Surgery* 58-A:754-765, 1976.
- 20 Insall, JN, WN Scott, CS Ranawat: The Total Condylar Knee prosthesis: A report of two hundred and twenty cases. *The Journal of Bone and Joint Surgery* 61-A:173-180, 1979.
- 21 Kershaw, CJ, AEG Themen: The Attenborough knee: A four- to ten-year review. *The Journal of Bone and Joint Surgery* 70-B:89-93, 1988.
- 22 Knutson, K, A Lindstrand, L Lidgren: Survival of knee arthroplasties: A nation-wide multicentre investigation of 8000 cases. *The Journal of Bone and Joint Surgery* 68-B:795-803, 1986.
- 23 Kim, YH: Knee arthroplasty using a cementless PCA prosthesis with a porous-coated central tibial stem: Clinical and radiographic review at five years. *The Journal of Bone and Joint Surgery* 72-B:412-417, 1990.
- 24 Laskin, RS: Tricon-M uncemented total knee arthroplasty: A review of 96 knees followed for longer than 2 years. *The Journal of Arthroplasty* 3:27-38, 1988.
- 25 Laupacis, A, R Bourne, C Rorabeck, D Feeny, C Wong, P Tugwell, K Leslie, R Bullas: The effect of elective total hip replacement on health-related quality of life. *The Journal of Bone and Joint Surgery* 72-A:1619-1626, 1993.
- 26 Laupacis, A, CH Rorabeck, RB Bourne, D Feeny, P Tugwell, DA Sim: Randomized trials in orthopaedics: Why, how, and when? *The Journal of Bone and Joint Surgery* 71-A:535-543, 1989.
- 27 Lettin, AWF, HS Ware, RW Morris: Survivorship analysis and confidence intervals: An assessment with reference to the Stanmore total knee replacement. *The Journal of Bone and Joint Surgery* 73-B:729-731, 1991.
- 28 Moran, CG, IM Pinder, TA Lees, MJ Midwinter: Survivorship analysis of the uncemented Porous-Coated Anatomic knee replacement. *The Journal of Bone and Joint Surgery* 73-A:848-857, 1991.

- 29 Ranawat, CS, WF Flynn, Jr, S Saddler, KK Hansraj, MJ Maynard: Long-term results of the Total Condylar Knee arthroplasty: A 15-year survivorship study. *Clinical Orthopaedics and Related Research* 286:94-102, 1993.
- 30 Ranawat, CS, J Insall, J Shine: Duo-Condylar knee arthroplasty: Hospital for Special Surgery design. *Clinical Orthopaedics and Related Research* 120:76-82, 1976.
- 31 Rand, JA: Cement or cementless fixation in total knee arthroplasty? *Clinical Orthopaedics and Related Research* 273:52-62, 1991.
- 32 Rand, JA, RS Bryan: Porous-ingrowth total knee arthroplasty. *Techniques in Orthopaedics* 1:31-40, 1987.
- 33 Ritter, MA, TJ Gie, EA Stringer: Radiolucency surrounding the Posterior Cruciate Condylar total knee prosthetic components. *Clinical Orthopaedics and Related Research* 160:149-152, 1981.
- 34 Rorabeck, MD, RB Bourne, L Nott.: The cemented Kinematic-II and the non-cemented Porous-Coated Anatomic prostheses for total knee replacement: A prospective evaluation. *The Journal of Bone and Joint Surgery* 70-A:483-490, 1988.
- 35 Rosenberg, AG, RM Barden, JO Galante: Cemented and ingrowth fixation of the Miller-Galante prosthesis: Clinical and roentgenographic comparison after three- to six-year follow-up studies. *Clinical Orthopaedics and Related Research* 260:71-79, 1990.
- 36 Rudicel, S, J Esdaile: The randomized clinical trial in orthopaedics: Obligation or option? *The Journal of Bone and Joint Surgery* 67-A:1284-1293, 1985.
- 37 Scott, WN, M Rubinstein, G Scuderi: Results after knee replacement with a posterior cruciate-substituting prosthesis. *The Journal of Bone and Joint Surgery* 70-A:1163-1173, 1988.
- 38 Scuderi, GR, JN Insall, RE Windsor, MC Moran: Survivorship of cemented knee replacements. *The Journal of Bone and Joint Surgery* 71-B:798-803, 1989.
- 39 Tew, M, W Waugh: Estimating the survival time of knee replacements. *The Journal of Bone and Joint Surgery* 64-B:579-582, 1982.
- 40 Wright, RJ, J Lima, RD Scott, TS Thornhill: Two- to four-year results of posterior cruciate-sparing condylar total knee arthroplasty with an uncemented femoral component. *Clinical Orthopaedics and Related Research* 260:80-86, 1990.
- 41 Bischoff UW, MA Freeman, D Smith, MA Tuke, PJ Gregson: Wear induced by motion between bone and titanium or cobalt-chrome alloys. *J. Bone and Joint Surgery Br.* 76(5):713-6, September 1994.
- 42 La Budde JK; JF Orosz, TA Bonfiglio, VD Pellegrini. Particulate titanium and cobalt-chrome metallic debris in failed total knee arthroplasty. A quantitative histological analysis. *J. Arthroplasty*, 9(3):291-304, June 1994.
- 43 Salvati EA; Betts F; Doty SB. Particulate metallic debris in cemented total hip arthroplasty. *Clin Orthop*, (293):p160-73, Aug 1993.
- 44 Blankston AB; Faris PM; Keating EM; Ritter MA. Polyethylene wear in total hip arthroplasty in patient-matched groups. A comparison of stainless steel, cobalt-chrome,



and titanium-bearing surfaces. *J. Arthroplasty*, 8(3):315-22, June 1993.

45. Peterson CD; Hillberry BM; Heck DA. Component wear of total knee prostheses using Ti-6Al-4V, titanium nitrided coated Ti-6Al-4V, and cobalt-chromium-molybdenum femoral components. *J Biomed Mater Res*, ss(10):887-903, Oct 1988.
46. Milliano MT; Whiteside LA. Articular surface material effect on metal-backed patellar components: A microscopic evaluation. *Clin. Orthop Relat Res.*, 273:204-214, 1991.
47. Whiteside, LA: Cementless Total Knee Arthroplasty. In Rand, JA, editor, *Total Knee Arthroplasty*, pp. 329-347. New York: Raven Press LTD., 1993.
48. Hanes C.; Dywer K. Analysis of Polyethylene Wear in Metal Backed Knee Arthroplasty. *British JBJS*, Jan 1992.



LABELING

8

INTERMEDICS ORTHOPEDICS® NATURAL-KNEE® SYSTEM

SURGICAL TECHNIQUE

Aaron A. Hofmann, MD
Professor of Orthopedic Surgery
University of Utah Medical Center
Salt Lake City, Utah



Intermedics Orthopedics, Inc.
A company of *SULZERmedica*

Inspired by nature. Driven by science.

NATURAL-KNEE® PRIMARY SYSTEM

Device Description

The Natural-Knee System consists of three anatomically designed components: the femoral, tibial and patellar prostheses. They are semiconstrained in design and both medial and lateral collateral ligaments must be intact. The tibial components are cruciate retaining.

The cast cobalt-chrome (CoCr) femoral components are anatomically designed with left and right components.

The tibial component consists of two parts, a metallic baseplate (Ti-6Al-4V) and a polyethylene insert (UHMWPE), which are assembled at the time of surgery via a snap-lock mechanism. The tibial baseplate is available in both a stemmed and resurfacing option. The tibial inserts form the bearing surface for tibiofemoral articulations. Both congruent and ultracongruent tibial insert options are available.

The metal-backed patellar component has a radially symmetric polyethylene (UHMWPE) dome attached to a circular baseplate (Ti-6Al-4V). The baseplate has three smooth pegs and is partially coated with Cancellous-Structured Titanium™ (CSTi™) on the inferior surface. The bearing surface conforms to the patellar groove on the anterior flange of the femoral component.

The bone-contacting surfaces of all three metallic components are partially coated with CSTi made of commercially pure titanium. The CSTi is metallurgically bonded to the prosthesis by a proprietary sintering process. The coating provides a surface consisting of interconnected three-dimensional pores for biologic fixation of the device.

Due to the design of the device, components of the Natural-Knee System should not be interchanged with components of other manufacturers.

Indications for Use

The Natural-Knee with Cancellous-Structured Titanium (CSTi) is indicated for noncemented use in skeletally mature individuals undergoing primary surgery for rehabilitating knees damaged as a result of Noninflammatory Degenerative Joint Disease (NIDJD) or Inflammatory Joint Disease (IJ).



NATURAL-KNEE® PRIMARY SYSTEM

Device Description

The Natural-Knee System consists of three anatomically designed components: the femoral, tibial and patellar prostheses. They are semiconstrained in design and both medial and lateral collateral ligaments must be intact. The tibial components are cruciate retaining.

The cast cobalt-chrome (CoCr) femoral components are anatomically designed with left and right components.

The tibial component consists of two parts, a metallic baseplate (Ti-6Al-4V) and a polyethylene insert (UHMWPE), which are assembled at the time of surgery via a snap-lock mechanism. The tibial baseplate is available in both a stemmed and resurfacing option. The tibial inserts form the bearing surface for tibiofemoral articulations. Both congruent and ultracongruent tibial insert options are available.

The metal-backed patellar component has a radially symmetric polyethylene (UHMWPE) dome attached to a circular baseplate (Ti-6Al-4V). The baseplate has three smooth pegs and is partially coated with Cancellous-Structured Titanium™ (CSTi™) on the inferior surface. The bearing surface conforms to the patellar groove on the anterior flange of the femoral component.

The bone-contacting surfaces of all three metallic components are partially coated with CSTi made of commercially pure titanium. The CSTi is metallurgically bonded to the prosthesis by a proprietary sintering process. The coating provides a surface consisting of interconnected three-dimensional pores for biologic fixation of the device.

Due to the design of the device, components of the Natural-Knee System should not be interchanged with components of other manufacturers.

Indications for Use

The Natural-Knee with Cancellous-Structured Titanium (CSTi) is indicated for noncemented use in skeletally mature individuals undergoing primary surgery for rehabilitating knees damaged as a result of Noninflammatory Degenerative Joint Disease (NIDJD) or Inflammatory Joint Disease (IJ).



Restoration of Normal Alignment

Normal alignment usually implies that the mechanical axis, from the center of the hip to the center of the ankle, will pass through the center of the knee. The implant should be positioned perpendicular to that line. Correct positioning is usually accomplished by cutting the tibia perpendicular or in slight varus in the frontal plane and by cutting the distal femur in 6 degrees of valgus from the anatomic axis (Figure 1). A standard 6-degree valgus cut of the femur is recommended for two reasons. First, the anatomic-mechanical axis angle can be measured from a radiograph, but it may be inaccurate by 1 degree to 2 degrees because of rotational inconsistency. Second, the true anatomic axis may be off by 1 degree to 2 degrees with all intramedullary instruments if the starting point on the distal femur is too medial or lateral, or if the medullary rod is not perfectly centered in the medullary canal.

For marked anatomic variation (i.e., malunion), the instrumentation can be used with an external alignment tower pointing toward the preoperatively marked femoral head. For minor anatomic variation and intraoperative correction of the distal femoral or proximal tibia cuts, a ± 2 -degree block is available.

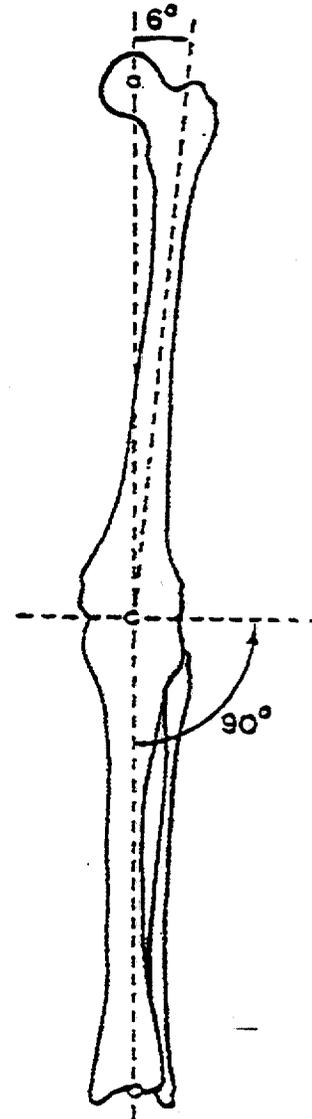


Figure 1

Preoperative Planning

Obtain 36-inch, or preferably 52-inch, standing anteroposterior and lateral radiographs of the extremity as well as a sunrise view of the patella. The entire femur should be visualized to rule out any structural abnormality, as the distal femoral cut will be referenced from an intramedullary rod in the medullary canal. If the intramedullary tibial instruments are used, the entire tibia should be visualized to identify any varus or valgus bowing, and the appropriate tibial entry point planned. Templating for size is most accurate on the lateral radiograph since many patients present with a flexion contracture that distorts magnification on the anteroposterior radiograph. The intraoperative management of tibial defects are planned using bone graft, cement and/or tibial spacers.

The degree of constraint in the tibial insert may be planned, such as the use of the ultracongruent insert for more constraint in patients with posterior cruciate ligament (PCL) deficiency or in the unstable varus or valgus knee.

Surgical Technique

Bone Cuts

Bone resorption and connective tissue formation occur when bone is surgically traumatized and heated to above 47 degrees centigrade for longer than one minute. To control thermal injury, the saw blade is cooled by constant irrigation when making bone cuts.¹² All bone cuts should be made with the low-profile, removable saw capture which allows for precision cuts (Figure 2).

To ensure that a perfectly flat surface has been created, the saw capture is removed and all bone cuts sighted (in two planes) against the cutting blocks. The flatness can also be checked using an auxiliary cutting block.

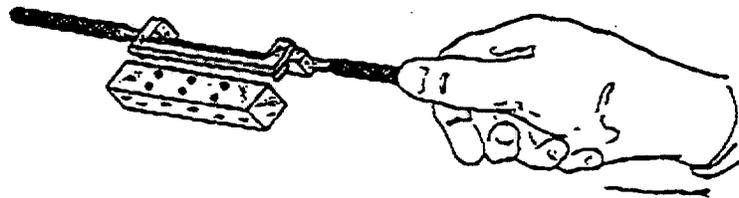


Figure 2

¹²Krause, W.R., et al., "Temperature Elevations in Orthopaedic Cutting Operations," *Journal of Biomechanics*, 1982, Vol. 15, No. 4, pp. 267-275.

90

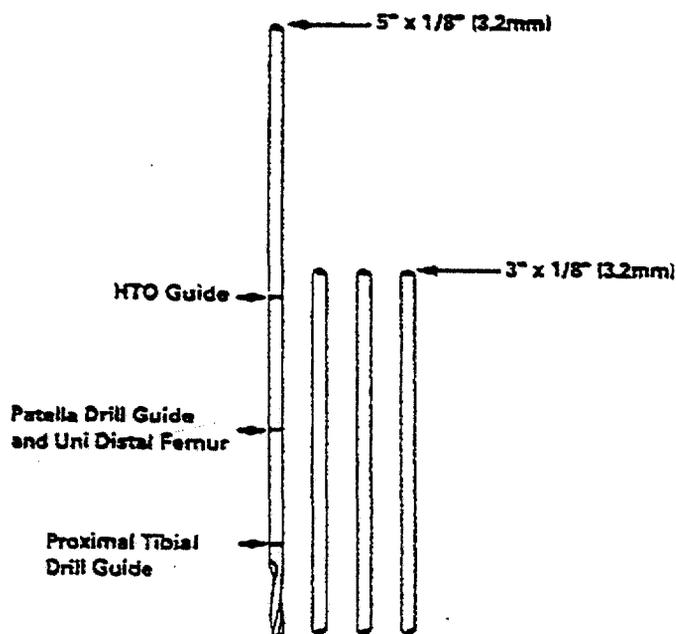


Figure 3

Each cutting block is stabilized first by drilling with a 1/8-inch (3.2mm) by 5-inch drill bit that remains loaded in the Jacob's chuck. The drilled holes are then filled with 1/8-inch by 3-inch smooth pins. The first calibrated mark on the drill point indicates the drilling depth of the tibial baseplate pegs; the second mark is for the metal-backed patella pegs. (The third calibration is for use with the Natural-Knee High Tibial Osteotomy System.) This drill bit can be found along with one 1/8-inch by 5-inch and four 1/8-inch by 3-inch pins in the Natural-Knee Disposable Drill and Pin Set (Catalog #2001-00-000) (Figure 3).

It is recommended that the Intermedics Orthopedics 1/2-inch wide and 1-inch wide (.039-inch thick) saw blades be used for accurate and consistent results. New 1-inch wide blades are used for each surgery. The 1/2-inch wide blade is used to make the step cut in the anterior chamfer and can be reused. Sharp saw blades will decrease both operating time as well as injury to the bone.

91

Surgical Technique Summary

Preparing the Distal Femur

The femur is prepared in five steps:

- (1) Locating the intramedullary canal (Figure 4)
- (2) Cutting the distal femur (Figure 5)
- (3) Drilling distal femoral holes and calibrating the femur (Figure 6)
- (4) Cutting the anteroposterior femur (Figure 7)
- (5) Making chamfer cuts (Figure 8).

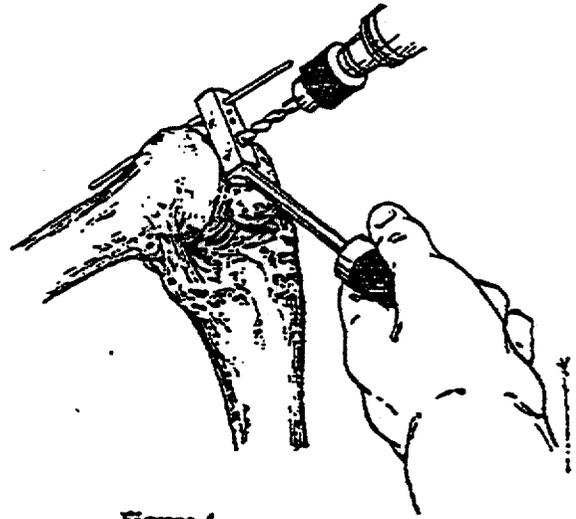


Figure 4

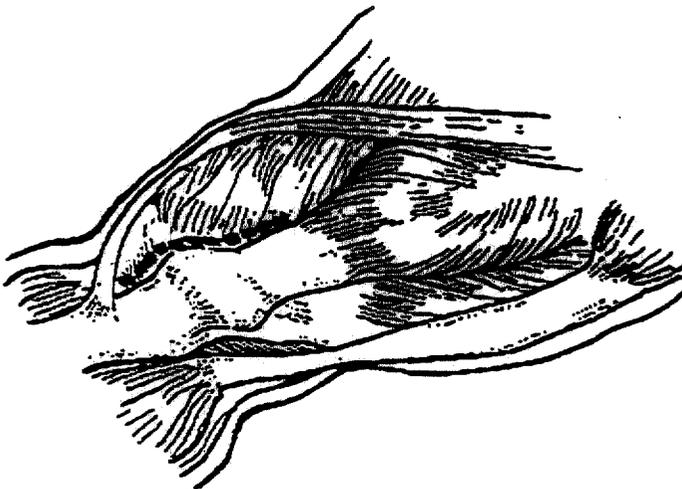


Figure 5

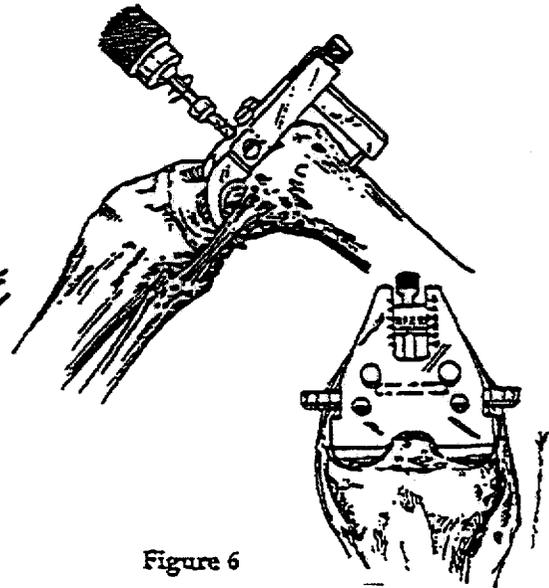


Figure 6

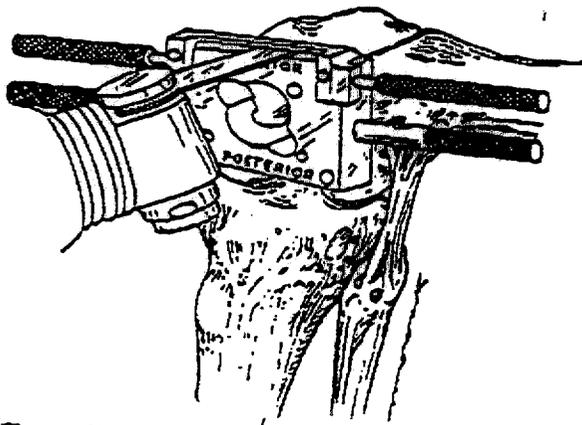


Figure 7

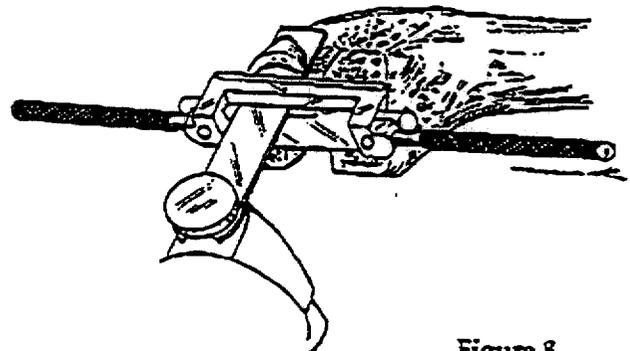


Figure 8

7
98

INTERMEDICS ORTHOPEDICS® NATURAL-KNEE® II SYSTEM

PRIMARY SURGICAL TECHNIQUE

Aaron A. Hofmann, MD
Professor of Orthopedic Surgery
University of Utah Medical Center
Salt Lake City, Utah

and

Kenneth A. Gustke, MD
Florida Orthopaedic Institute
Tampa, Florida



Intermedics Orthopedics, Inc.
A company of **SULZERmedica**

Inspired by nature. Driven by science.

NATURAL-KNEE® II PRIMARY SYSTEM

Device Description

The Natural-Knee II System consists of three anatomically designed components: the femoral, tibial and patellar prostheses. They are semiconstrained in design and both medial and lateral collateral ligaments must be intact. The tibial components are cruciate retaining.

The cast cobalt-chrome (CoCr) femoral components are anatomically designed with left and right components.

The tibial component consists of two parts, a metallic baseplate (Ti-6Al-4V) and a polyethylene insert (UHMWPE), which are assembled at the time of surgery via a snap-lock mechanism. The tibial baseplate is available in both a stemmed and resurfacing option. The tibial inserts form the bearing surface for tibiofemoral articulations. Both congruent and ultracongruent tibial insert options are available.

The metal-backed patellar component has a radially symmetric polyethylene (UHMWPE) dome attached to a circular baseplate (Ti-6Al-4V). The baseplate has three smooth pegs and is partially coated with Cancellous-Structured Titanium™ (CSTi™) on the inferior surface. The bearing surface conforms to the patellar groove on the anterior flange of the femoral component.

The bone-contacting surfaces of all three metallic components are partially coated with CSTi made of commercially pure titanium. The CSTi is metallurgically bonded to the prosthesis by a proprietary sintering process. The coating provides a surface consisting of interconnected three-dimensional pores for biologic fixation of the device.

Due to the design of the device, components of the Natural-Knee II System should not be interchanged with components of other manufacturers.

Indications for Use

The Natural-Knee II with Cancellous Structured Titanium (CSTi) is indicated for noncemented use in skeletally mature individuals undergoing primary surgery for rehabilitating knees damaged as a result of Noninflammatory Degenerative Joint Disease (NIDJD) or Inflammatory Joint Disease (IJD).

Restoration of Normal Alignment

Normal alignment usually implies that the mechanical axis, from the center of the hip to the center of the ankle, will pass through the center of the knee. The implant should be positioned perpendicular to that line. Correct positioning is usually accomplished by cutting the tibia perpendicular or in slight varus in the frontal plane and by cutting the distal femur in 6 degrees of valgus from the anatomic axis (Figure 1). A standard 6-degree valgus cut of the femur is recommended for two reasons. First, the anatomic-mechanical axis angle can be measured from a radiograph, but it may be inaccurate by 1 degree to 2 degrees because of rotational inconsistency. Second, the true anatomic axis may be off by 1 degree to 2 degrees with all intramedullary instruments if the starting point on the distal femur is too medial or lateral, or if the medullary rod is not perfectly centered in the medullary canal.

For marked anatomic variation (i.e., malunion), the instrumentation can be used with an external alignment tower pointing toward the preoperatively marked femoral head. For minor anatomic variation and intraoperative correction of the distal femoral or proximal tibia cuts, a ± 2 -degree block is available.

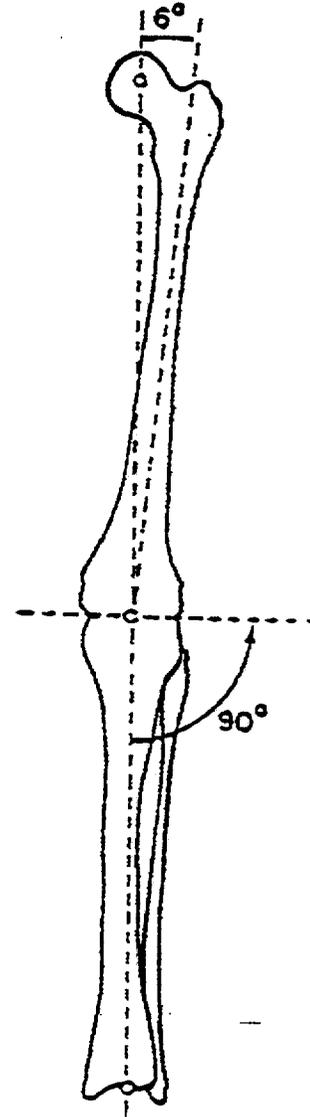


Figure 1

95

Preoperative Planning

Obtain 36-inch, or preferably 52-inch, standing anteroposterior and lateral radiographs of the extremity as well as a sunrise view of the patella. The entire femur should be visualized to rule out any structural abnormality, as the distal femoral cut will be referenced from an intramedullary rod in the medullary canal. If the intramedullary tibial instruments are used, the entire tibia should be visualized to identify any varus or valgus bowing, and the appropriate tibial entry point planned. Templating for size is most accurate on the lateral radiograph since many patients present with a flexion contracture that distorts magnification on the anteroposterior radiograph. The intraoperative management of tibial defects are planned using bone graft, cement and/or tibial spacers.

The degree of constraint in the tibial insert may be planned, such as the use of the ultracongruent insert or traditional posterior stabilized components for more constraint in patients with posterior cruciate ligament (PCL) deficiency or in the unstable varus or valgus knee.

¹²Krause, W.R., et al., "Temperature Elevations in Orthopaedic Cutting Operations," *Journal of Biomechanics*, 1982, Vol. 15, No. 4, pp. 267-275.

Surgical Technique

Bone Cuts

Bone resorption and connective tissue formation occur when bone is surgically traumatized and heated to above 47 degrees centigrade for longer than one minute. To control thermal injury, the saw blade is cooled by constant irrigation when making bone cuts.¹² All bone cuts should be made with the low-profile, removable saw capture which allows for precision cuts (Figure 2).

To ensure that a perfectly flat surface has been created, the saw capture is removed and all bone cuts sighted (in two planes) against the cutting blocks. The flatness can also be checked using an auxiliary cutting block.

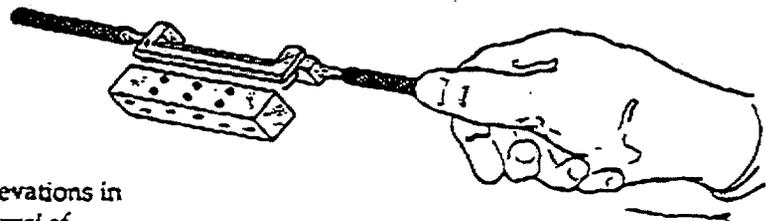


Figure 2

3
96

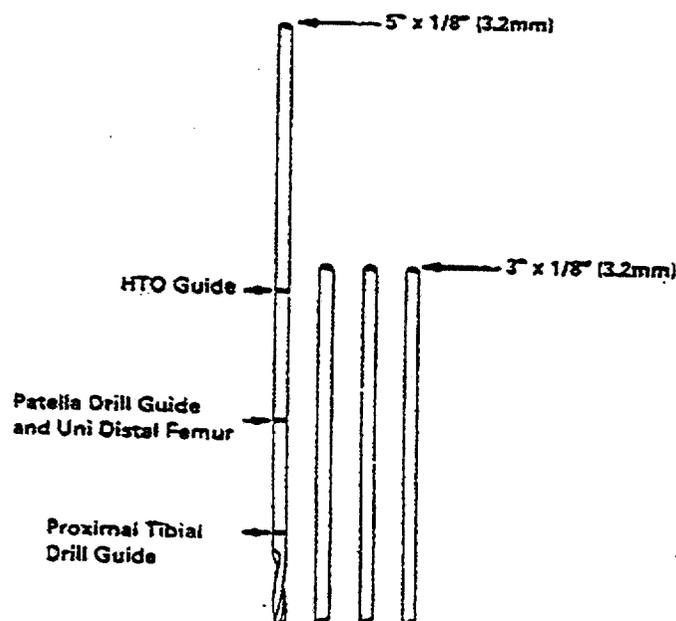


Figure 3

Each cutting block is stabilized first by drilling with a 1/8-inch (3.2mm) by 5-inch drill bit that remains loaded in the Jacob's chuck. The drilled holes are then filled with 1/8-inch by 3-inch smooth pins. The first calibrated mark on the drill point indicates the drilling depth of the tibial baseplate pegs; the second mark is for the metal-backed patella pegs. (The third calibration is for use with the Natural-Knee High Tibial Osteotomy System.) This drill bit can be found along with one 1/8-inch by 5-inch and four 1/8-inch by 3-inch pins in the Natural-Knee Disposable Drill and Pin Set (Catalog #2001-00-000) (Figure 3).

It is recommended that the Intermedics Orthopedics 1/2-inch wide and 1-inch wide (.039-inch thick) saw blades be used for accurate and consistent results. New 1-inch wide blades are used for each surgery. The 1/2-inch wide blade is used to make the step cut in the anterior chamfer and can be reused. Sharp saw blades will decrease both operating time as well as injury to the bone.

Surgical Technique Summary

Preparing the Femur, Tibia and Patella

The femur is prepared in five steps:

- (1) Locating the intramedullary canal (Figure 4)
- (2) Cutting the distal femur (Figure 5)
- (3) Drilling distal femoral holes and calibrating the femur (Figure 6)
- (4) Cutting the anteroposterior femur (Figure 7)
- (5) Making chamfer cuts (Figure 8).

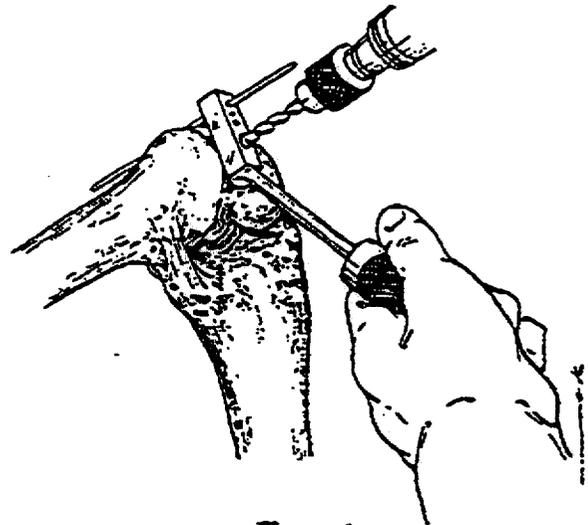


Figure 4

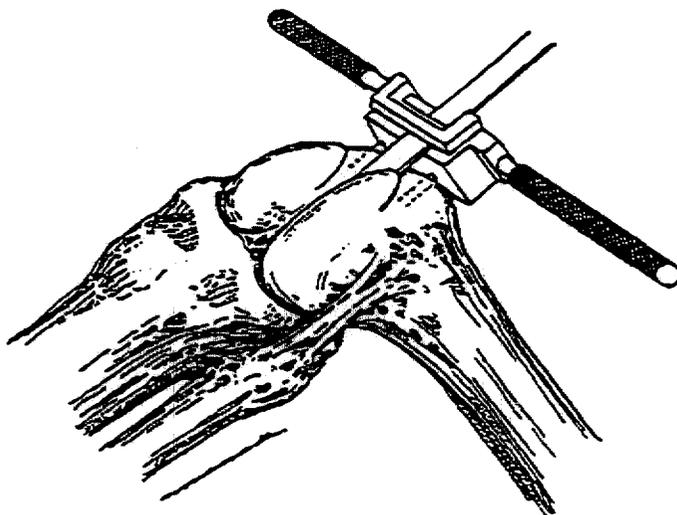


Figure 5

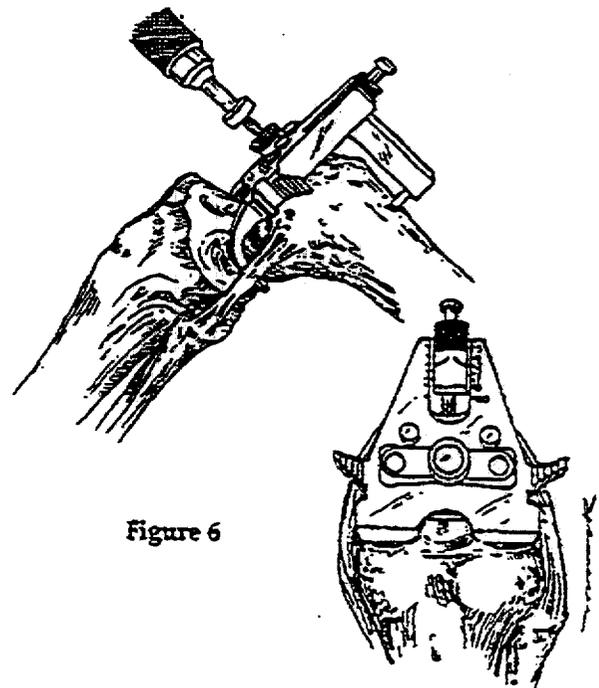


Figure 6

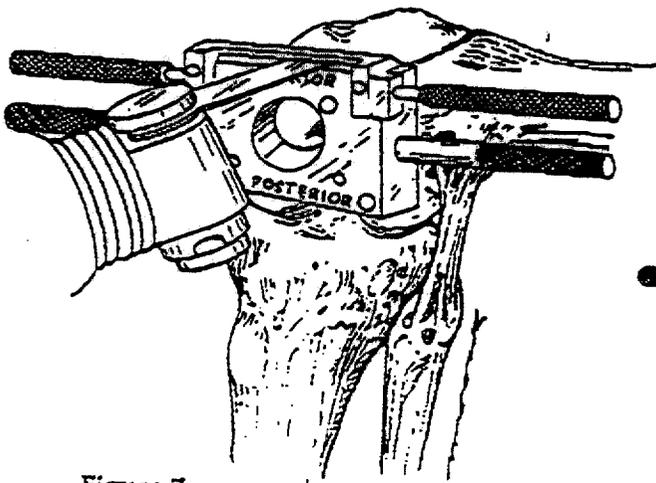


Figure 7

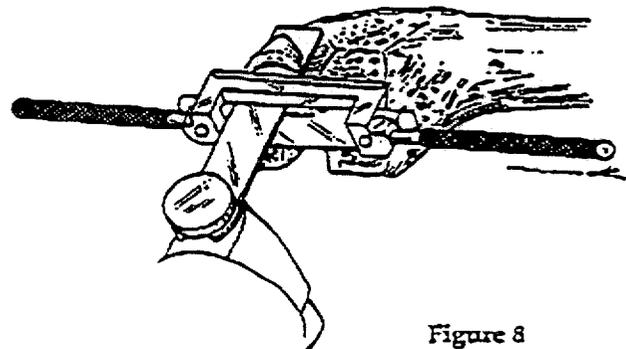


Figure 8

7 98

Sulzer Orthopedics Inc.

CAUTION: Federal Law (U.S.A.) restricts this device to sale by or on the order of a physician.

IMPORTANT INFORMATION FOR THE OPERATING SURGEON

NATURAL-KNEE® SYSTEM

INDICATIONS FOR USE

The Natural-Knee with Cancellous-Structured Titanium™ (CSTi™) is indicated for uncemented use in skeletally mature individuals with intact medial and lateral collateral ligaments undergoing primary surgery for rehabilitating knees damaged as a result of Noninflammatory Degenerative Joint Disease (NIDJD) or Inflammatory Joint Disease (IJD).

DESCRIPTION OF PROSTHESIS

The Sulzer Orthopedics Inc., Natural-Knee® System is a semi-constrained total knee prosthesis consisting of three anatomically designed components: the femoral, tibial and patellar prostheses.

The femoral components are manufactured from cast cobalt chrome (CoCr, ASTM F75) and are available in 6 sizes.

The tibial component consists of two parts, a metal tray (baseplate) and a fixed polyethylene bearing insert, assembled at the time of surgery.

Both stemmed and resurfacing baseplate options are available in six sizes (0-5). The baseplates are made of wrought Ti-6Al-4V (resurfacing option) or cast Ti-6Al-4V (stemmed option) conforming to ASTM F136 and F1108, respectively, and are partially coated with CSTi at the bone/implant interfaces. Two baseplate screw holes accept 6.5mm titanium cancellous type bone screws (ASTM F136) for fixation and stability of the tibial baseplate. The tibial baseplate features a central screw hole for supplemental fixation of the insert to the tray. The supplemental insert fixation screw is made of Ti-6Al-4V (ASTM F136).

The tibial inserts are made from Ultra-High Molecular Weight Polyethylene (UHMWPE, ASTM F648). Both congruent and ultracongruent tibial insert options are available. The tibial inserts have a central hole for mechanical fixation to the baseplate. Mechanical fixation for the congruent insert is optional, but it is required for the ultracongruent insert. Natural-Knee congruent tibial inserts are available in 5 thicknesses (9-19mm) while the ultracongruent option is available in 6 thicknesses (9-22mm).

The metal-backed patellar component has a radially symmetric UHMWPE (ASTM F648) dome attached to a circular Ti-6Al-4V (ASTM F136 or F1108) baseplate. Patellas are available in four sizes (0-3).

The bone-contacting surfaces of all three metallic components are partially coated with CSTi made from commercially pure titanium (ASTM F67). The CSTi is metallurgically bonded to the prosthesis by a proprietary sintering process. The sintered coating provides a surface coating consisting of interconnected three-dimensional pores. The function of the porous coating is to afford pores into which bone tissue can grow.

CONTRAINDICATIONS

The uncemented use of the Natural-Knee System with CSTi is contraindicated for the following:

- Patients with active infection; and
- Patients with physical conditions that would eliminate or tend to eliminate adequate implant support or prevent the use of an appropriately sized implant e.g., insufficient quality or quantity of bone stock in the affected limb to render the procedure unjustifiable or such that successful uncemented fixation is unlikely.

If, at the time of surgery, one or more the following contraindications becomes apparent, uncemented implantation of the involved prosthetic component(s) is contraindicated, and the component(s) should be fixed with cement:

- Patients with vascular deficiency at the bone site;
- Patients with inadequate bone stock to assure both a firm press fit and close apposition of the cut bone surfaces to the prosthesis;
- Patients with inadequate bone quality (e.g., severe osteoporosis);
- The inability to make bone cuts so as to assure both correct component position and intimate apposition of bone and prosthetic surfaces; or
- Lack of stability of the implanted components throughout a full range of motion.

WARNINGS

1. Preoperative

- The preoperative planning and surgical technique for implantation of the Natural-Knee System represent principles that are basic to sound surgical management in total knee replacement. Thorough familiarity with the surgical technique is essential. The use of certain surgical instruments is suggested in the performance of this surgery. Review of the use and handling of these instruments is important. The alignment and cutting jigs should be checked prior to surgery. Bent or damaged instruments may lead to improper implant position and result in implant failure. A surgical technique brochure fully describing the procedure is available from Sulzer Orthopedics Inc.
- X-ray templates should be used to estimate implant sizes, placement and joint alignment. An adequate inventory of implant sizes should be available at the time of surgery, including sizes larger and smaller than those expected to be used. Extra implant components are

recommended. All packages and implants should be thoroughly inspected prior to surgery for possible damage (see "Sterilization" section).

- A surgical implant must not be reused under any circumstances. Once implanted and subsequently removed, an implant should be discarded. Even though the implant appears undamaged, it may have small defects and internal stress patterns which may lead to failure. Only new implants may be used. Do not alter implants prior to use.

2. Intraoperative

- The correct selection of the implant is extremely important. Selection of the implant refers to the appropriate type and size for each patient with consideration of the anatomical and biomechanical factors involved. Such factors include patient age, activity level, weight, bone and muscle conditions.
- Failure to use the optimum size implant, adequately seat the component on bone, and ensure that the component is stable through the whole range of motion may result in loosening, dislocation, subsidence or fracture of the components. In particular, it is necessary that there be a close bone/prosthesis interface.
- The components, instruments, and trial prostheses of the Natural-Knee with CSTi should not be used with those of another manufacturer. Because dimensional compatibility cannot be assured, adverse outcomes can result from the use of components from different manufacturers. With the exception of the patellar component, Natural-Knee and Natural-Knee II components are not to be interchanged between systems.
- The patellar component has the smallest bearing and fixation surfaces, therefore it is more vulnerable to subluxation and loosening/dislocation. Particular attention during surgery to patellar tracking is necessary for fully successful uncemented application of the device.
- The tibial component should be seated so there is adequate coverage of the cortical bone in all directions (Medial-Lateral and Anterior-Posterior).
- Proper cleaning and preparation of the tibial surfaces have been stated to be important in enhancing prosthesis fixation. Bone excision should be limited to the amount necessary to accommodate the implants. Excessive bone removal may result in mechanical disturbances and bone resorption with subsequent failure of the procedure due to loosening or deformation of the implant. When preparing and positioning tibial components, proper tibial alignment must be ensured.
- Prior to closure, the surgical site should be thoroughly cleansed of bone chips, ectopic bone, bone cement, etc. Foreign particles at the metal/plastic articular interface may cause excessive wear and/or friction. Ectopic bone and/or bone spurs may lead to dislocation or painful and restricted motion. Range of motion should be thoroughly checked for early contact or instability.

PRECAUTIONS

1. Preoperative

- When total knee replacement is being considered, particularly for the young and the active patient, the surgeon should discuss all aspects of the surgery and the implant with the patient before surgery. The discussion should include the limitations of joint reconstruction, limitations particular to the patient, the possible consequences resulting from these limitations and, therefore, the necessity of following the physician's preoperative instructions.
- Allergies and other reactions to implant materials, although rare, have been reported in the literature and therefore should be considered and ruled out preoperatively.
- The correct handling of the implant is extremely important. The Natural-Knee with CSTi should not be allowed to contact any metallic or other hard surface prior to implantation. The Natural-Knee should be used without nicks, scratches, or other alterations; these can produce defects and stresses which may become the focal point for eventual failure of the implant.
- CSTi should not be allowed to contact cloth or other fibers releasing materials prior to implantation. Conventional cleaning techniques cannot be relied upon to remove lint, dirt or body tissue from CSTi.
- Polyethylene inserts, once snapped in place, should not be removed and reinserted.
- The safety and effectiveness of the use of this device in bilateral applications have not been established.

2. Intraoperative

- In the event the device is not stable during manipulation or reduction while the patient is under general anesthesia, the device should be fixated with cement.

3. Postoperative

Postoperative care is important. The patient should be instructed on the limitations of this device and should be cautioned regarding the load-bearing, range of motion, and activity levels permissible. Early load-bearing should be carefully controlled.

- Early postoperative care should be carefully structured to maintain range of motion, and to prevent dislocation or thromboembolism.
- Postoperative therapies, patient handling (e.g., changing dressings, placing on bedpans, etc.) and patient activities should be structured to prevent excessive loading of the operative knee. Surgical procedure chosen, patient's age and/or bone quality may necessitate extending the period of limited weight bearing.
- Periodic X-rays are recommended for close comparison with immediate postoperative X-rays to detect long-term evidence or progressive changes in implant position or loosening, evidence of bending,

cracking of component, and/or disassembly of components.

- The patient should be encouraged to promptly report any unusual changes in the operative extremity to his physician.

ADVERSE EVENTS

The operative-site and systemic complications reported for patients entered into the clinical study of the Natural-Knee, with an average of length of follow-up of 63 months, are presented in Tables 2 and 3, respectively. The percentage rates in these tables are based on the 281 patients (326 implants) entered into the clinical study. The most frequently reported operative site complications include adhesion /decreased range of motion, effusion, knee pain, subluxation, polyethylene wear, bursitis, knee instability, deep infection, and fractured patella. The most frequently reported systemic complications include cardiac disorder, hip problems, spinal/back problems, foot/ankle problems, contralateral osteoarthritis, cancer, contralateral knee problems, shoulder problems, hand/wrist/elbow problems, cerebrovascular accident, digestive system problems, pulmonary embolus, other urinary problems, and deep vein thrombosis.

In addition to the adverse events reported in the clinical study, there are other potential adverse events occurring with any total knee replacement. These events commonly include:

- Cardiovascular disorders, including damage to blood vessels, wound hematoma, venous thrombosis, pulmonary embolism and myocardial infarction.
- Pulmonary disorders including pneumonia and atelectasis.
- Temporary or permanent neuropathies.
- Fractures of the tibia or femur. Postoperative fractures are usually stress fractures. Fractures are usually evidence of defects in the cortex due to prior screw holes and misdirected reaming and/or inadequate maldistributed bone cement. Intraoperative fractures are usually associated with revision surgery deformity and/or severe osteoporosis.
- Urological complications, especially urinary retention and infection.
- Other complications associated with general surgery, drugs, ancillary devices used, blood, etc.
- Changing position of the prosthesis (bending, fracture and/or disassembly of components) with or without loosening or clinical symptoms.
- Subluxation, dislocation, decreased range of motion and shortening or lengthening of the extremity.
- Ectopic ossification.
- Early or late infection.
- Aggravated conditions in other joints or back due to intraoperative

trauma, leg length discrepancy, femoral medialization, or muscular deficiencies.

- Excessive wear of the tibial component from damage to mating wear surfaces or debris particles.
- Tissue reactions and allergies to corrosion or wear products.
- Aseptic loosening.

CLINICAL STUDIES

A nonconcurrently-controlled, prospective, multicenter IDE clinical trial was conducted to determine the safety and efficacy of uncemented fixation of the porous-coated device, the Natural-Knee System. All of the clinical results were derived from a version of the Natural-Knee device with a femoral component constructed from Ti alloy; a tibial baseplate and polyethylene insert which did not allow supplemental screw fixation; a thinner tibial baseplate and polyethylene insert; and no congruent or ultracongruent tibial insert options. Clinical evaluations using the Modified Hospital for Special Surgery knee rating scale were performed preoperatively and postoperatively at 3, 6, and 12 month intervals and yearly thereafter; incident and severity of complications observed were also recorded.

The control group used in the study consisted of subjects receiving a standard total knee prosthesis as represented by other previously published studies with similar patient populations. The study population consisted of 346 devices. Twenty (20) of the 346 devices have been placed into an excluded group due to use of cement with one of the components or omission of the patellar component. Therefore, results are presented on the remaining 326 devices. The average age for these patients was 67.6 years; the average weight was 182.5 lbs. The range of postoperative follow-up presented is 3 to 65 months with an average of 49 months. Patient follow-up information is depicted in Table 1.

The preoperative mean total MHSS score was 53.3. This improved to an average 90.8 at 2 years (285 devices) and 90.1 at 5 years (224 devices). Both the pain and functional components of the knee rating scale showed significant improvement at 3 months as compared to the preoperative exam. The pain component leveled off at an average of 28 out of 30 possible points by the 1 year interval; the functional component leveled off at 20 of 22 possible points by the 2 year interval.

Radiographically, 25% of the implants x-rays demonstrated radiolucencies at 1 year; this dropped to 13% by 5 years. Approximately 93% of the reported radiolucencies were less than 1 mm in size.

Tables 2 and 3 depict the frequencies of both operative site and systemic complications.

The six year patient survival estimates at 95% confidence intervals were 87.2% (83.1-91.3). The probability of any or all of the components of the prosthesis not being revised at six years are 94.0% (91.2-96.8).

Comparison of efficacy measures between the Natural-Knee with CSTi and cemented and uncemented literature controls revealed that the Natural-Knee with CSTi performs as well as or better than the literature controls, has similar or lower complication rates than the literature controls, and had similar or better survivorship than the literature controls.

INFORMATION FOR USE

In using the Natural-Knee System, the surgeon should be aware that the following factors can be of extreme importance to the eventual success of the procedure:

- A. **Correct and initial size selection** of the implant is extremely important. The potential for success in joint replacement is increased by selecting the proper size, shape and design of the implant. This total joint prosthesis requires careful seating and adequate bone and cement support, and should be restricted to limited functional stress.
- B. **Patient selection** for total joint replacement, the following factors can be of extreme importance to the eventual success of the procedure:

1. The patient's weight: An overweight or obese patient can produce loads on the prosthesis which can lead to failure of the cement and/or device.
2. The patient's occupation or activity: If the patient is involved in an occupation or activity that involves walking, running, lifting and/or muscle strain, the resultant forces can cause failure of the cement, biological fixation, and/or device.
3. A condition of senility, mental illness, or substance abuse, e.g., alcoholism: These conditions, among others, may cause the patient to ignore certain necessary limitations and precautions in the use of the device, leading to implant failure or other complications.
4. Certain degenerative diseases: In some cases, the progression of degenerative disease may be so advanced at the time of implantation that it may substantially decrease the expected life of the device. In such cases, total knee replacement can only be considered as a temporary relief from pain or as an intermediate procedure.
5. Foreign body sensitivity: Where material sensitivity is suspected, appropriate tests should be made prior to material selection or implantation.
6. Infection: Local infection, recent or chronic, may be a contraindication for the use of a total joint replacement. Extreme care should be used in patient selection in the event of recent or chronic infection.

C. **Device handling:**

USE CAUTION IN HANDLING POROUS-COATED COMPONENTS TO PREVENT CONTAMINATION OF THE COATING AND ENTRAPMENT OF CLOTH OR OTHER DEBRIS.

1. The CSTi should not be allowed to contact cloth or other lint-shedding or dirty materials prior to implantation. Conventional cleaning techniques cannot be relied upon to remove lint, dirt or body tissue from CSTi.
2. The Natural-Knee System's porous-coated devices should be protected from mechanical damage and not be allowed to contact any metallic or other hard surface.
3. Protect the prosthesis, particularly surfaces to be mated with polyethylene components, from contact with metal or other hard objects.

D. **Assembly of Components:**

1. The Sulzer Orthopedics Natural-Knee metal tibial component consists of two parts to be assembled at the time of surgery. The metal tray or baseplate is recessed to allow for encapsulation of the plastic inserts, which form the bearing surface for femoral-tibial articulations. At the time of surgery, the surgeon will snap the appropriate tibial insert into a baseplate. **NOTE: THE SNAP MECHANISM MAY BE ENGAGED ONLY ONE TIME. DO NOT ATTEMPT TO REINSERT AN ALREADY UTILIZED TIBIAL INSERT.**
2. Natural-Knee components are not to be interchanged with systems of other manufacturers. With the exception of the patellar component, Natural-Knee and Natural-Knee II devices are not to be interchanged between systems.

STERILIZATION

Unless otherwise indicated, all components have been sterilized by a minimum of 25 kGy (2.5 Mrads) of gamma irradiation and are supplied packaged in protective trays. Inspect packages for punctures and other damage prior to surgery.

Sulzer Orthopedics does not recommend resterilization of implantable medical devices.

Additional information regarding the Natural-Knee® System may be obtained from Sulzer Orthopedics Inc.

TABLE 1
Patient Follow-Up for the Natural-Knee

	Evaluation						
	1-yr	2-yr	3-yr	4-yr	5-yr	6-yr	7-yr
Theoretically Due ^a	326	326	326	326	326	314	52
Death	2	3	7 ^b	7 ^c	15 ^d	8 ^e	3
Revision/Reoperation	2/3	0/1	0/1	2/1	1/4	½	0/1
Implants Expected ^f	322	319	312	303	285	268 ^g	43 ^h
Implants Evaluated	301	291	282	267	232	206	27
MHSS Evaluation							
Complete	297	285	276	257	224	188	23
Partial	4	6	5	10	8	18	4
X-ray only	0	0	1	0	0	0	0
Radiographic Evaluation							
Complete	280	258	246	243	208	175	23
Partial	18	29	34	21	21	19	3
No X-rays taken	3	4	2	3	3	12	1
‡ Theoretical Follow-up ⁱ	91.1	87.4	84.7	78.8	68.7	57.7	44.2
‡ Expected Follow-up ^j	93.5	91.2	90.4	88.1	81.4	77.4	62.8

- ^a Theoretically Due is defined as the number of implants that would have been examined if all patients had returned on the exact anniversary of their respective surgery dates.
- ^b Five patient deaths involving seven study implants (two bilateral patients died).
- ^c Five patient deaths involving seven study implants (two bilateral patients died).
- ^d Twelve patient deaths involving 15 study implants (three bilateral patients died).
- ^e Seven patient deaths involving eight study implants (two bilateral patients died; however, the "death" of one patient's first implant occurred and is counted in the 7-year interval).
- ^f Implants Expected is defined as theoretically due minus cumulative deaths and revisions.
- ^g Forty-six of the 48 cumulative deaths and revisions were theoretically due for a 6-year evaluation.
- ^h Nine of the 51 cumulative deaths and revisions were theoretically due for a 7-year evaluation.
- ⁱ Computed as complete MHSS evaluations divided by theoretically due.
- ^j Computed as implants evaluated divided by implants expected.

TABLE 2
 INCIDENCE OF OPERATIVE SITE COMPLICATIONS FOR THE Natural-Knee
 (NIDJD AND IJD IMPLANTS)

Complication	Overall Incidence ^a	
	N	%
Adhesion, Decreased R.O.M.	27	8.3
Effusion ^a	10	3.1
Knee Pain	8	2.4
Subluxation	7	2.2
Poly Wear	4	1.2
Bursitis - Knee ^b	4	1.2
Knee Instability	3	1.0
Deep Infection ^c	3	1.0
Fractured Patella	3	1.0
Femoral Wear/Patella Breakdown	2	0.6
Device Failure	2	0.6
Patella Polyethylene Wear	2	0.6
Hematoma	2	0.6
Knee Tendonitis	2	0.6
Ankylosis	1	0.3
Wear of Patella/Femur/Poly Insert	1	0.3
Sepsis	1	0.3
Wound Slough	1	0.3
Patellar tendon calcification	1	0.3
Ruptured Quadriceps Mechanism	1	0.3
Loose Component	1	0.3
Synovitis - Knee	1	0.3
Stitch Abscess	1	0.3
Knee Ecchymosis	1	0.3
Knee Contusion	1	0.3
Knee Bursitis/Tendonitis	1	0.3
Necrosis of Skin	1	0.3
Hemarthrosis	1	0.3
Knee Sprain	1	0.3
Wound Drainage	1	0.3
Knee Swelling	1	0.3
Tibial Bone Cyst	1	0.3

^a Minimum 2+ effusion.

^b Four reports were received; one patient reported Knee Bursitis twice. Only three reports are counted to compute percent incidence.

^c Four reports were received; the same ongoing infection was reported twice for one patient. Only three reports are counted to compute percent incidence.

* The patients were evaluated at an average time point of 63 months and with a maximum time point of 88 months.

TABLE 3
INCIDENCE OF SYSTEMIC COMPLICATIONS FOR THE Natural-Knee
(NIDJD AND IJD PATIENTS)

Complication	Cohort and IJD Patients*		Complication	Cohort and IJD Patients*	
	N	%		N	%
Cardiac Disorder	31	11.0	Parkinson's Disease	2	0.7
Hip Problems	23	8.2	Humeral Fracture	1	0.4
Spinal/Back Problems	20	7.1	Respiratory Infections	1	0.4
Foot/Ankle Problems	20	7.1	Leg/Hip Pain	1	0.4
Contralateral Osteoarthritis	19	6.8	Hypertension	1	0.4
Cancer	19	6.8	Brow Ptosis	1	0.4
Contralateral Knee Problems	19	6.8	Gout	1	0.4
Shoulder Problems	18	6.4	Ulcer	1	0.4
Hand/Wrist/Elbow Problems	15	5.3	General Inflammatory Arthritis	1	0.4
Cerebrovascular Accident	13	4.6	Hernia	1	0.4
Digestive System Problems	9	3.2	Sinus Infection	1	0.4
Pulmonary Embolus	6	2.1	Chest Pain	1	0.4
Other Urinary Problems	6	2.1	Vascular Occlusion	1	0.4
Deep Vein Thrombosis	6	2.1	Skin Rash	1	0.4
Fall	5	1.8	Leg Pain	1	0.4
Respiratory Problems	5	1.8	Sepsis	1	0.4
Diabetes Mellitus	5	1.8	Sebaceous Cyst	1	0.4
Sciatica	5	1.8	Yeast Infection	1	0.4
Urinary Tract Infection	5	1.8	Sore Pelvis and Knees	1	0.4
Cranial/Head Problems	4	1.4	Ataxia	1	0.4
Thigh Pain	2	0.7	Tractor Accident	1	0.4
Multiple Injuries/MVA	2	0.7	Chest Muscle Strain	1	0.4
Allergic Reaction†	2	0.7	Prostatitis	1	0.4
Phlebitis	2	0.7	Retinal Detachment	1	0.4
Anemia	2	0.7	Ear Infection	1	0.4

* The patients were evaluated at an average time point of 63 months and with a maximum time point of 88 months. † Allergic reactions were the result of surgery or medications not a reaction to the implant itself.

109

Sulzer Orthopedics Inc.

CAUTION: Federal Law (U.S.A.) restricts this device to sale by or on the order of a physician.

IMPORTANT INFORMATION FOR THE OPERATING SURGEON

NATURAL-KNEE® II SYSTEM

INDICATIONS FOR USE

The Natural-Knee II with Cancellous-Structured Titanium™ (CSTi™) is indicated for uncemented use in skeletally mature individuals with intact medial and lateral collateral ligaments undergoing primary surgery for rehabilitating knees damaged as a result of Noninflammatory Degenerative Joint Disease (NIDJD) or Inflammatory Joint Disease (IJD).

DESCRIPTION OF PROSTHESIS

The Sulzer Orthopedics Inc., Natural-Knee® II System is a semi-constrained total knee prosthesis consisting of three anatomically designed components: the femoral, tibial and patellar prostheses.

The femoral components are manufactured from cast cobalt chrome (CoCr, ASTM F75) and are available in 7 sizes.

The tibial component consists of two parts, a metal tray (baseplate) and a fixed polyethylene bearing insert, assembled at the time of surgery.

Both stemmed and resurfacing baseplate options are available in seven sizes (00-5). The baseplates are made of wrought Ti-6Al-4V (resurfacing option) or cast Ti-6Al-4V (stemmed option) conforming to ASTM F136 and F1108, respectively, and are partially coated with CSTi at the bone/implant interfaces. Two baseplate screw holes accept 6.5mm titanium cancellous type bone screws (ASTM F136) for fixation and stability of the tibial baseplate.

The tibial inserts are made from Ultra-High Molecular Weight Polyethylene (UHMWPE, ASTM F648). Both congruent and ultracongruent tibial insert options are available. Natural-Knee II congruent and ultracongruent tibial inserts are available in 6 thicknesses (9-22mm).

The metal-backed patellar component has a radially symmetric UHMWPE (ASTM F648) dome attached to a circular Ti-6Al-4V (ASTM F136 or F1108) baseplate. Patellas are available in four sizes (0-3).

The bone-contacting surfaces of all three metallic components are partially coated with CSTi made from commercially pure titanium (ASTM F67). The CSTi is metallurgically bonded to the prosthesis by a proprietary sintering process. The sintered coating provides a surface coating consisting of interconnected three-

110

dimensional pores. The function of the porous coating is to afford pores into which bone tissue can grow.

CONTRAINDICATIONS

The uncemented use of the Natural-Knee II System with CSTi is contraindicated for the following:

- Patients with active infection; and
- Patients with physical conditions that would eliminate or tend to eliminate adequate implant support or prevent the use of an appropriately sized implant e.g., insufficient quality or quantity of bone stock in the affected limb to render the procedure unjustifiable or such that successful uncemented fixation is unlikely.

If, at the time of surgery, one or more the following contraindications becomes apparent, uncemented implantation of the involved prosthetic component(s) is contraindicated, and the component(s) should be fixed with cement:

- Patients with vascular deficiency at the bone site;
- Patients with inadequate bone stock to assure both a firm press fit and close apposition of the cut bone surfaces to the prosthesis;
- Patients with inadequate bone quality (e.g., severe osteoporosis);
- The inability to make bone cuts so as to assure both correct component position and intimate apposition of bone and prosthetic surfaces; or
- Lack of stability of the implanted components throughout a full range of motion.

WARNINGS

1. Preoperative

- The preoperative planning and surgical technique for implantation of the Natural-Knee II System represent principles that are basic to sound surgical management in total knee replacement. Thorough familiarity with the surgical technique is essential. The use of certain surgical instruments is suggested in the performance of this surgery. Review of the use and handling of these instruments is important. The alignment and cutting jigs should be checked prior to surgery. Bent or damaged instruments may lead to improper implant position and result in implant failure. A surgical technique brochure fully describing the procedure is available from Sulzer Orthopedics Inc.
- X-ray templates should be used to estimate implant sizes, placement and joint alignment. An adequate inventory of implant sizes should be available at the time of surgery, including sizes larger and smaller than those expected to be used. Extra implant components are recommended. All packages and implants should be thoroughly inspected prior to surgery for possible damage (see "Sterilization" section).
- A surgical implant must not be reused under any circumstances. Once

implanted and subsequently removed, an implant should be discarded. Even though the implant appears undamaged, it may have small defects and internal stress patterns which may lead to failure. Only new implants may be used. Do not alter implants prior to use.

2. Intraoperative

- The correct selection of the implant is extremely important. Selection of the implant refers to the appropriate type and size for each patient with consideration of the anatomical and biomechanical factors involved. Such factors include patient age, activity level, weight, bone and muscle conditions.
- Failure to use the optimum size implant, adequately seat the component on bone, and ensure that the component is stable through the whole range of motion may result in loosening, dislocation, subsidence or fracture of the components. In particular, it is necessary that there be a close bone/prosthesis interface.
- The components, instruments, and trial prostheses of the Natural-Knee II System with CSTi should not be used with those of another manufacturer. Because dimensional compatibility cannot be assured, adverse outcomes can result from the use of components from different manufacturers. With the exception of the patellar component, Natural-Knee and Natural-Knee II components are not to be interchanged between systems.
- The patellar component has the smallest bearing and fixation surfaces, therefore it is more vulnerable to subluxation and loosening/dislocation. Particular attention during surgery to patellar tracking is necessary for fully successful uncemented application of the device.
- The tibial component should be seated so there is adequate coverage of the cortical bone in all directions (Medial-Lateral and Anterior-Posterior).
- Proper cleaning and preparation of the tibial surfaces have been stated to be important in enhancing prosthesis fixation. Bone excision should be limited to the amount necessary to accommodate the implants. Excessive bone removal may result in mechanical disturbances and bone resorption with subsequent failure of the procedure due to loosening or deformation of the implant. When preparing and positioning tibial components, proper tibial alignment must be ensured.
- Prior to closure, the surgical site should be thoroughly cleansed of bone chips, ectopic bone, bone cement, etc. Foreign particles at the metal/plastic articular interface may cause excessive wear and/or friction. Ectopic bone and/or bone spurs may lead to dislocation or painful and restricted motion. Range of motion should be thoroughly checked for early contact or instability.

PRECAUTIONS

1. Preoperative

- When total knee replacement is being considered, particularly for the

young and the active patient, the surgeon should discuss all aspects of the surgery and the implant with the patient before surgery. The discussion should include the limitations of joint reconstruction, limitations particular to the patient, the possible consequences resulting from these limitations and, therefore, the necessity of following the physician's preoperative instructions.

- Allergies and other reactions to implant materials, although rare, have been reported in the literature and therefore should be considered and ruled out preoperatively.
- The correct handling of the implant is extremely important. The Natural-Knee II with CSTi should not be allowed to contact any metallic or other hard surface prior to implantation. The Natural-Knee II should be used without nicks, scratches, or other alterations; these can produce defects and stresses which may become the focal point for eventual failure of the implant.
- CSTi should not be allowed to contact cloth or other fibers releasing materials prior to implantation. Conventional cleaning techniques cannot be relied upon to remove lint, dirt or body tissue from CSTi.
- Polyethylene inserts, once snapped in place, should not be removed and reinserted.
- The safety and effectiveness of the use of this device in bilateral applications have not been established.

2. Intraoperative

- In the event the device is not stable during manipulation or reduction while the patient is under general anesthesia, the device should be fixated with cement.

3. Postoperative

Postoperative care is important. The patient should be instructed on the limitations of this device and should be cautioned regarding the load-bearing, range of motion, and activity levels permissible. Early load-bearing should be carefully controlled.

- Early postoperative care should be carefully structured to maintain range of motion, and to prevent dislocation or thromboembolism.
- Postoperative therapies, patient handling (e.g., changing dressings, placing on bedpans, etc.) and patient activities should be structured to prevent excessive loading of the operative knee. Surgical procedure chosen, patient's age and/or bone quality may necessitate extending the period of limited weight bearing.
- Periodic X-rays are recommended for close comparison with immediate postoperative X-rays to detect long-term evidence or progressive changes in implant position or loosening, evidence of bending, cracking of component, and/or disassembly of components.
- The patient should be encouraged to promptly report any unusual changes

in the operative extremity to his physician..

ADVERSE EVENTS

See the Table 2 and Table 3 for the operative-site and systemic complications reported during the clinical study of the Natural-Knee, with an average length to follow-up of 63 months. The percentage rates in these tables are based on the 281 patients (326 implants) entered into the clinical study. The most frequently reported operative site complications include adhesion /decreased range of motion, effusion, knee pain, subluxation, polyethylene wear, bursitis, knee instability, deep infection, and fractured patella. The most frequently reported systemic complications include cardiac disorder, hip problems, spinal/back problems, foot/ankle problems, contralateral osteoarthritis, cancer, contralateral knee problems, shoulder problems, hand/wrist/elbow problems, cerebrovascular accident, digestive system problems, pulmonary embolus, other urinary problems, and deep vein thrombosis.

In addition to the adverse events reported in the clinical study, there are other potential adverse events occurring with any total knee replacement. These events commonly include:

- Cardiovascular disorders, including damage to blood vessels, wound hematoma, venous thrombosis, pulmonary embolism and myocardial infarction.
- Pulmonary disorders including pneumonia and atelectasis.
- Temporary or permanent neuropathies.
- Fractures of the tibia or femur. Postoperative fractures are usually stress fractures. Fractures are usually evidence of defects in the cortex due to prior screw holes and misdirected reaming and/or inadequate maldistributed bone cement. Intraoperative fractures are usually associated with revision surgery deformity and/or severe osteoporosis.
- Urological complications, especially urinary retention and infection.
- Other complications associated with general surgery, drugs, ancillary devices used, blood, etc.
- Changing position of the prosthesis (bending, fracture and/or disassembly of components) with or without loosening or clinical symptoms.
- Subluxation, dislocation, decreased range of motion and shortening or lengthening of the extremity.
- Ectopic ossification.
- Early or late infection.
- Aggravated conditions in other joints or back due to intraoperative trauma, leg length discrepancy, femoral medialization, or muscular deficiencies.
- Excessive wear of the tibial component from damage to mating wear

surfaces or debris particles.

- Tissue reactions and allergies to corrosion or wear products.
- Aseptic loosening.
- Possible detachment of CSTi coating could be associated with increased metal debris.

CLINICAL STUDIES

A nonconcurrently-controlled, prospective, multicenter IDE clinical trial was conducted to determine the safety and efficacy of uncemented fixation of the porous-coated the Natural-Knee. All of the clinical results were derived from a version of the Natural-Knee device with a femoral component constructed from Ti alloy; a tibial baseplate and polyethylene insert which did not allow supplemental screw fixation; a thinner tibial baseplate and polyethylene insert; and no congruent or ultracongruent tibial insert options. There is no clinical data on the Natural-Knee II device. However both the clinically evaluated version of the Natural-Knee and the Natural-Knee II devices utilize the same fixation method, bone and/or fibrous tissue ingrowth into the CSTi porous coating. Clinical evaluations using the Modified Hospital for Special Surgery knee rating scale were performed preoperatively and postoperatively at 3, 6, and 12 month intervals and yearly thereafter; incident and severity of complications observed were also recorded.

The control group used in the study consisted of subjects receiving a standard total knee prosthesis as represented by other previously published studies with similar patient populations. The study population consisted of 346 devices. Twenty (20) of the 346 devices have been placed into an excluded group due to use of cement with one of the components or omission of the patellar component. Therefore, results are presented on the remaining 326 devices. The average age for these patients was 67.6 years; the average weight was 182.5 lbs. The range of postoperative follow-up presented is 3 to 65 months with an average of 49 months. Patient follow-up is depicted in Table 1.

The preoperative mean total MHSS score was 53.3. This improved to an average 90.8 at 2 years (285 devices) and 90.1 at 5 years (224 devices). Both the pain and functional components of the knee rating scale showed significant improvement at 3 months as compared to the preoperative exam. The pain component leveled off at an average of 28 out of 30 possible points by the 1 year interval; the functional component leveled off at 20 of 22 possible points by the 2 year interval. The clinical results obtained with the Natural-Knee were significantly better than the PCA, Kinematic II, and Tricon M at 2 years and the Total Condylar, Duocondylar, and Geometric at 3 years.

Radiographically, 25% of the implants x-rays demonstrated radiolucencies at 1 year; this dropped to 13% by 5 years. Approximately 93% of the reported radiolucencies were less than 1 mm in size.

Tables 2 and 3 depict the frequencies of both operative site and systemic complications.

The six year patient survival estimates at 95% confidence intervals were 87.2% (83.1-91.3). The probability of any or all of the components of the prosthesis not being revised at six years are 94.0% (91.2-96.8).

Comparison of efficacy measures between the Natural-Knee with CSTi and cemented and

uncemented literature controls revealed that the Natural-Knee with CSTi performs as well as or better than the literature controls, has similar or lower complication rates than the literature controls, and had similar or better survivorship than the literature controls.

INFORMATION FOR USE

In using the Natural-Knee System II, the surgeon should be aware that the following factors can be of extreme importance to the eventual success of the procedure:

- A. **Correct and initial size selection** of the implant is extremely important. The potential for success in joint replacement is increased by selecting the proper size, shape and design of the implant. This total joint prosthesis requires careful seating and adequate bone and cement support, and should be restricted to limited functional stress.
- B. **Patient selection** for total joint replacement, the following factors can be of extreme importance to the eventual success of the procedure:
1. The patient's weight: An overweight or obese patient can produce loads on the prosthesis which can lead to failure of the cement and/or device.
 2. The patient's occupation or activity: If the patient is involved in an occupation or activity that involves walking, running, lifting and/or muscle strain, the resultant forces can cause failure of the cement, biological fixation, and/or device.
 3. A condition of senility, mental illness, or substance abuse, e.g., alcoholism: These conditions, among others, may cause the patient to ignore certain necessary limitations and precautions in the use of the device, leading to implant failure or other complications.
 4. Certain degenerative diseases: In some cases, the progression of degenerative disease may be so advanced at the time of implantation that it may substantially decrease the expected life of the device. In such cases, total knee replacement can only be considered as a temporary relief from pain or as an intermediate procedure.
 5. Foreign body sensitivity: Where material sensitivity is suspected, appropriate tests should be made prior to material selection or implantation.
 6. Infection: Local infection, recent or chronic, may be a contraindication for the use of a total joint replacement. Extreme care should be used in patient selection in the event of recent or chronic infection.
- C. **Device handling**:

USE CAUTION IN HANDLING POROUS-COATED COMPONENTS TO PREVENT CONTAMINATION OF THE COATING AND ENTRAPMENT OF CLOTH OR OTHER DEBRIS.

1. The CSTi should not be allowed to contact cloth or other lint-shedding or dirty materials prior to implantation. Conventional cleaning techniques cannot be relied upon to remove lint, dirt or body tissue from CSTi.
2. The Natural-Knee II System's porous-coated devices should be protected from mechanical damage and not be allowed to contact any metallic or

other hard surface.

3. Protect the prosthesis, particularly surfaces to be mated with polyethylene components, from contact with metal or other hard objects.

D. **Assembly of Components:**

1. The Sulzer Orthopedics Natural-Knee II metal tibial component consists of two parts to be assembled at the time of surgery. The metal tray or baseplate is recessed to allow for encapsulation of the plastic inserts, which form the bearing surface for femoral-tibial articulations. At the time of surgery, the surgeon will snap the appropriate tibial insert into a baseplate. **NOTE: THE SNAP MECHANISM MAY BE ENGAGED ONLY ONE TIME. DO NOT ATTEMPT TO REINSERT AN ALREADY UTILIZED TIBIAL INSERT.**
2. Natural-Knee II components are not to be interchanged with systems of other manufacturers. With the exception of the patellar component, Natural-Knee and Natural-Knee II devices are not to be interchanged between systems.

STERILIZATION

Unless otherwise indicated, all components have been sterilized by a minimum of 25 kGy (2.5 Mrads) of gamma irradiation and are supplied packaged in protective trays. Inspect packages for punctures and other damage prior to surgery.

Sulzer Orthopedics does not recommend resterilization of implantable medical devices.

Additional information regarding the Natural-Knee®II System may be obtained from Sulzer Orthopedics Inc.

TABLE 1
Patient Follow-Up for the Natural-Knee

	Evaluation						
	1-yr	2-yr	3-yr	4-yr	5-yr	6-yr	7-yr
Theoretically Due ^a	326	326	326	326	326	314	52
Death	2	3	7 ^b	7 ^c	15 ^d	8 ^e	3
Revision/Reoperation	2/3	0/1	0/1	2/1	1/4	½	0/1
Implants Expected ^f	322	319	312	303	285	268 ^g	43 ^h
Implants Evaluated	301	291	282	267	232	206	27
MHSS Evaluation							
Complete	297	285	276	257	224	188	23
Partial	4	6	5	10	8	18	4
X-ray only	0	0	1	0	0	0	0
Radiographic Evaluation							
Complete	280	258	246	243	208	175	23
Partial	18	29	34	21	21	19	3
No X-rays taken	3	4	2	3	3	12	1
% Theoretical Follow-up ⁱ	91.1	87.4	84.7	78.8	68.7	57.7	44.2
% Expected Follow-up ^j	93.5	91.2	90.4	88.1	81.4	77.4	62.8

- ^a Theoretically Due is defined as the number of implants that would have been examined if all patients had returned on the exact anniversary of their respective surgery dates.
- ^b Five patient deaths involving seven study implants (two bilateral patients died).
- ^c Five patient deaths involving seven study implants (two bilateral patients died).
- ^d Twelve patient deaths involving 15 study implants (three bilateral patients died).
- ^e Seven patient deaths involving eight study implants (two bilateral patients died; however, the "death" of one patient's first implant occurred and is counted in the 7-year interval).
- ^f Implants Expected is defined as theoretically due minus cumulative deaths and revisions.
- ^g Forty-six of the 48 cumulative deaths and revisions were theoretically due for a 6-year evaluation.
- ^h Nine of the 51 cumulative deaths and revisions were theoretically due for a 7-year evaluation.
- ⁱ Computed as complete MHSS evaluations divided by theoretically due.
- ^j Computed as implants evaluated divided by implants expected.

18

TABLE 2
INCIDENCE OF OPERATIVE SITE COMPLICATIONS FOR THE Natural-Knee
(NIDJD AND IJD IMPLANTS)

Complication	Overall Incidence*	
	N	%
Adhesion, Decreased R.O.M.	27	8.3
Effusion ^a	10	3.1
Knee Pain	8	2.4
Subluxation	7	2.2
Poly Wear	4	1.2
Bursitis - Knee ^b	4	1.2
Knee Instability	3	1.0
Deep Infection ^c	3	1.0
Fractured Patella	3	1.0
Femoral Wear/Patella Breakdown	2	0.6
Device Failure	2	0.6
Patella Polyethylene Wear	2	0.6
Hematoma	2	0.6
Knee Tendonitis	2	0.6
Ankylosis	1	0.3
Wear of Patella/Femur/Poly Insert	1	0.3
Sepsis	1	0.3
Wound Slough	1	0.3
Patellar tendon calcification	1	0.3
Ruptured Quadriceps Mechanism	1	0.3
Loose Component	1	0.3
Synovitis - Knee	1	0.3
Stitch Abscess	1	0.3
Knee Ecchymosis	1	0.3
Knee Contusion	1	0.3
Knee Bursitis/Tendonitis	1	0.3
Necrosis of Skin	1	0.3
Hemarthrosis	1	0.3
Knee Sprain	1	0.3
Wound Drainage	1	0.3
Knee Swelling	1	0.3
Tibial Bone Cyst	1	0.3

^a Minimum 2+ effusion.

^b Four reports were received; one patient reported Knee Bursitis twice. Only three reports are counted to compute percent incidence.

^c Four reports were received; the same ongoing infection was reported twice for one patient. Only three reports are counted to compute percent incidence.

* The patients were evaluated at an average time point of 63 months and with a maximum time point of 88 months.

TABLE 3
INCIDENCE OF SYSTEMIC COMPLICATIONS FOR THE Natural-Knee
(NIDJD AND IJD PATIENTS)

Complication	Cohort and IJD Patients*		Complication	Cohort and IJD Patients*	
	N	%		N	%
Cardiac Disorder	31	11.0	Parkinson's Disease	2	0.7
Hip Problems	23	8.2	Humeral Fracture	1	0.4
Spinal/Back Problems	20	7.1	Respiratory Infections	1	0.4
Foot/Ankle Problems	20	7.1	Leg/Hip Pain	1	0.4
Contralateral Osteoarthritis	19	6.8	Hypertension	1	0.4
Cancer	19	6.8	Brow Ptosis	1	0.4
Contralateral Knee Problems	19	6.8	Gout	1	0.4
Shoulder Problems	18	6.4	Ulcer	1	0.4
Hand/Wrist/Elbow Problems	15	5.3	General Inflammatory Arthritis	1	0.4
Cerebrovascular Accident	13	4.6	Hernia	1	0.4
Digestive System Problems	9	3.2	Sinus Infection	1	0.4
Pulmonary Embolus	6	2.1	Chest Pain	1	0.4
Other Urinary Problems	6	2.1	Vascular Occlusion	1	0.4
Deep Vein Thrombosis	6	2.1	Skin Rash	1	0.4
Fall	5	1.8	Leg Pain	1	0.4
Respiratory Problems	5	1.8	Sepsis	1	0.4
Diabetes Mellitus	5	1.8	Sebaceous Cyst	1	0.4
Sciatica	5	1.8	Yeast Infection	1	0.4
Urinary Tract Infection	5	1.8	Sore Pelvis and Knees	1	0.4
Cranial/Head Problems	4	1.4	Ataxia	1	0.4
Thigh Pain	2	0.7	Tractor Accident	1	0.4
Multiple Injuries/MVA	2	0.7	Chest Muscle Strain	1	0.4
Allergic Reaction [†]	2	0.7	Prostatitis	1	0.4
Phlebitis	2	0.7	Retinal Detachment	1	0.4
Anemia	2	0.7	Ear Infection	1	0.4

* The patients were evaluated at an average time point of 63 months and with a maximum time point of 88 months.
† Allergic reactions were the result of surgery or medications not a reaction to the implant itself.

120

Preoperative Planning

Obtain 36-inch, or preferably 52-inch, standing anteroposterior and lateral radiographs of the extremity as well as a sunrise view of the patella. The entire femur should be visualized to rule out any structural abnormality, as the distal femoral cut will be referenced from an intramedullary rod in the medullary canal. If the intramedullary tibial instruments are used, the entire tibia should be visualized to identify any varus or valgus bowing, and the appropriate tibial entry point planned. Templating for size is most accurate on the lateral radiograph since many patients present with a flexion contracture that distorts magnification on the anteroposterior radiograph. The intraoperative management of tibial defects are planned using bone graft, cement and/or tibial spacers.

The degree of constraint in the tibial insert may be planned, such as the use of the ultracongruent insert for more constraint in patients with posterior cruciate ligament (PCL) deficiency or in the unstable varus or valgus knee.

Surgical Technique

Bone Cuts

Bone resorption and connective tissue formation occur when bone is surgically traumatized and heated to above 47 degrees centigrade for longer than one minute. To control thermal injury, the saw blade is cooled by constant irrigation when making bone cuts.¹² All bone cuts should be made with the low-profile, removable saw capture which allows for precision cuts (Figure 2).

To ensure that a perfectly flat surface has been created, the saw capture is removed and all bone cuts sighted (in two planes) against the cutting blocks. The flatness can also be checked using an auxiliary cutting block.

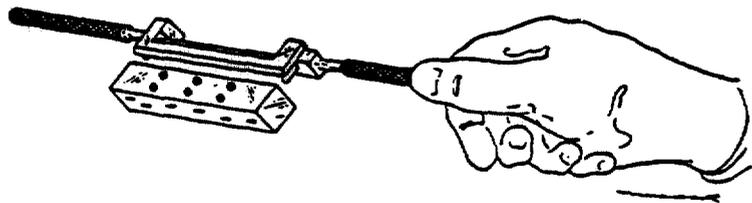


Figure 2

¹²Krause, W.R., et al., "Temperature Elevations in Orthopaedic Cutting Operations," *Journal of Biomechanics*, 1982, Vol. 15, No. 4, pp. 267-275.

BH

Each cutting block is stabilized first by drilling with a 1/8-inch (3.2mm) by 5-inch drill bit that remains loaded in the Jacob's chuck. The drilled holes are then filled with 1/8-inch by 3-inch smooth pins. The first calibrated mark on the drill point indicates the drilling depth of the tibial baseplate pegs; the second mark is for the metal-backed patella pegs. (The third calibration is for use with the Natural-Knee High Tibial Osteotomy System.) This drill bit can be found along with one 1/8-inch by 5-inch and four 1/8-inch by 3-inch pins in the Natural-Knee Disposable Drill and Pin Set (Catalog #2001-00-000) (Figure 3).

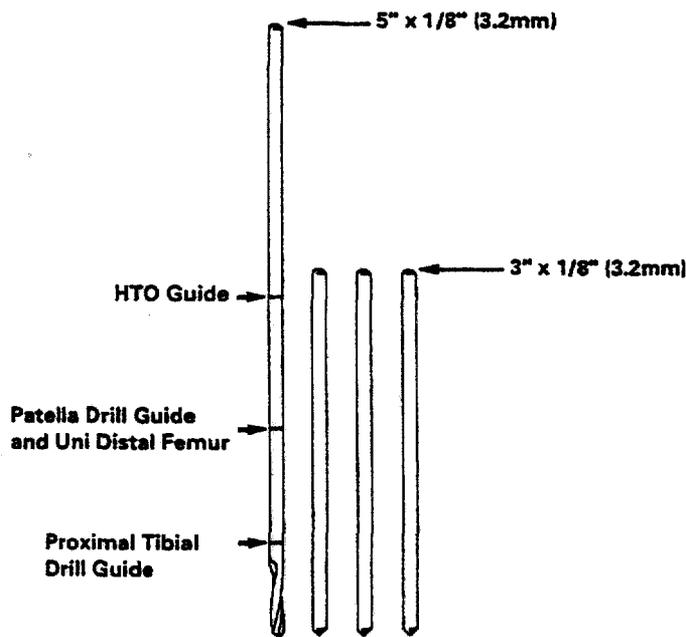


Figure 3

It is recommended that the Intermedics Orthopedics 1/2-inch wide and 1-inch wide (.039-inch thick) saw blades be used for accurate and consistent results. New 1-inch wide blades are used for each surgery. The 1/2-inch wide blade is used to make the step cut in the anterior chamfer and can be reused. Sharp saw blades will decrease both operating time as well as injury to the bone.

Handwritten signature

Surgical Technique Summary

Preparing the Distal Femur

The femur is prepared in five steps:

- (1) Locating the intramedullary canal (Figure 4)
- (2) Cutting the distal femur (Figure 5)
- (3) Drilling distal femoral holes and calibrating the femur (Figure 6)
- (4) Cutting the anteroposterior femur (Figure 7)
- (5) Making chamfer cuts (Figure 8).

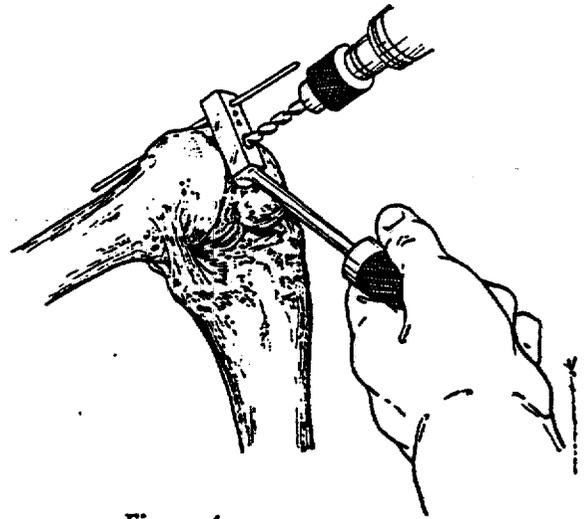


Figure 4

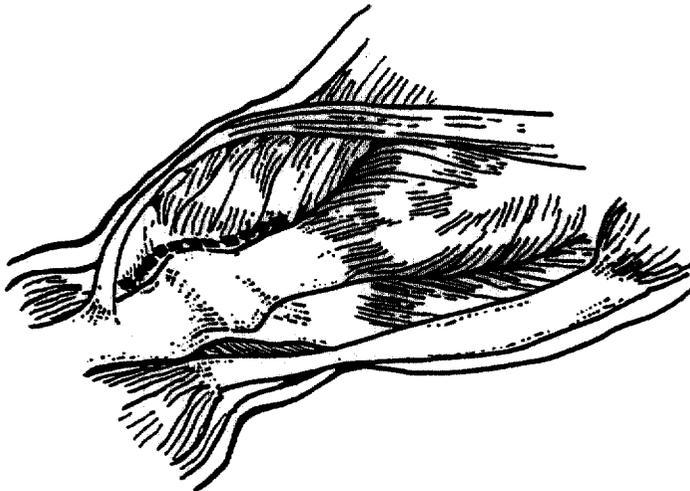


Figure 5

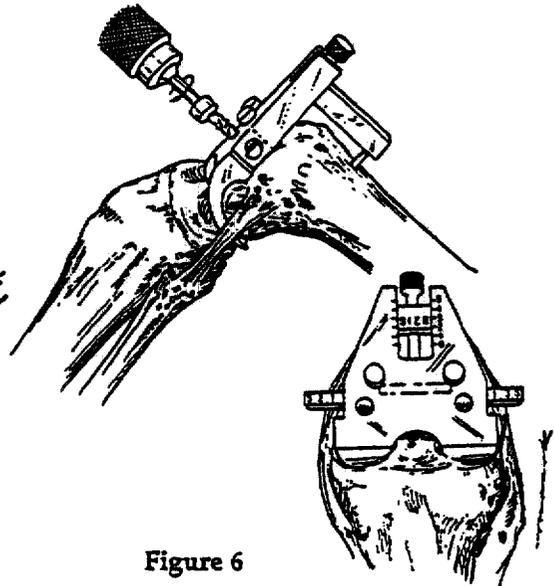


Figure 6

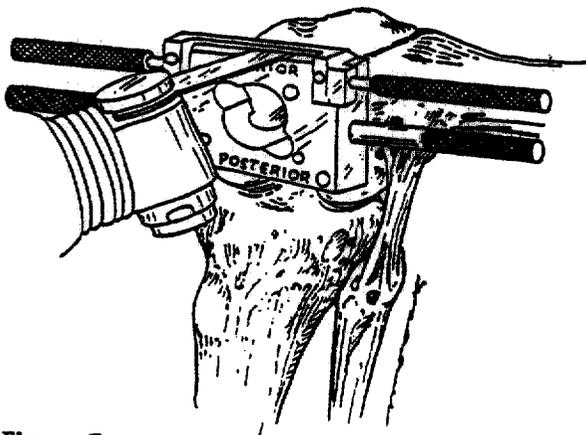


Figure 7

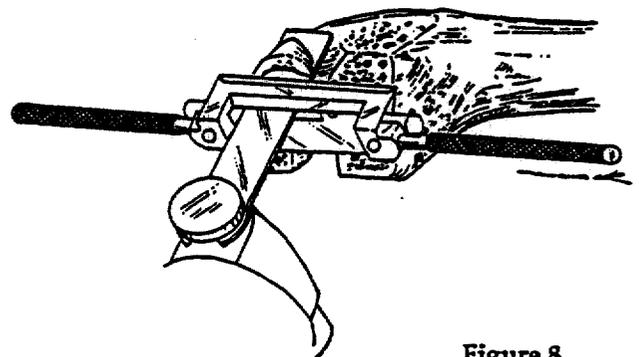


Figure 8

Preparing the Tibia

The tibia is prepared in three additional steps:

- (1) Cutting the proximal tibia (Figure 9)
- (2) Sizing and drilling the proximal tibia (Figure 10)
- (3) Broaching the tibia for stemmed components only (Figure 11).

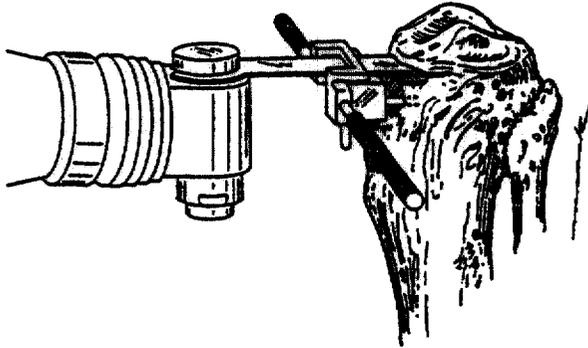


Figure 9

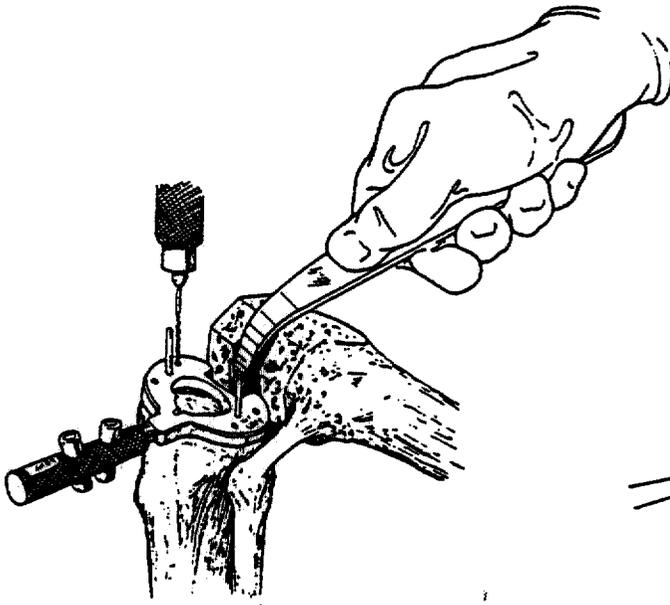


Figure 10

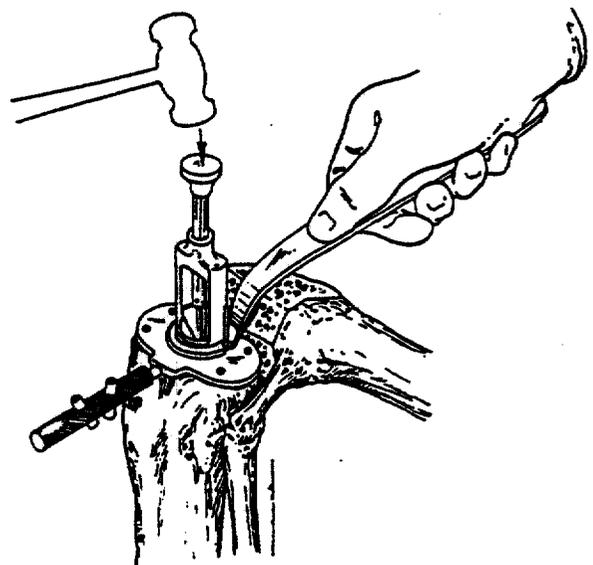


Figure 11

24

Preparing the Patella

The patella is prepared in four steps:

- (1) Determining the patella thickness (Figure 12)
- (2) Osteotomizing the patella (Figure 13)
- (3) Planing the patella (Figure 14)
- (4) Drilling holes for the pegs (Figure 15).

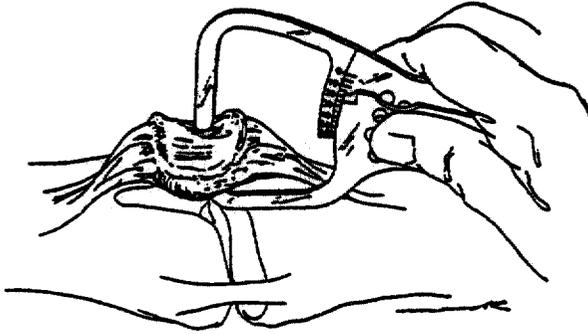


Figure 12

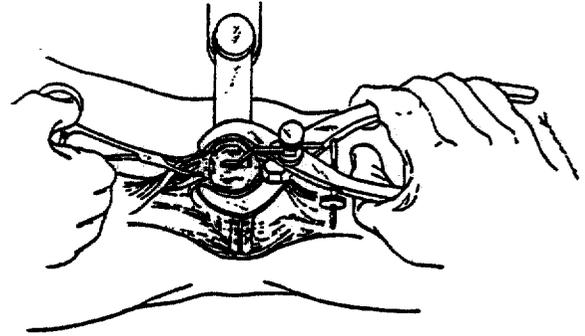


Figure 13

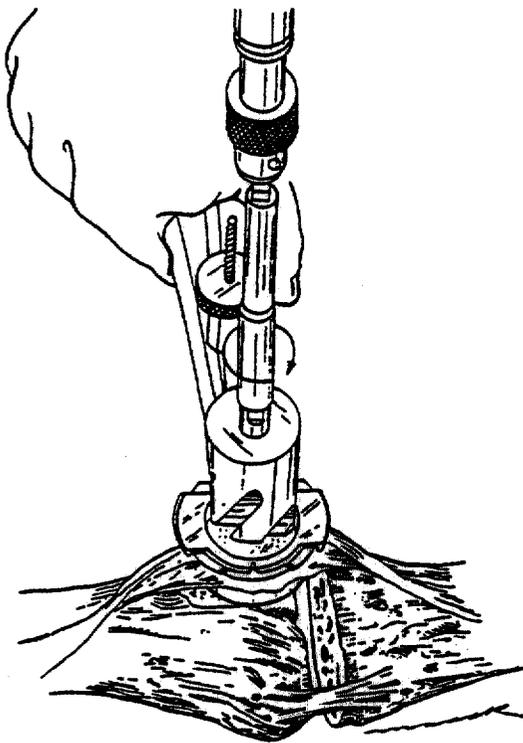


Figure 14

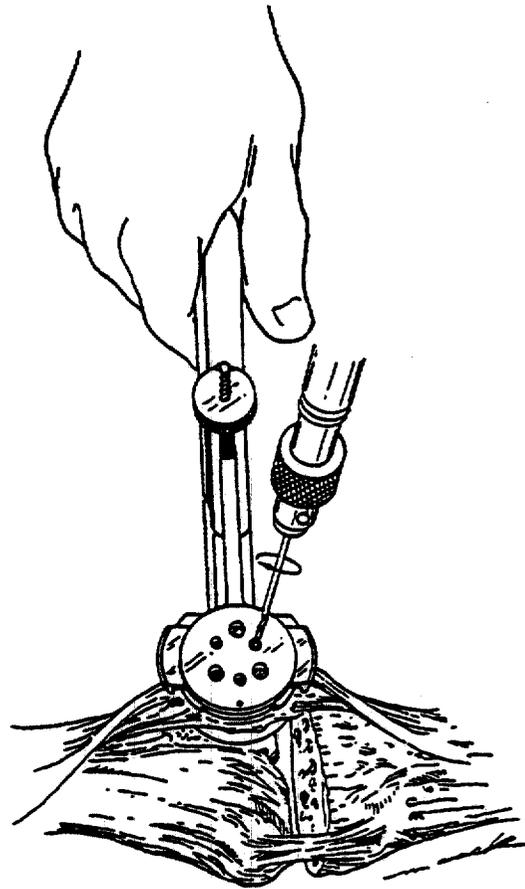


Figure 15

Patient Positioning

A sandbag is taped to the table to allow 90 degrees knee flexion and a lateral trochanteric pad allows for excellent stability of the extremity (Figure 16).

Surgical Approach

A straight, anterior skin incision is made with the knee flexed. This incision avoids the use of skin retractors and provides excellent visibility, especially in the heavier leg. The incision should extend four fingerbreadths proximal to the patella to allow for easy eversion and should continue distally to the medial side of the tibial tubercle.

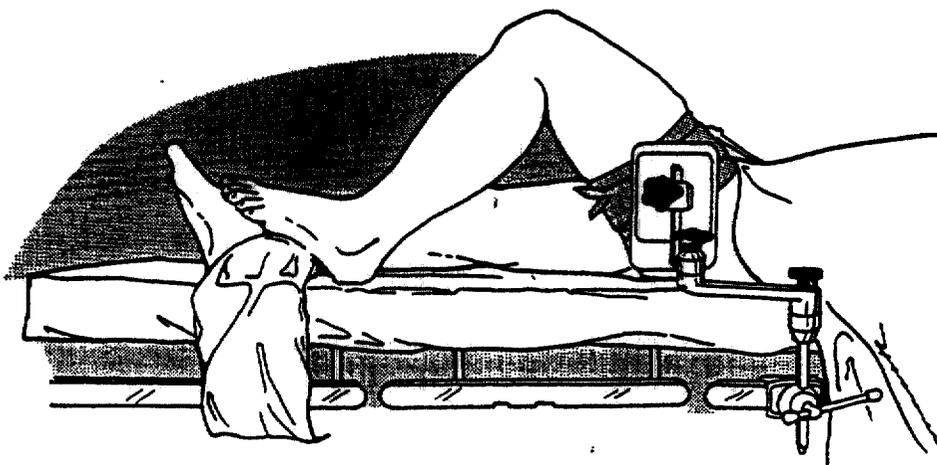


Figure 16

Handwritten signature or initials.

A standard medial parapatellar arthrotomy may be used (Figure 17a). The subvastus is preferable for many primary total knee arthroplasties¹³ (Figure 17b). The subvastus approach should be avoided in situations that may make patellar eversion difficult, such as with previous lateral compartment scarring, obesity and severe fixed varus alignment. With a subvastus approach, the deep fascia of the thigh overlying the vastus medialis is incised in line with the skin incision. Using blunt dissection, this fascia is elevated off of the vastus medialis obliquus (VMO). The inferior edge of the vastus is identified and lifted off the intermuscular septum using blunt dissection. The vastus medialis muscle belly is then lifted anteriorly. While under tension, 1cm- to 2cm-wide tendinous insertion to the medial capsule is cut at the level of the midpatella, leaving the underlying synovium intact.

The arthrotomy is then performed vertically adjacent to the patella and the patellar tendon. The fat pad is incised at the medial edge to minimize bleeding and is not excised unless redundant. The patella is then carefully everted and

dislocated as the knee is maximally flexed to provide generous exposure of the distal femur. If the patella is difficult to evert, a partial lateral release can be performed here for the heavy patient or the valgus leg with subluxating patella. The anterior horns of the medial and lateral meniscus are removed. Preliminary proximal release of the tibial soft tissue is performed and should extend to the posteromedial corner of the tibia. All osteophytes are removed to identify true bony landmarks and dimension. If a marked deformity is present, further soft tissue release may need to be performed prior to making the bone cuts. However, this can usually be best titrated once the trials are in place.

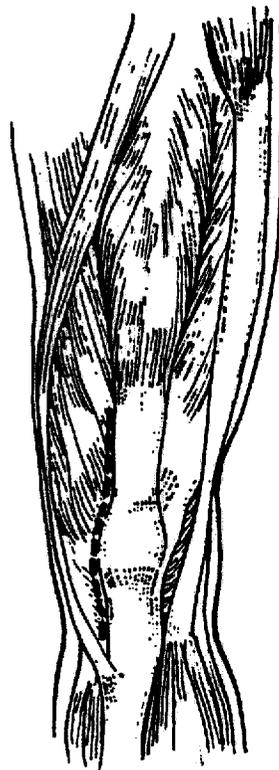


Figure 17a

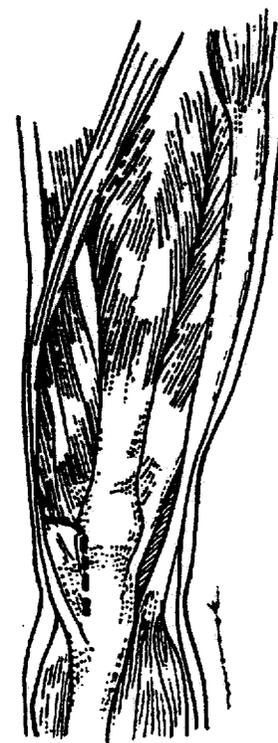


Figure 17b

¹³Hofmann, A.A., MD, et al., "Subvastus (Southern) Approach for Primary Total Knee Arthroplasty," *Clinical Orthopaedics and Related Research*, August 1991, No. 269, pp. 70-77.

Locating the Medullary Canal

A 5/16-inch (8mm) hole is made in line with the femoral shaft using the intercondylar drill guide. A 1/8-inch by 5-inch smooth pin in the superior alignment tower hole aids in sighting and aligning the drill hole down the center of the femoral shaft (Figure 18a). The starting point is centered distally on the trochlear groove 1mm to 2mm anterior to the true roof of the intercondylar notch (Figure 18b). The flexion-extension position of the femoral component on the femur is determined by the placement of this hole. The drill hole must be aligned with the femoral shaft in both the frontal and lateral planes. Incorrect anterior drill hole placement leads to extension of the femoral component with potential notching of the anterior cortex. Incorrect posterior drill hole placement leads to flexion of the femoral component (Figures 18c and 18d).

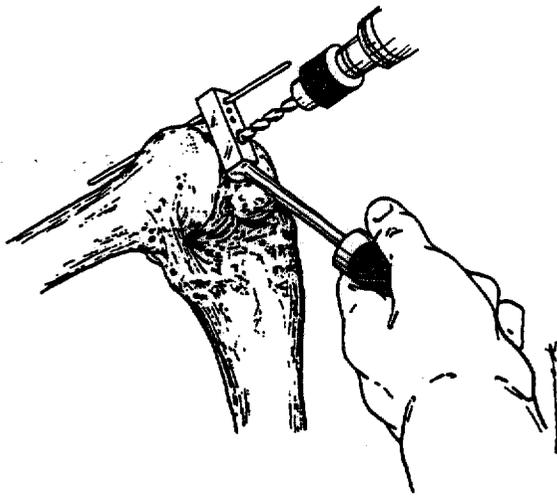
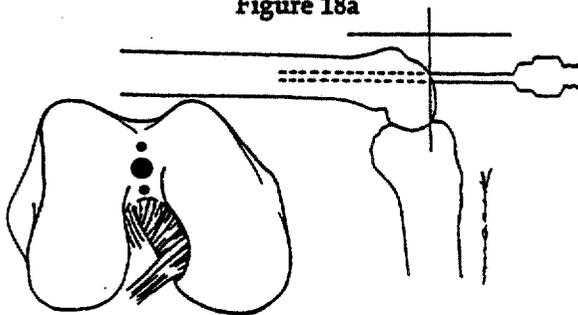
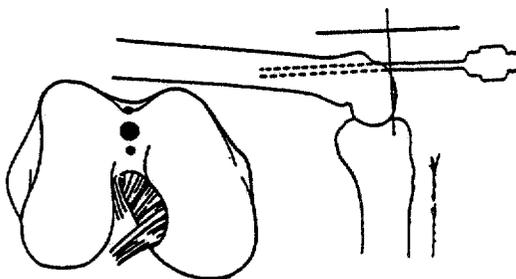


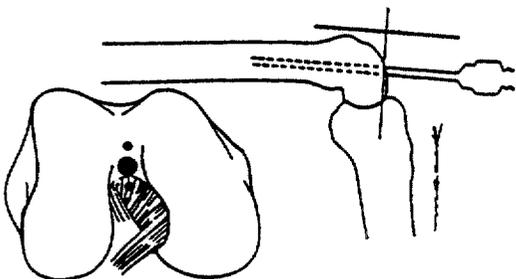
Figure 18a



Correct
Figure 18b



Incorrect
Figure 18c



Incorrect
Figure 18d

A slight toggling of the drill upon entering is desirable, as it will help center the intramedullary rod and provide additional venting of the medullary canal to prevent pressurization.

The fluted 5/16-inch intramedullary rod is slowly and fully inserted into the isthmus (Figure 19). If the rod is not easily inserted, the orientation of the hole must be reassessed to ensure that it is in line with the femoral shaft. An error commonly made is to run into the medial cortex instead of aiming slightly laterally.

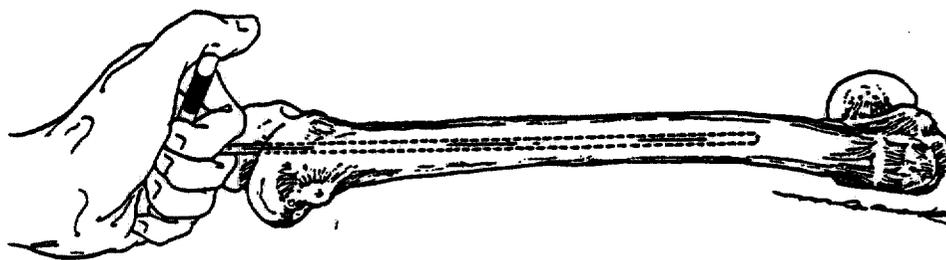


Figure 19

Distal Femoral Cut

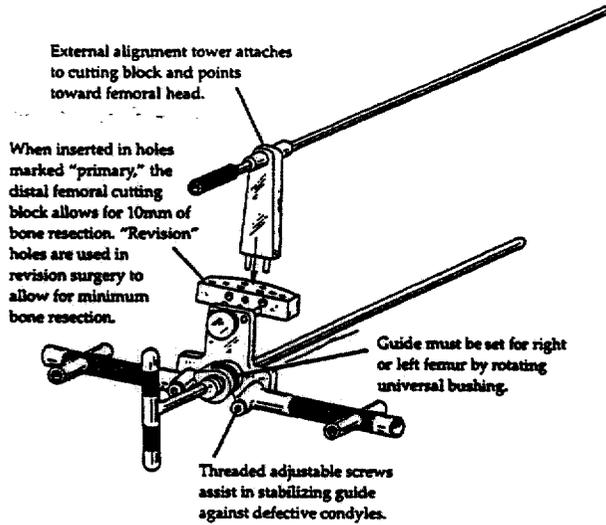


Figure 20

The distal femoral alignment guide (Figure 20) is applied and further stabilized by dialing the medial or lateral adjustable screw down to the defective distal femoral condyle (Figure 21). If both condyles are defective (i.e., with rheumatoid arthritis), both adjustable screws are dialed down slightly to compensate for the lost cartilage.

By lining up the posterior portion of the guide with a line that runs parallel to the posterior femoral condyles before stabilizing the cutting block, the correct rotational alignment of the guide can be established (Figure 22). The lateral cannulated adjustable screw is drilled and filled with a 1/8-inch by 5-inch smooth pin to prevent rotation.

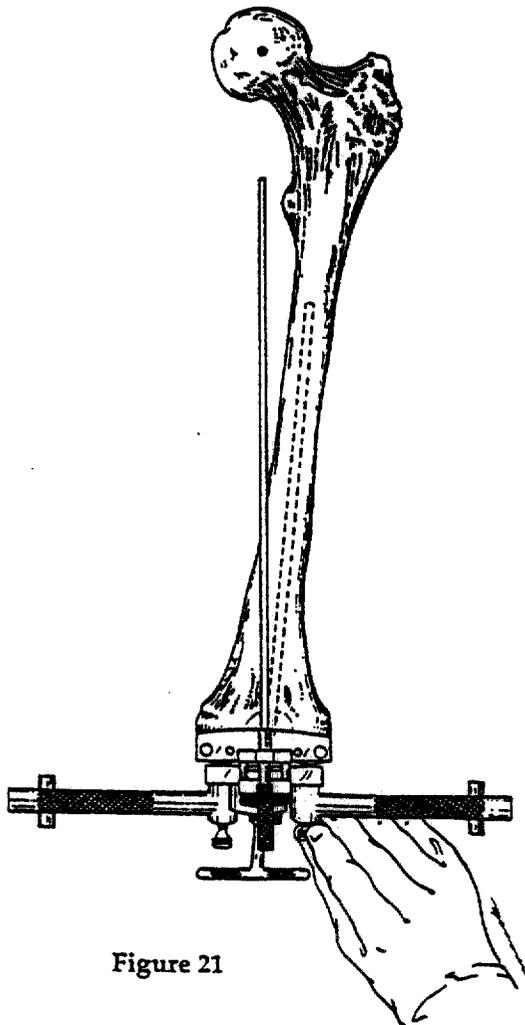


Figure 21

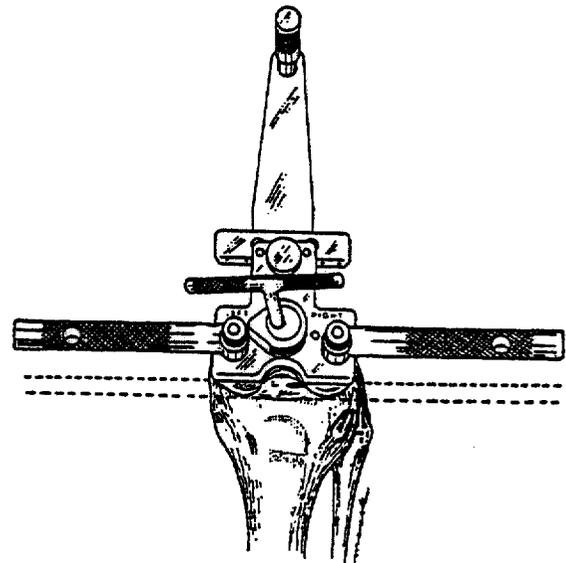


Figure 22

130

The guide allows for cutting the femur at 6 degrees valgus from the anatomic axis. This positioning should orient the first cut perpendicular to the mechanical axis. The position can be checked by putting on the external alignment tower which should be in direct alignment with the femoral head (Figure 23). Minor varus-valgus adjustments can be made by further adjusting the threaded screws.

The cutting block is stabilized by drilling completely through the condyles (for easy insertion and extraction) and filling the holes with two 1/8-inch by 3-inch smooth pins (Figure 24). The thumbscrew is released from the cutting block, and the distal femoral alignment assembly is removed leaving the cutting block in place.

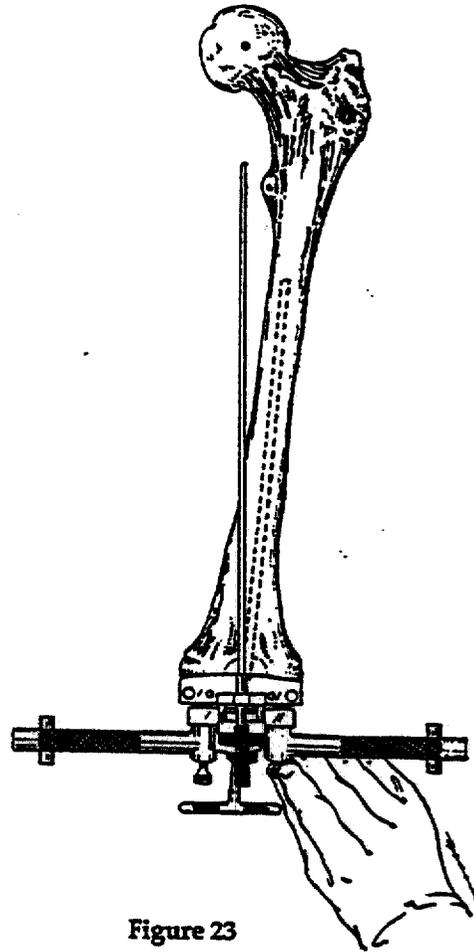


Figure 23

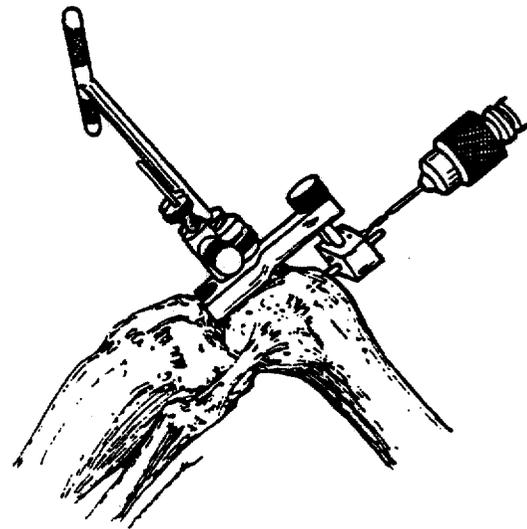


Figure 24

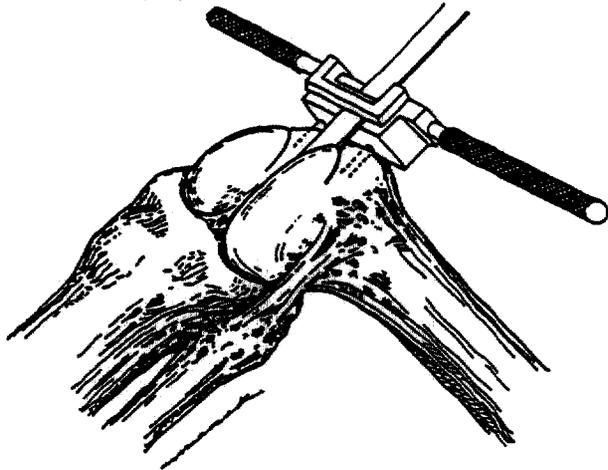


Figure 25

The smooth pins are tapped flush with the cutting block to eliminate impingement with the saw and to allow ease of removal and replacement of the cutting block. The distal femoral condyles are then cut using a new 1-inch saw blade (Figure 25). The ± 2 -degree cutting block can be used to cut the femur at 4 degrees or 8 degrees, but is rarely needed. If employed, this block should be placed over the pins at the 11mm holes. Because all other femoral cuts are based on the distal cut, it must be perfectly flat before the surgery is continued. A central high spot near the intercondylar notch may persist and will require additional planing. The high spot must be eliminated to keep the femoral component from getting "high centered" when it is implanted. The high spot is eliminated by making a few extra passes with the saw blade using a slight upward spring of the blade against the bone.

Drill Distal Femoral Holes and Calibrate Femur

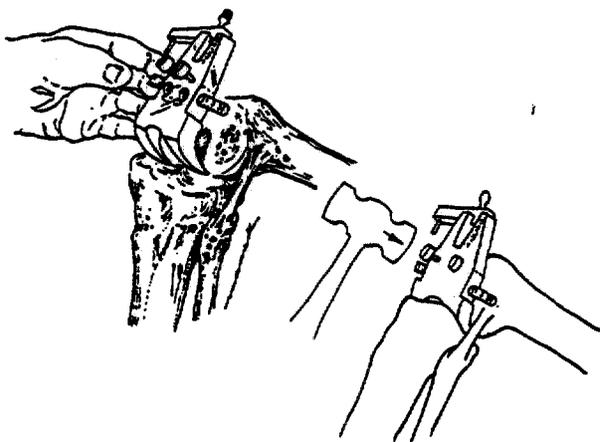


Figure 26

With the knee in a maximally flexed position, the distal femoral drill guide is centered medial to lateral on the femoral condyles. The guide is positioned by referencing the posterior femoral condyles on the skids and stabilized by seating the two captured set pins into the distal femur (Figure 26). If a defective posterior condyle is present, the good condyle is pinned with the jig, and the opposite posterior skid is rotated away from the

Handwritten signature or initials.

posterior defect 1mm to 2mm if the defect is only cartilage. If the surgeon prefers a

3-degree external rotation of the femoral

component, this can be achieved by

seating the medial set pin and externally rotating the distal femoral drill guide to leave a 3mm gap between the lateral skid and the posterior condyle. The lateral set pin is then seated.

Two reference drill holes are made with the 1/4-inch stop drill (Figure 27a) for placement of the anterior/posterior and chamfer femoral cutting blocks. The distal femoral drill guide also acts as a caliper to determine the correct anterior/posterior and medial/lateral femoral size (Figure 27b). If the mark falls between sizes, the larger size is chosen to avoid notching the anterior cortex.

Anterior/Posterior Cuts

The appropriate-size anterior/posterior cutting block is placed into the reference holes. The anterior cut is made initially with the blade flexed anteriorly (in the saw capture) to avoid anterior notching. Once the exit point is noted, the anterior cut is fine-tuned with the blade flexed posteriorly (Figure 28). Care is taken to protect the collateral ligaments during the posterior cut by employing the small

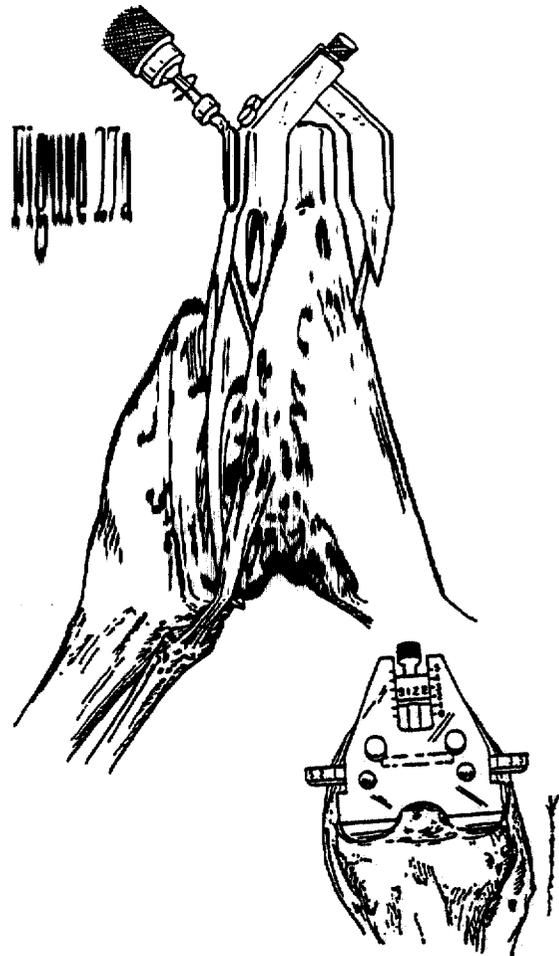
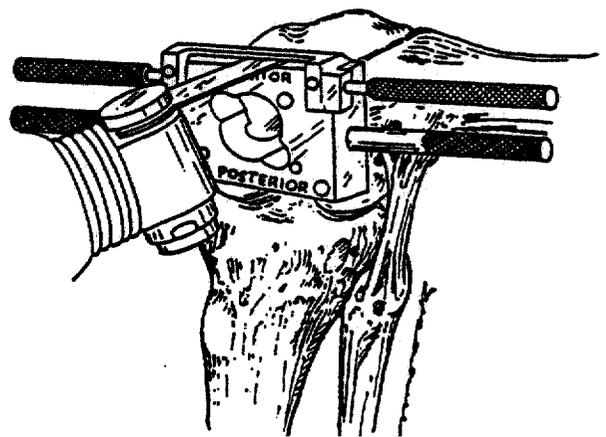


Figure 27b



Chamfer Cuts

The appropriate-size chamfer cutting block is used to make the anterior/posterior chamfer and notch cuts (Figure 29). After checking the anterior and posterior chamfer cuts (Figure 30a), the vertical cuts of the notch are initiated with a reciprocating saw or with a 1-inch oscillating saw blade using the chamfer cutting block as a guide. For a more accurate cut, the blade is held between the index and middle finger like a pool cue (Figure 30b). The cut is completed using a 1/2-inch saw blade or a 3/4-inch osteotome held flush with the anterior step in the chamfer cutting block (Figure 30c). Handles can be attached to the chamfer guide for easy removal (Figure 30d).

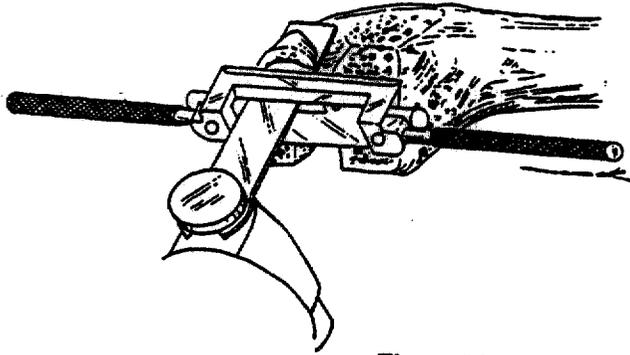


Figure 29

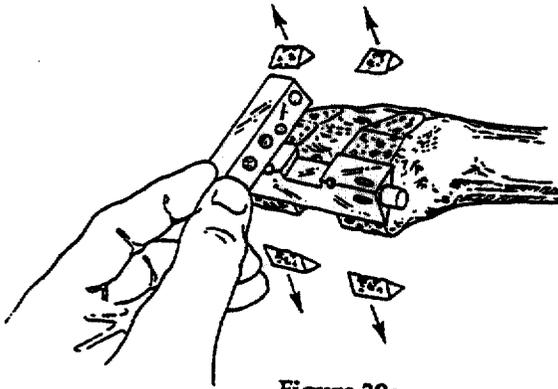


Figure 30a



Figure 30b

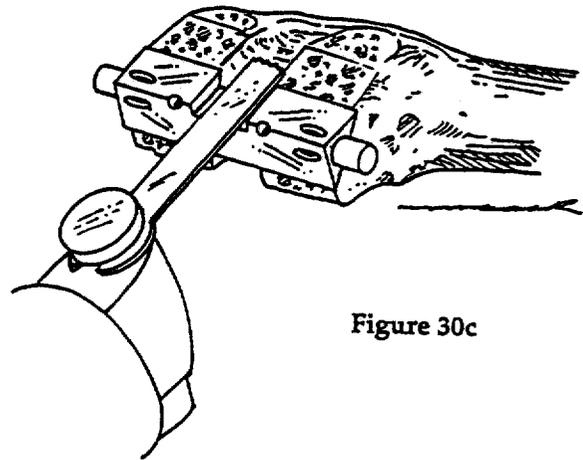


Figure 30c

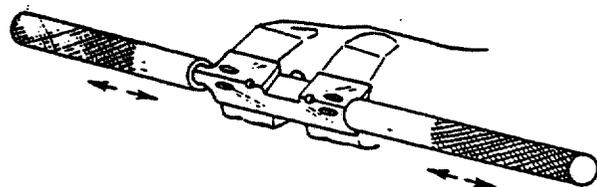


Figure 30d

34

Preparing the Proximal Tibia

With the knee maximally flexed, the anterior cruciate ligament is excised along with any remaining meniscus. The PCL can be recessed about 8mm to 9mm using a small knife blade. The large bent-knee retractor is placed behind the tibia just lateral to the PCL to sublaxate the posterior margin of the tibia anterior to the femur. The PCL can be protected by placing a small (1/4-inch or 1/2-inch) osteotome just anterior and deep to the ligament, preventing the saw blade from going too posterior (Figure 31). A smaller bent-knee retractor is placed medially. Two retractors are placed laterally with one anterolaterally to retract the patellar tendon and fat pad.

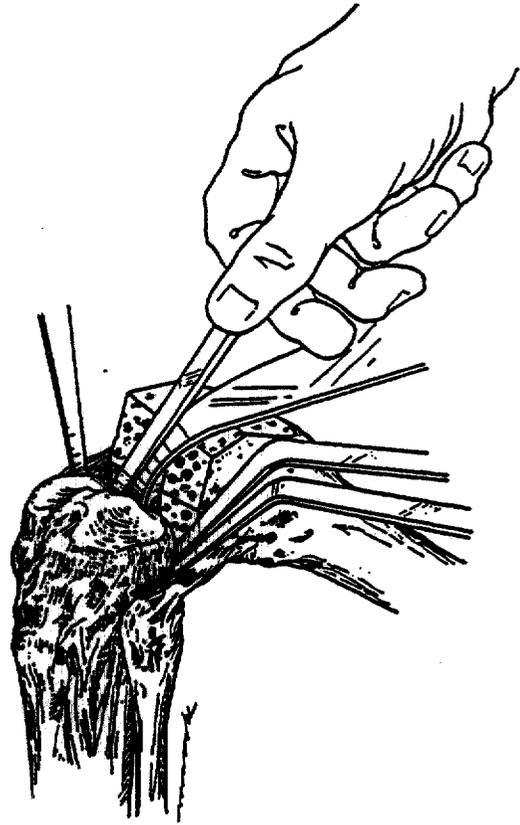


Figure 31

Extramedullary Tibial Technique

After adjusting the proximal tibial cutting guide to the approximate tibial length, the jig is placed on the tibia and is stabilized by tapping the longest pin of the proximal portion of the guide into the central tibial plateau just anterior to the tibial spine in the midline medial to lateral (Figure 32).

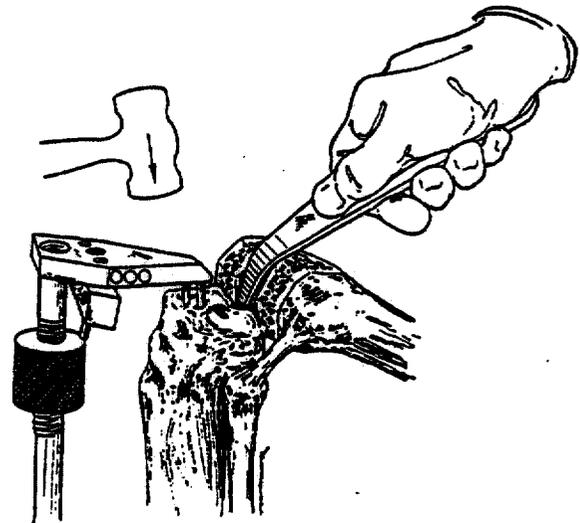


Figure 32

35

Rotation

Obtaining proper rotational alignment is the first adjustment. Several references can be used, but the most important is the tibial tubercle. The cutting jig should be aligned just medial to the tibial tuberosity (Figure 33a). Two other references include the malleoli and the posterior tibia. The ankle cradle is aligned with the 25-degree angle between the medial and lateral malleoli (Figure 33b). The posterior edges of the proximal tibial plateau should be aligned parallel with the cutting block (Figure 33c). The jig is locked into position by tapping the shorter pin into the proximal tibia (Figure 33d).

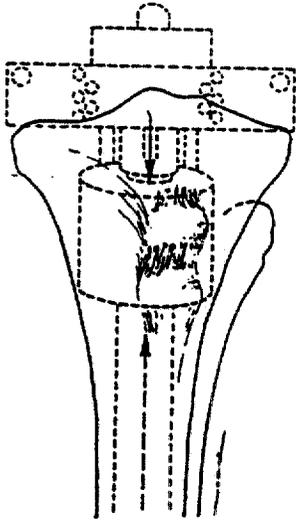


Figure 33a

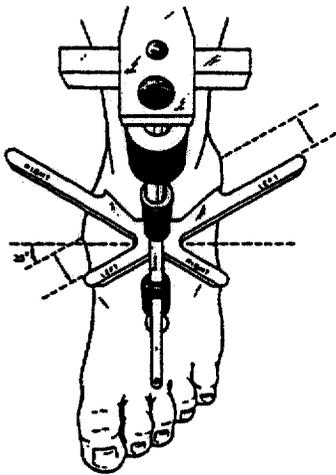


Figure 33b

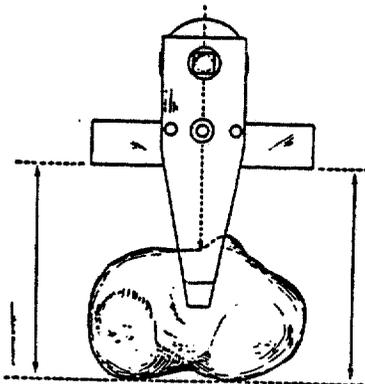


Figure 33c

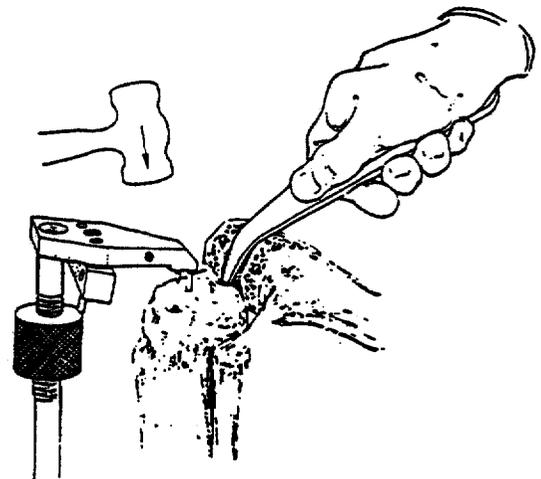


Figure 33d

Posterior Slope

Reestablishment of the patient's posterior slope is the second adjustment. A 1/8-inch by 5-inch smooth pin is inserted through the 16mm hole of the cutting block and over the least involved portion of the tibial plateau.

The posterior slope of the proximal tibia is reproduced by moving the distal portion of the jig anteriorly or posteriorly until the pin is parallel to the proximal tibia (Figure 34). The posterior tilt of the tibia may range from 4 degrees to 12 degrees.¹⁴ The goal is to cut parallel to the joint surfaces.

Level of Resection

Establishing the level of the tibial cut is the final adjustment. The stylus end marked "PRIMARY" is placed over the least involved weight-bearing portion of the tibial plateau to re-create the joint line (Figure 35a). The stylus position will reference a 7mm bone cut, which is the minimum amount of bone that should be resected to accommodate the thinnest tibial component (9mm). With a varus deformity, the reference point is typically the highest portion of the lateral plateau. With a valgus deformity, the reference point is typically the highest portion of the tibial plateau.

¹⁴Hofmann, A.A., MD, et al., "Effect of the Tibial Cut on Subsidence Following Total Knee Arthroplasty," *Clinical Orthopaedics*, August 1991, Vol. 269, pp. 63-69.

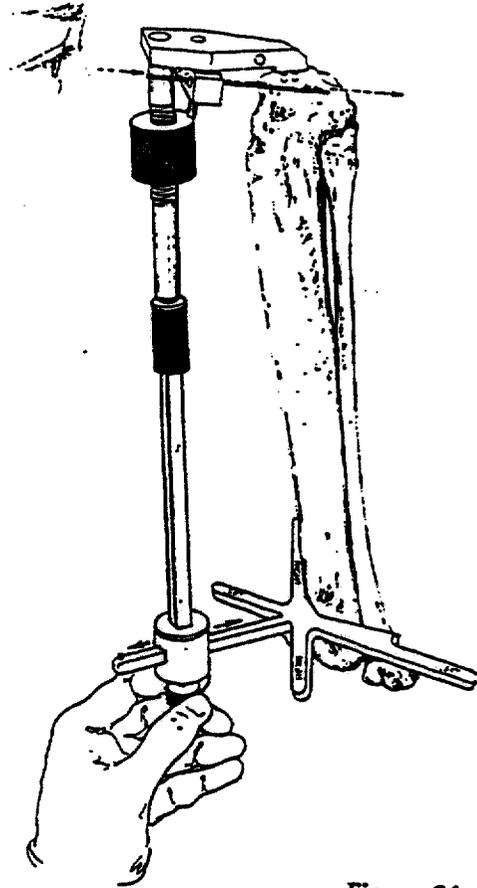


Figure 34

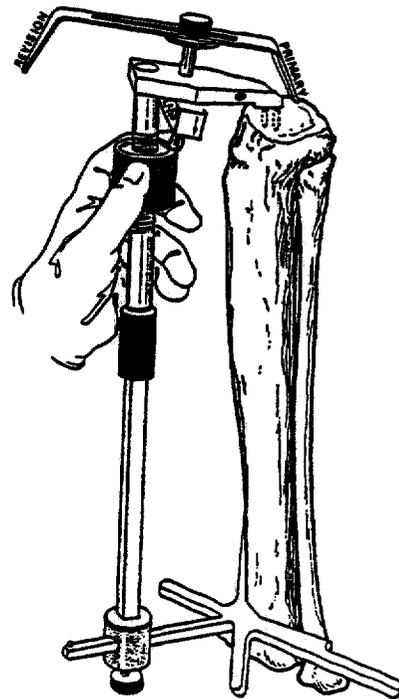


Figure 35a

137

The cutting block is dialed down until the tip of the stylus has reached the good bone and the large, threaded nut falls free from the cutting block (Figure 35b). The cutting block is then stabilized by drilling through the 7mm holes and filling them with two 1/8-inch smooth pins. To avoid the drill point skiving off the medial cortex, first mark the drilling location through the appropriate drill hole in the tibia saw guide. Next take the drill bit outside the saw guide and drill through the cortex at the previously marked spot. Finally, place the drill bit back through the appropriate drill hole and drill through the tibia. Once the cutting block has been stabilized (Figure 36), the stylus is removed. The remainder of the proximal tibial cutting guide is removed using the slaphammer (Figure 37). The 1/8-inch smooth pins should be tapped so that they are flush with the cutting block.

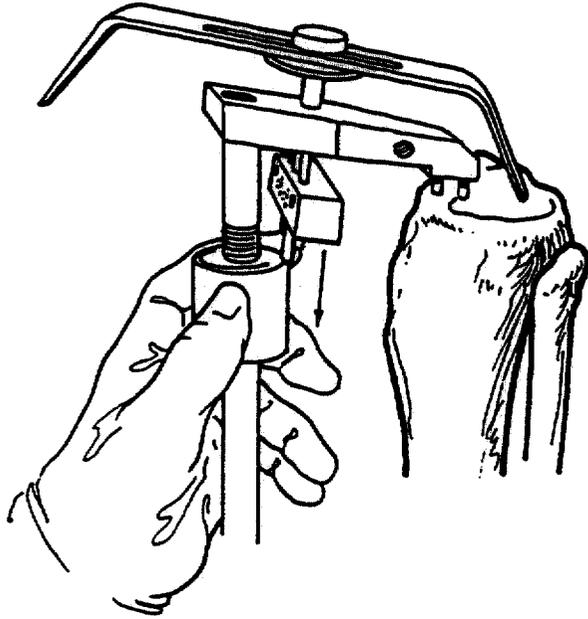


Figure 35b

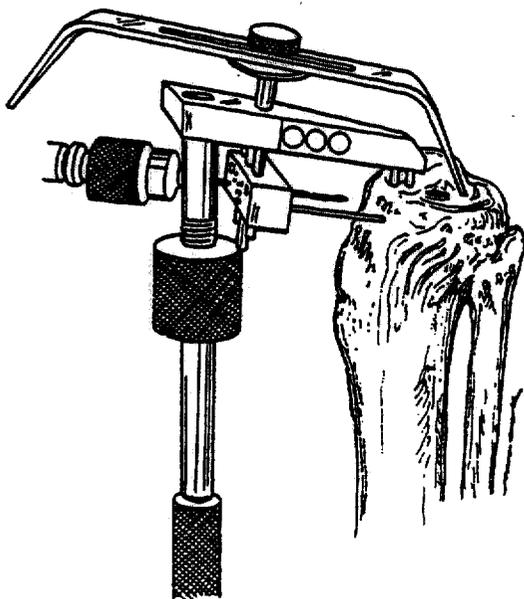


Figure 36

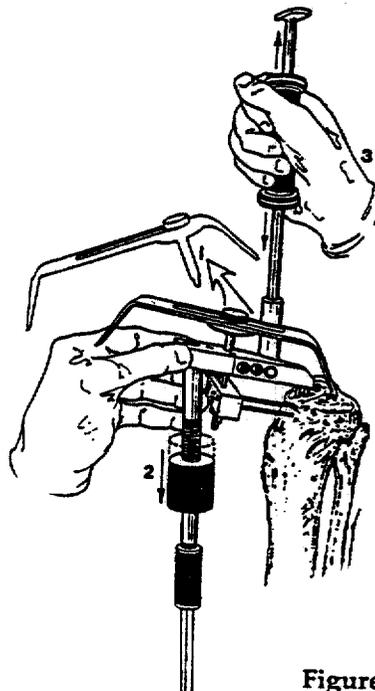


Figure 37

The tibial alignment checker is then placed on the cutting block. The tip of the rod should fall in the middle of the ankle for a perpendicular cut (Figure 38). If the patient has an excessive proximal tibial varus deformity, it is advisable to use the ± 2 -degree varus/valgus block in the varus mode to allow resection of a more symmetrical wedge of proximal tibia. The alignment rod should still fall within the confines of the ankle joint, although it will be slightly (2 degrees) lateralized (Figure 39) at the distal tibiofemoral joint.

Most patients will require a minimum of 9mm of resection to allow use of at least a 9mm polyethylene insert. The cutting block can be moved down in 2mm increments to eliminate bone defects and match the thicknesses of available tibial inserts. The small angled knee retractors should be used to protect the medial and lateral collateral ligaments. The PCL should be well protected with the large angled knee retractor and a 1/4-inch osteotome (Figure 40).

Perpendicular
Cut

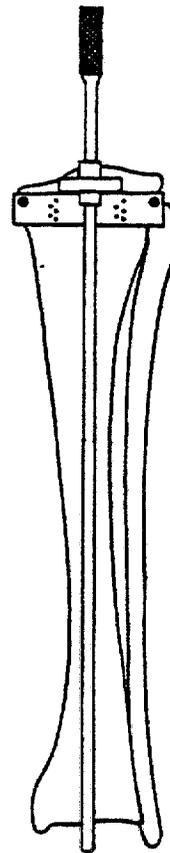


Figure 38

2-Degree
Varus Cut

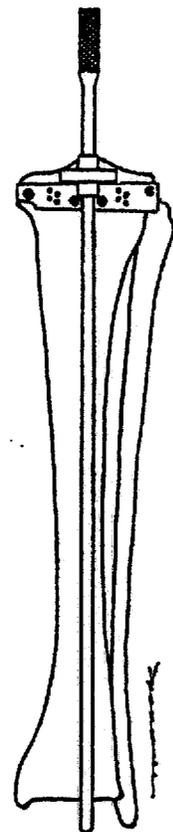


Figure 39

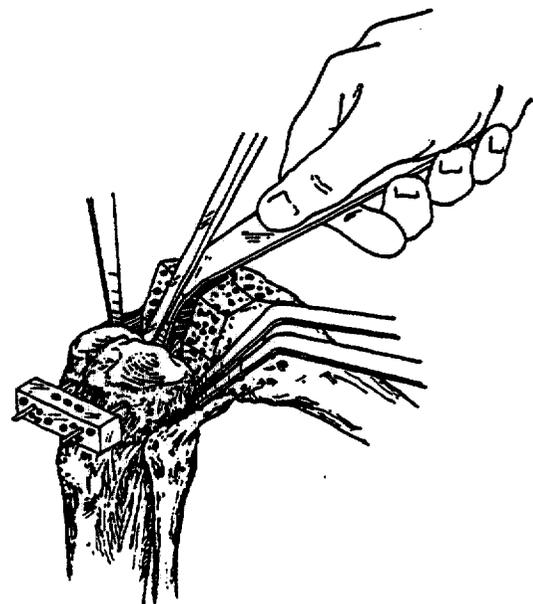


Figure 40

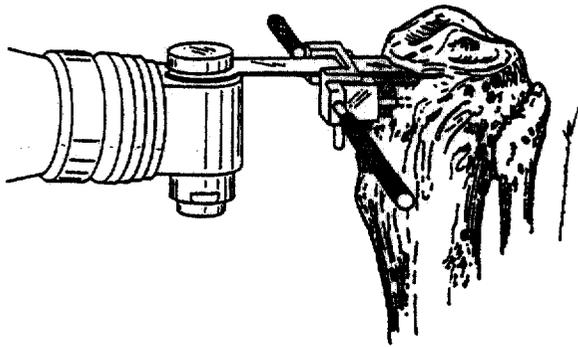


Figure 41

Using the 1-inch saw blade, the proximal tibial cut is made (Figure 41).

The caliper is used to measure the resected tibia in areas of relatively normal cartilage (Figure 42). Adding 1mm to this measurement for bone loss from the saw blade will predict the thickness of the tibial replacement.

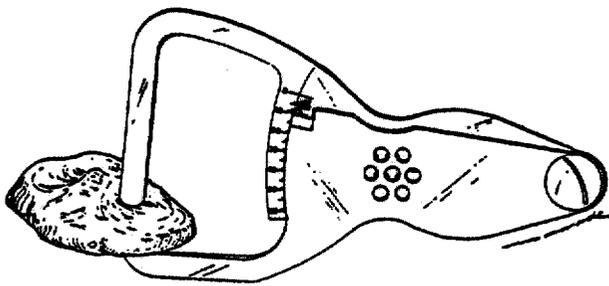


Figure 42

The tibial cut is checked for flatness by sighting along the block or by using an auxiliary cutting block as a level (Figure 43).

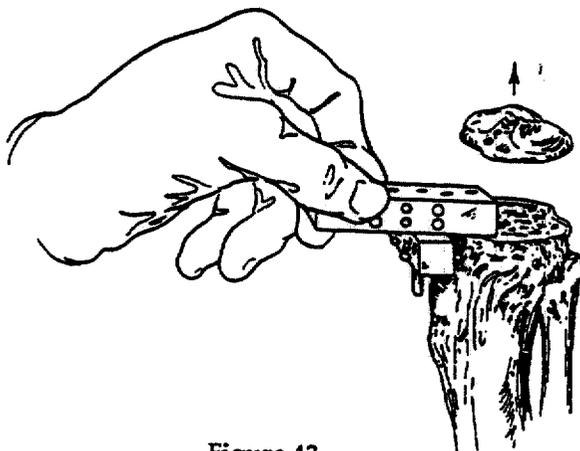


Figure 43

140

Proximal Tibia Sizing and Drilling

The proximal tibial drill guides are positioned on the cut surface of the proximal tibia to select the largest-size tibial baseplate that does not overhang. (Medial overhang is a recognized source of pes bursitis and should be avoided.) To prevent medial overhang, the central hole on the medial side is drilled to the first mark of the calibrated drill bit and filled with a 1/8-inch by 3-inch smooth pin. The final rotation is now adjusted based on the tibial tubercle, and the lateral central hole is drilled and filled. The alignment of the tibial cut may be checked using the proximal tibial drill guide in conjunction with an alignment rod. The remaining four peripheral holes are drilled to the same depth, except when implanting a nonporous baseplate (Figure 44). Inserting smooth pins through these holes will further stabilize the drill guide. If a drill hole for one of the four baseplate pegs is in sclerotic bone, the hole should be slightly enlarged by toggling the drill bit. The implant requires fitting a 4.8mm peg into a 3.2mm hole. The small (size 0 baseplate), medium (sizes 1 to 2 baseplates) or large (sizes 3 to 5 baseplates) tibial broach is inserted and implanted if a metal-backed stemmed tibial component is to be used (Figure 45).

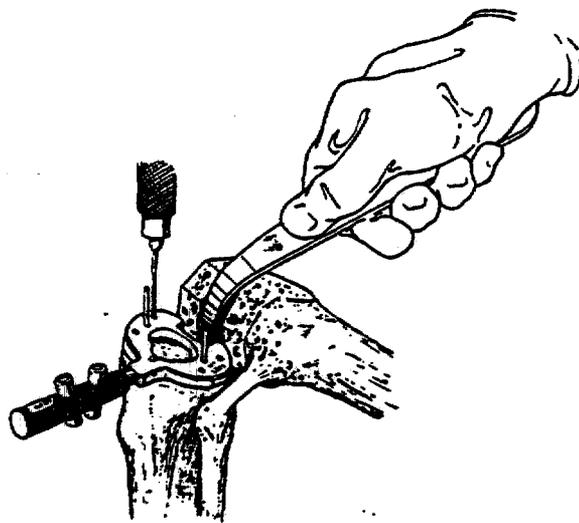


Figure 44

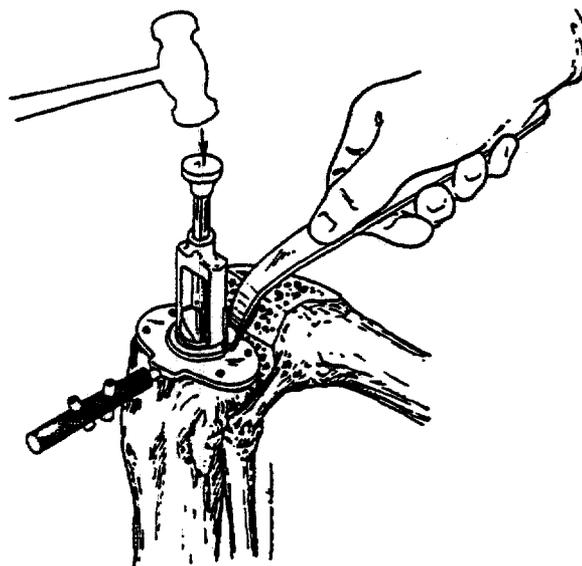


Figure 45

Patellar Preparation

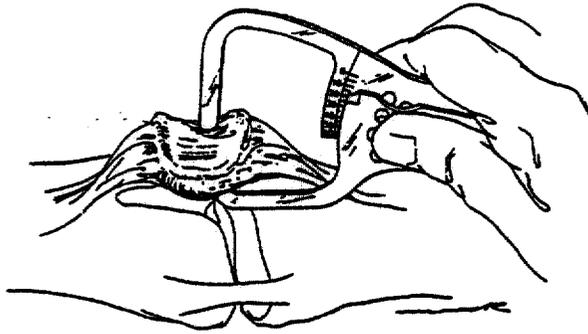


Figure 46

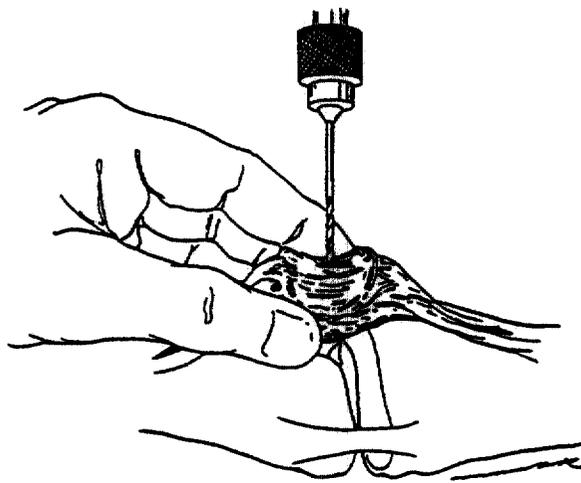


Figure 47

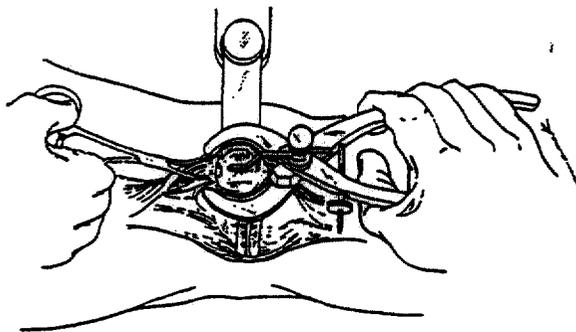


Figure 48

The patella is prepared in the standard fashion by placing the leg in full extension and stabilizing the patella with two inverted towel clips or by using a rake retractor to keep the patella everted. Soft tissue around the patella is incised down to the insertion of the quadriceps and patellar tendons using an electro-cautery knife. Before making any bone cuts, the maximum thickness of the patella is determined using a caliper (Figure 46). Using the calibrated 1/8-inch drill point, the highest portion of the medial facet is drilled perpendicular to the articular surface to a depth of approximately 12mm (Figure 47). This will act as a guide for proper medialization of the patella. Next, the patella osteotomy guide is used with the stylus set for the desired amount of resection (usually 7mm). If the patella is very worn, less bone should be resected. A minimum of 10mm of patella should be retained.

The guide is applied with the jaws at the osteochondral juncture medial and lateral and the handles of the jig oriented toward the foot. The jaws should be parallel to the dorsal surface of the patella. The stylus is positioned over the most prominent point on the patella. If the 10mm component is countersunk, it is recommended that the stylus be positioned at 7mm of resection. The cut is made with the 1-inch saw blade (Figure 48).

Using the sizing template (Figure 49), the maximum-size patella that does not overhang is selected (sizes 0 to 3). Eccentric placement of the patella 3mm to 4mm toward the medial facet allows for better tracking.¹⁵ Use the 1/8-inch drill hole as a reference for proper medialization.

The patella clamp with the appropriate-size patella bushing is placed over the cut surface of the patella and centered slightly toward the medial facet and over the 1/8-inch drill hole (Figure 50).

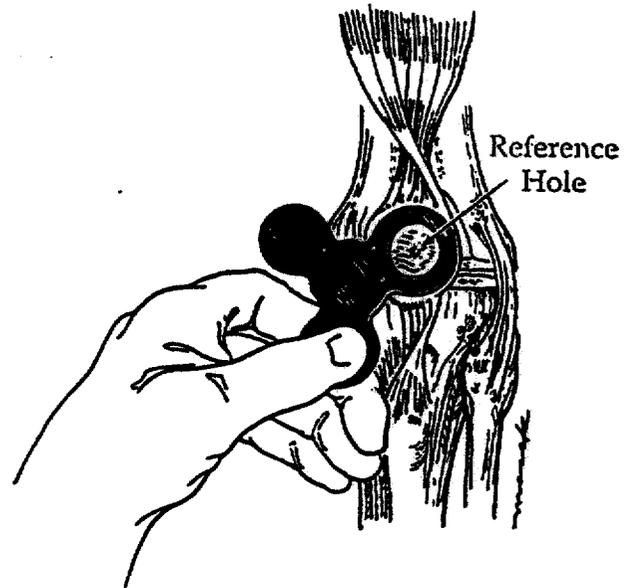


Figure 49

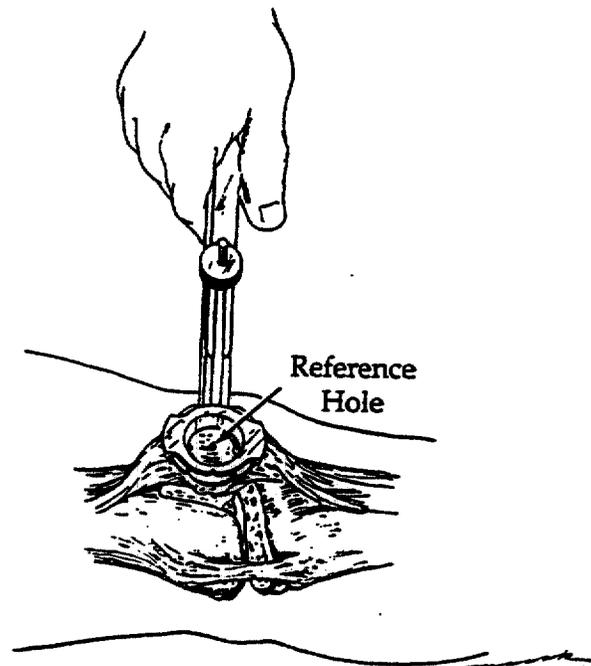


Figure 50

¹⁵Annual Knee Society Meeting, AAOS, New Orleans, 1994.

VP

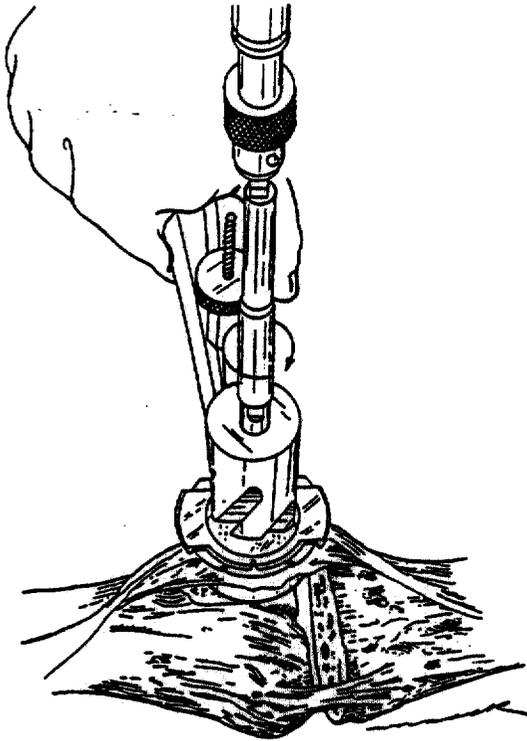


Figure 51

The surface is prepared by applying gentle pressure with the matching size cutter (Figure 51) for 5 seconds to 10 seconds at a time until the desired thickness is achieved. This is determined by placing the caliper through the inferior hole of the patella clamp and over the patella bushing (Figure 52). If the 10mm metal-backed component is selected, it should be recessed 2mm to 3mm. (Although it is contraindicated to countersink the 7mm all-poly patella, the 10mm all-poly patella may be countersunk if desired.) Example: If the patella thickness was 25mm, the thickness should be 18mm after resection. The final patella thickness of the countersunk area should be 15mm for use with a 10mm thick patella component.

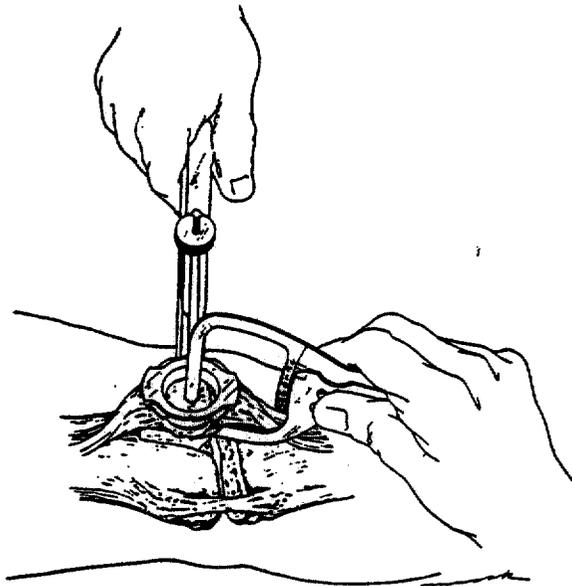


Figure 52

44

With the clamp still in place, the drill guide is inserted into the patella bushing. If the metal-backed patella is selected, the three smaller holes for the patella pegs are drilled with a 1/8-inch by 5-inch drill bit and successively filled with 3.2mm smooth pins (Figure 53). Each hole must be drilled and filled before proceeding to the next hole to ensure equal distance between holes. If the all-poly patella component is selected, the all-poly patella stop drill is used to drill the three larger holes. The peg holes are in the same location on all sizes of patellae.

Separate patella trials are available for 7mm and 10mm all-poly patellae as well as 10mm metal-backed patellae. Due to the wall thickness of the patella bushing, occasionally the next larger size 7mm all-poly patellar component can be used to maximize cortical bone contact. However, avoid any overhang.

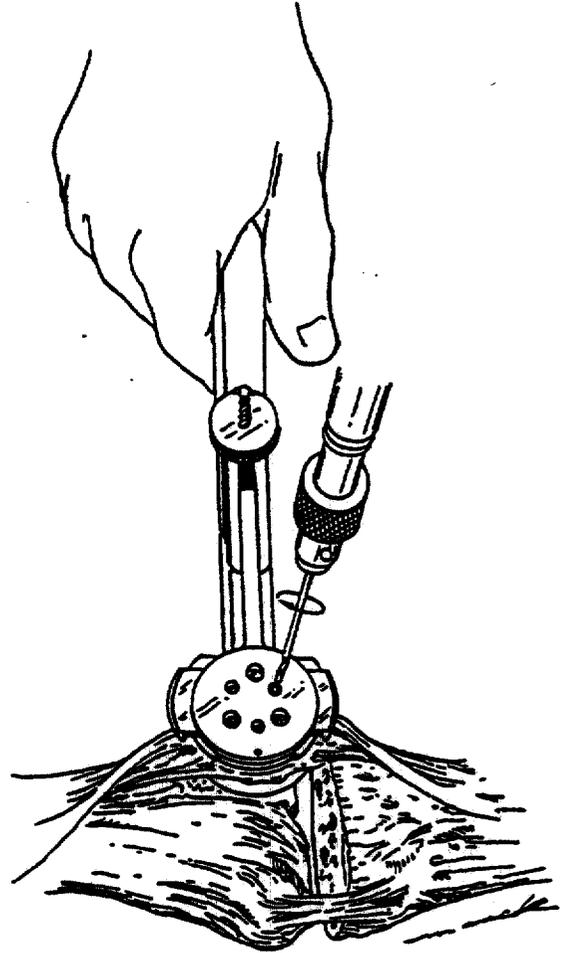


Figure 53

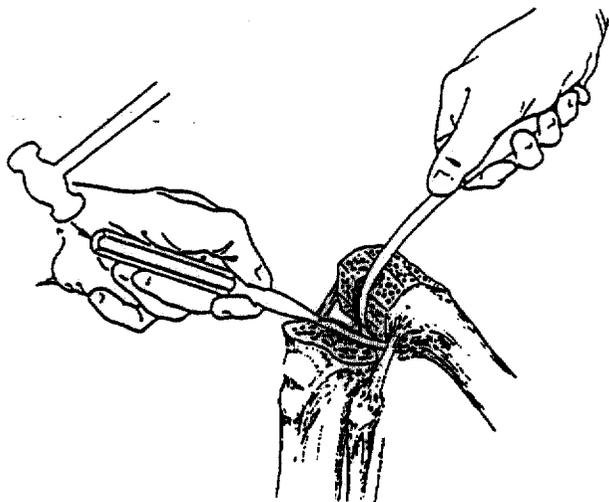


Figure 54

Trial Reduction

Prior to trial reduction, posterior osteophytes on the femur are removed using a 3/4-inch curved osteotome while lifting the femur with a bone hook (Figure 54). Osteophyte removal is required for maximum knee flexion.

The tibial baseplate and insert trials are applied first, followed by appropriate femoral trial (Figure 55). A 9mm or larger trial tibial insert is then inserted. Any fine-tuning of soft tissue releases should be done at this time (see Soft Tissue Balancing section). Stability is checked in full extension, 20 degrees of flexion and full flexion. If the PCL is intact, slight medial and lateral laxity should be allowed. Full extension must be obtained on the operating table. If the PCL is absent, the next larger size (thickness) tibial insert must be selected. The slight flexion deformity this creates will stretch out over the first 6 months. It is suggested that the PCL be resected intentionally if the patient has more than 10 degrees varus or valgus deformity or more than a 10-degree to 15-degree flexion contracture preoperatively. The ultracongruent insert is recommended for the PCL deficient knee. **Note: See Soft Tissue Balancing.**



Figure 55

46

With the leg in full extension, the alignment rod (two pieces assembled together) is held between the center of the ankle and approximately 2cm medial to the anterior superior iliac spine (Figure 56). This positioning should allow the alignment bar to fall at the center of the knee. The trial components are then removed. The femoral trial component is removed by inserting the slaphammer/extractor tool between the condyles (Figure 57).

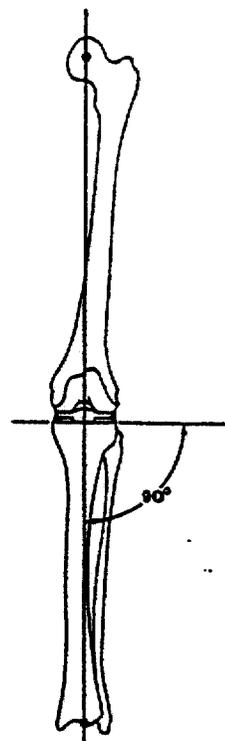


Figure 56

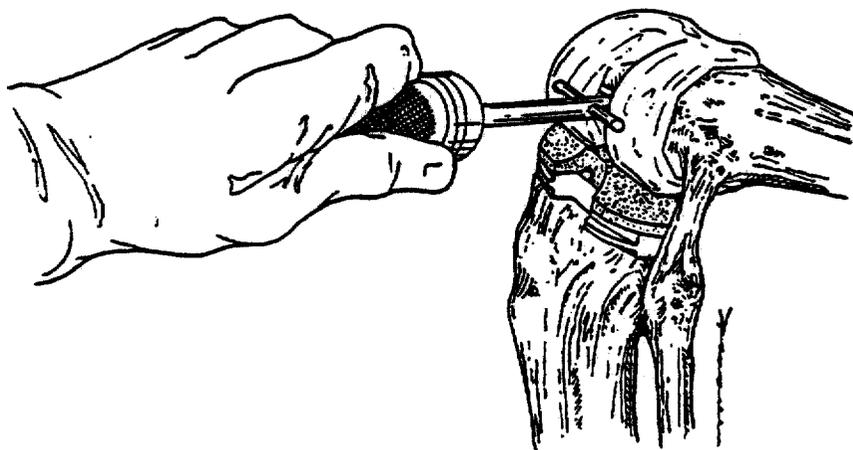


Figure 57

Implanting the Components

The patella is initially implanted using the patella clamp in combination with the patella inserter (Figure 58). Final seating of the component is ensured by light taps of the mallet on the inserter.

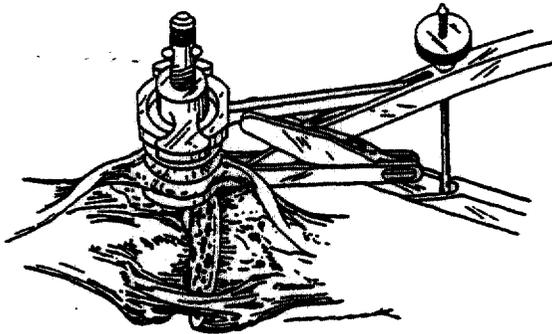


Figure 58

The tibial baseplate is pressed onto the proximal tibia using the tibiofemoral impactor (Figure 59).

The tibial baseplate is further stabilized with 6.5mm titanium cancellous bone screws (Figure 60). In all cases, two 50mm screws are used with slight central angulation medially and 10 degrees central angulation laterally.

An attempt should be made to keep the screws inside the cortex to avoid soft tissue impingement.

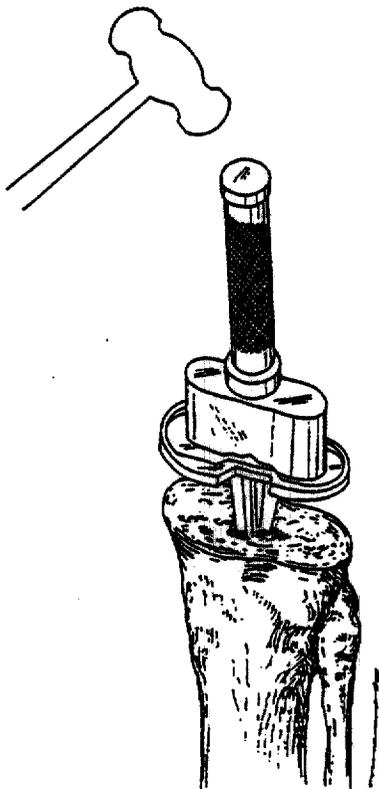


Figure 59

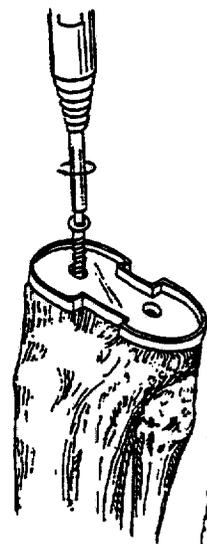


Figure 60

48

The polyethylene insert of the chosen thickness is positioned by first engaging the heels of the insert posteriorly and then snapping the component down anteriorly utilizing the tibial insert impactor and mallet (Figure 61). Soft tissue must be cleared away to allow for easy insertion. The insert fixation screw is applied. Screw through the first area of resistance until a dead stop is engaged. To insure optimal insert-baseplate fixation, it is recommended that the screw fixation feature be utilized with the congruent insert. The insert screw must be utilized with the ultracongruent insert.



Figure 61

The femoral component is implanted using the tibiofemoral impactor (Figure 62). Range of motion and ligament stability are checked again.

The knee is taken through a range of motion to observe patella tracking. A lateral release should be done if the patella tends to track laterally. An outside-in technique is preferred with the knee flexed to titrate any release that is needed. Attempts are made to save the lateral superior geniculate artery and to keep the synovium intact. Many knees will not require a lateral release with this more anatomic replacement, but it should be performed routinely if the patella tracked laterally on the preoperative sunrise view of the patella. The tourniquet is released prior to closure. Insertion of a large (1/4-inch) drain is recommended for 48 hours.

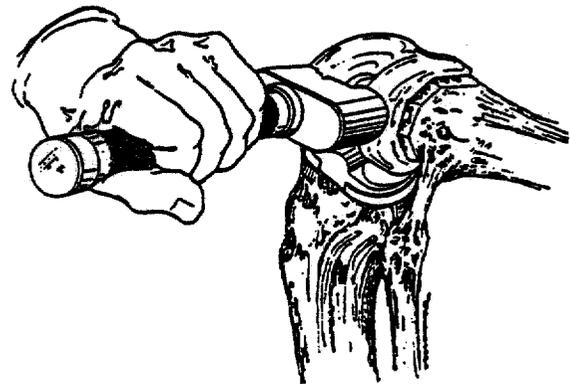


Figure 62

Postoperative Care

The lower extremity is placed in a bulky Jones dressing for 72 hours.

Alternatively, a long-leg surgical support stocking is applied over a sterile occlusive dressing. Continuous passive motion (CPM) is used starting from 0 degrees to 40 degrees and advanced a minimum of 10 degrees per day.

Discharge is allowed when the patient achieves 90 degrees of flexion. Most patients are discharged on a home exercise program. Fifty percent weight bearing on crutches is allowed the first 6 weeks, and a cane is used thereafter until the patient can walk without a limp. Most patients are walking without assistant devices within 3 months after surgery.

Intramedullary Tibial Option

Reference Hole

Placement of the intramedullary guide is accomplished by first drilling a 1/4-inch hole in the proximal tibia. This reference hole should be centered from medial to lateral. Anterior/posterior positioning should fall between the middle and anterior one-third of the tibial plateau (Figure 63). The 1/4-inch, fluted intramedullary rod is slowly inserted to locate the medullary canal. The rod is removed and reinserted through the preassembled intramedullary guide consisting of the alignment guide with the saw guide and tibial stylus affixed (Figure 64).

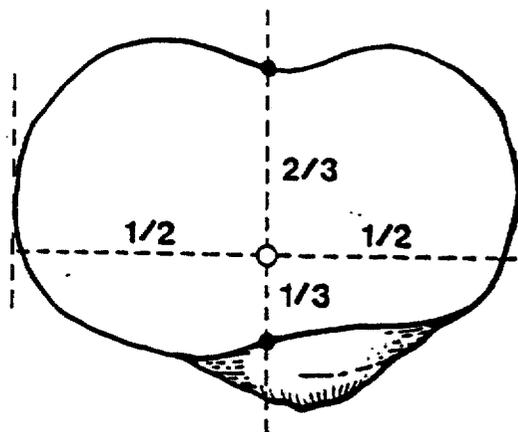


Figure 63

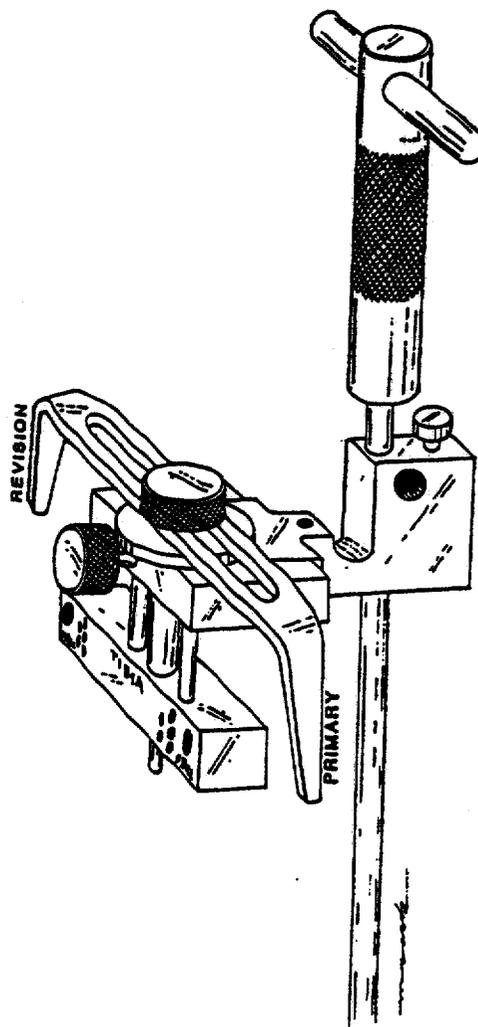


Figure 64

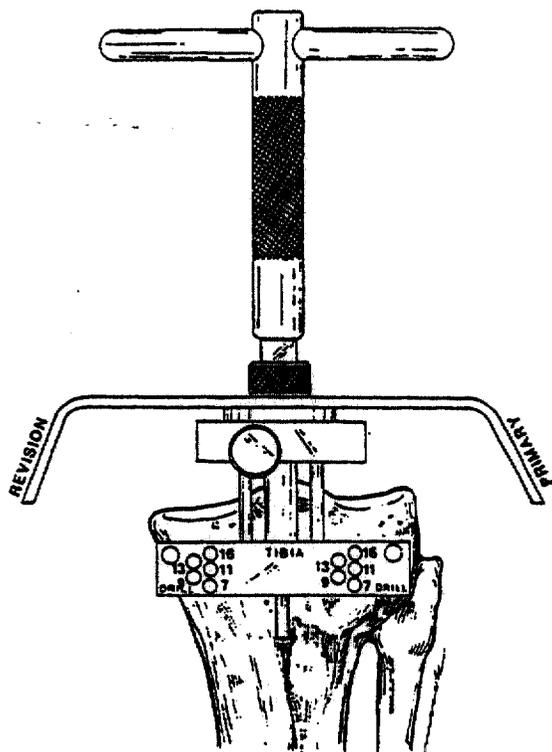


Figure 65

Rotation

Rotational alignment is adjusted first using the tibial tubercle. The distal pin of the cutting block should be positioned just medial to the tibial tubercle (Figure 65).

As a second reference, the posterior surface of the cutting block should be parallel to the posterior edge of the tibial plateau (Figure 66). Ideally, both references should be used. Rotation is then locked in place by impacting the set pin with a mallet (Figure 67). Additional stability can be obtained, if necessary, by drilling and pinning through the auxiliary hole located anteriorly.

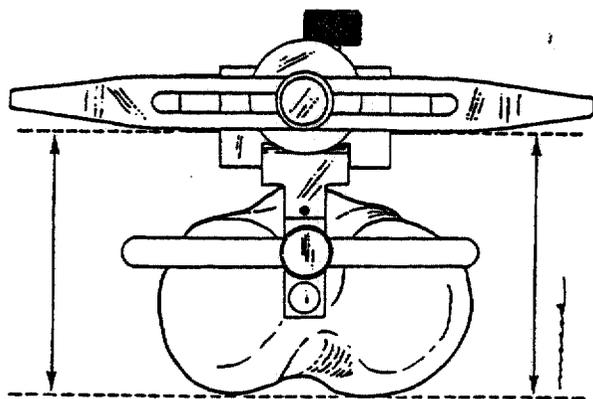


Figure 66

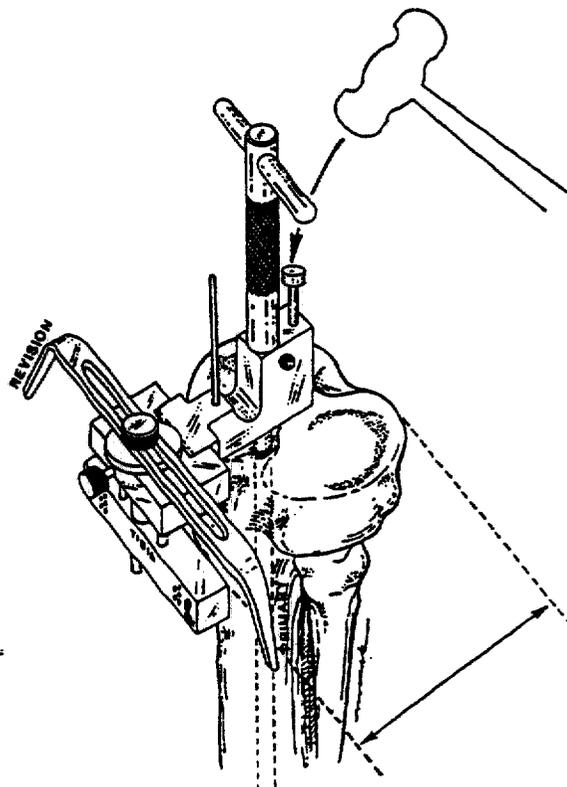


Figure 67

Handwritten signature or mark.

Posterior Slope

The determination of the posterior slope is the second adjustment. Replication is accomplished by placing a 1/8-inch by 5-inch pin through the 16mm hole of the cutting guide over the least affected plateau and adjusting the thumb screw on the anterior side of the guide until the pin touches both the anterior and posterior rims of the proximal plateau. When the desired slope has been achieved, the 1/8-inch by 5-inch pin is removed (Figure 68). The scribed mark on the cutting guide is a 0-degree reference. For collapsed prior tibial osteotomies or revision situations, the posterior slope should be set at approximately 5 degrees.

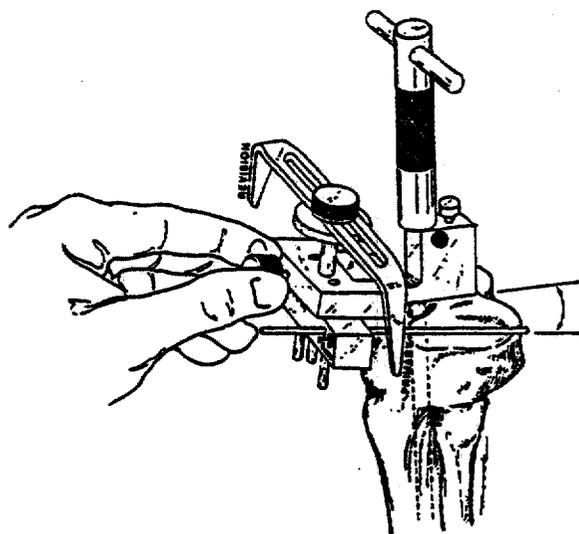


Figure 68

Level of Resection

Establishing the level of the tibial cut is the final adjustment. The stylus end marked "PRIMARY" is placed over the least involved weight-bearing portion of the tibial plateau to re-create the joint line (Figure 69).

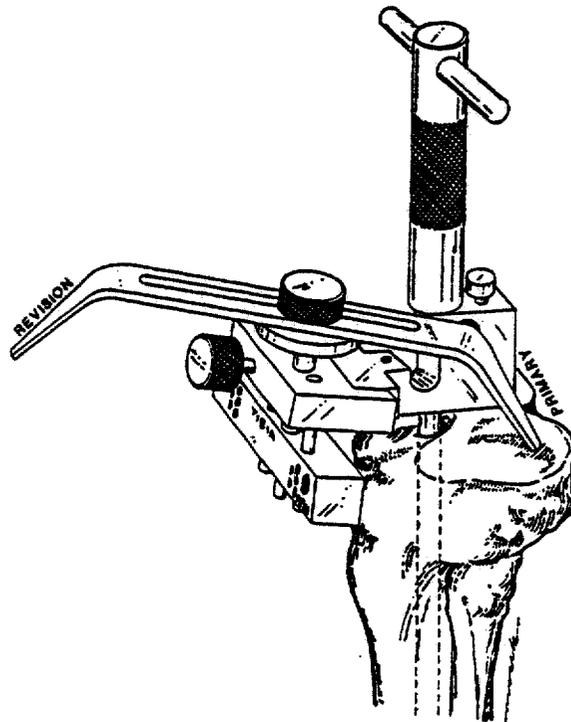


Figure 69

152

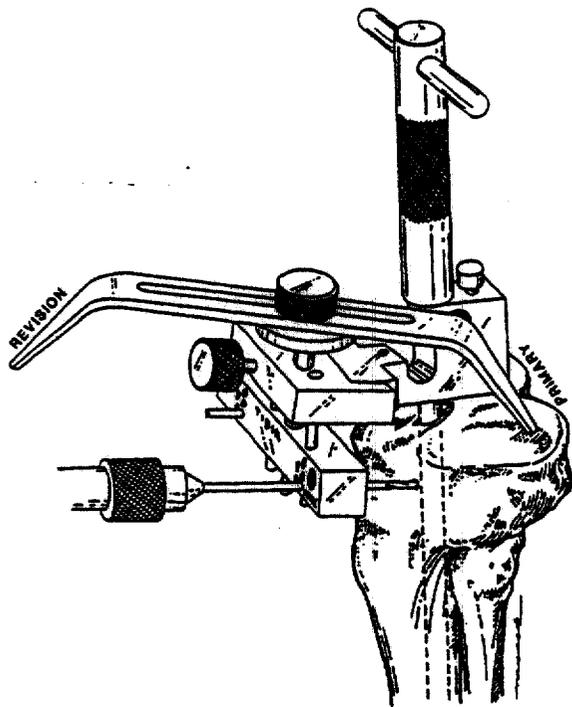


Figure 70

The cutting guide is then stabilized by drilling and pinning through the 7mm medial and lateral holes of the cutting guide (Figure 70). Disassembly of the jig is then achieved by removing the stylus and intramedullary rod. A slaphammer hole is located posteriorly on the guide to aid in removal of the intramedullary rod and jig, leaving the saw guide fixed to the anterior face of the tibia (Figure 71).

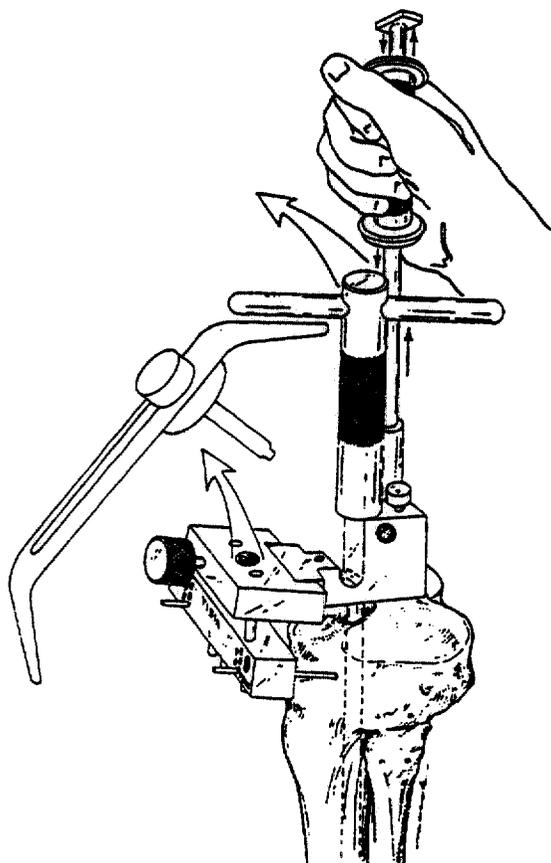


Figure 71

Tibial Spacer Option

(Addressing Medial and Lateral Tibial Defects with 4mm Modular Spacers)

Bony defects greater than 9mm of the medial or lateral tibial plateau will require a minimum 9mm osteotomy and should be considered for a tibial spacer rather than more bone resection.

After standard preparation of the proximal tibia, the spacer cutting guide and alignment plate are assembled for size 0, sizes 1 and 2 or sizes 3, 4 and 5 tibias. The assembly is set for medial or lateral, and left or right, using the reference marks on the ends of the spacer alignment plate (Figure 72). The alignment plate is stabilized using three smooth pins placed in the nondefective tibial plateau surface previously drilled with the proximal tibial drill guide. For added stability, at least one pin is placed through one of the holes located anteriorly on the spacer cutting guide (Figure 73).

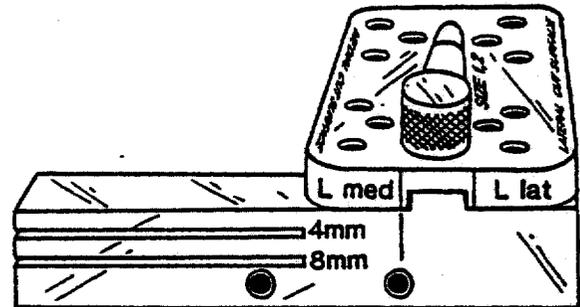


Figure 72

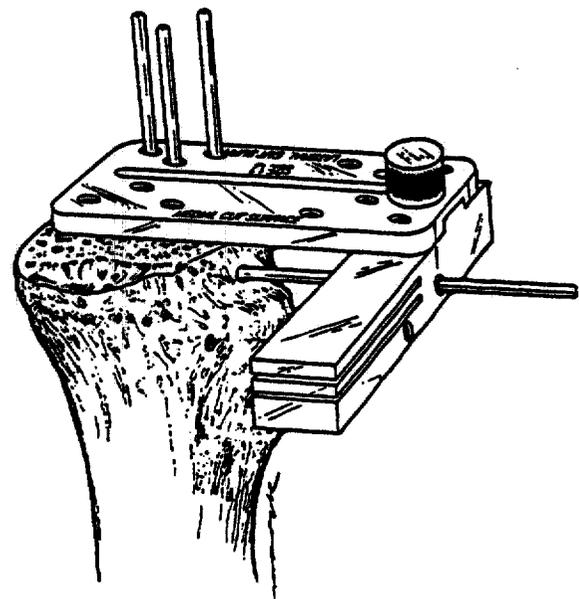


Figure 73

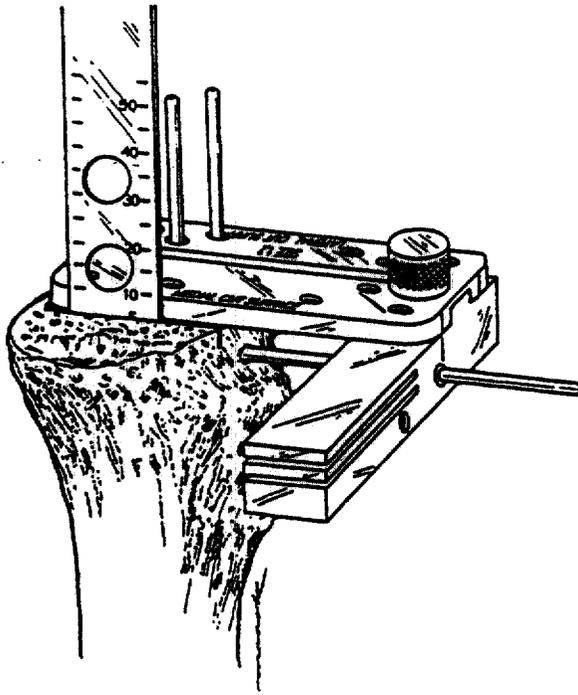


Figure 74

A vertical osteotomy is made using a calibrated 1-inch wide saw blade (Figure 74). This saw cut is approximately 4mm or 8mm deep depending on the size of the defect. A free saw blade is left imbedded in the bone to act as a protector to avoid undercutting the uninvolved tibial plateau surface when the horizontal osteotomy is performed.

The horizontal portion of the step cut is then made through the 4mm or the 8mm slot, once again depending on the size of the defect (Figure 75).

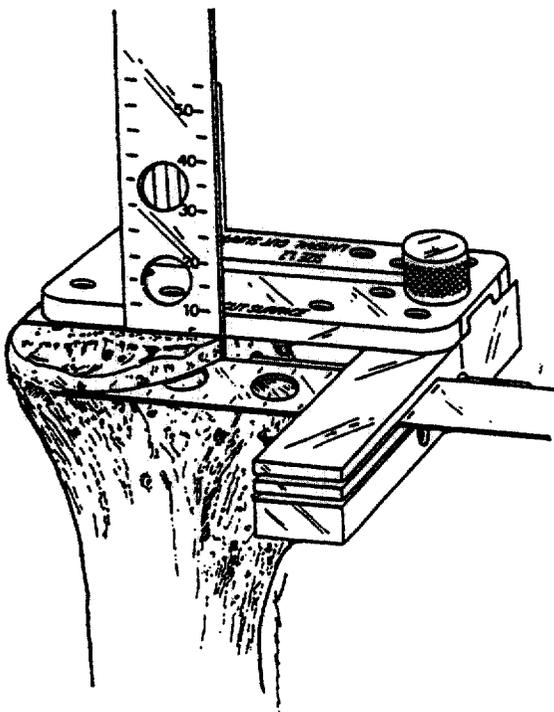


Figure 75

The trial spacer and the trial tibial baseplate are assembled and inserted, followed by the trial component (Figure 76). The tibial trial insert of the appropriate thickness is selected based on flexion and extension stability and the measured thickness of the tibial wafer of bone.

The metal spacer implant is secured to the underside of the final prosthetic tibial metal baseplate using methylmethacrylate. Two stacked 4mm spacers are used for an 8mm defect. Cement restrictors may be removed at this time.

The composite is placed on the prepared surface of the tibia and secured in place with two 50mm titanium cancellous bone screws (Figure 77), which provide excellent pressurization of the cement. The appropriate-size polyethylene tibial insert is placed followed by the femoral component.

Note: The tibial spacers may not be utilized with the nonporous stemmed baseplate or the all-poly tibia. For optimal stability, tibial spacers must be used with pegged baseplates only.

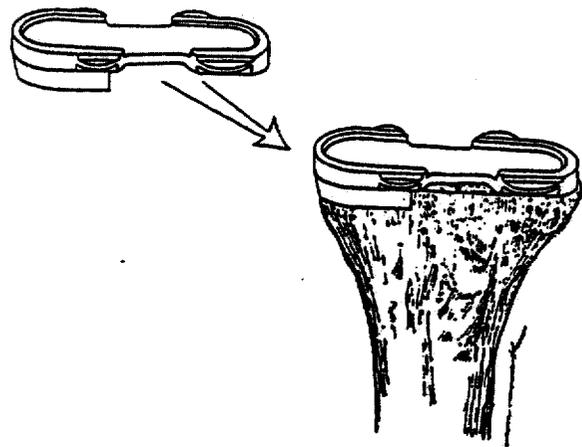


Figure 76

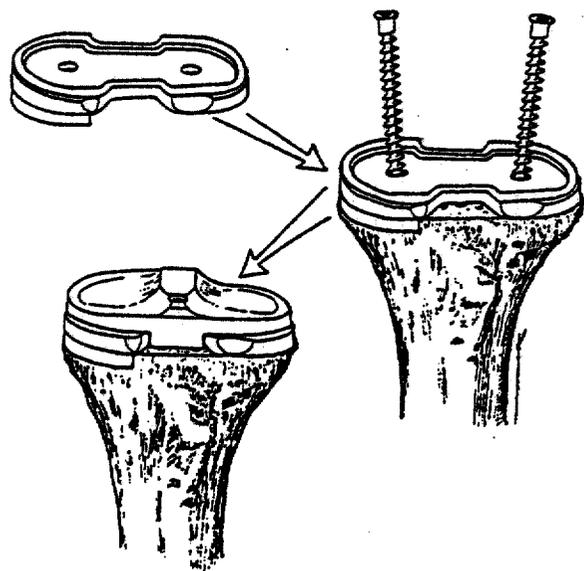
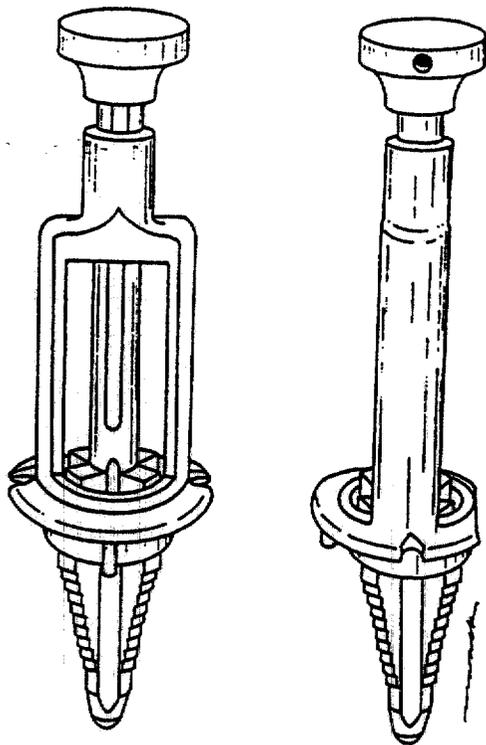


Figure 77





Front View

Side View

Figure 78

All-Poly Tibial Option

Tibial Preparation

The all-poly tibial components utilize their own unique broaches for preparation of the cruciate stem. The appropriate-size broach is inserted into the proximal tibial sizer drill guide and is fully driven into the proximal tibia with a mallet. The small broach is used for sizes 0, 1 and 2 and the large broach is used for sizes 3, 4 and 5 all-poly tibial components (Figure 78). These broaches provide for a 1.5mm cement mantle around the stem.

Tibial Implantation

The all-poly tibia is cemented in place using the all-poly tibia impactor (Figure 79).

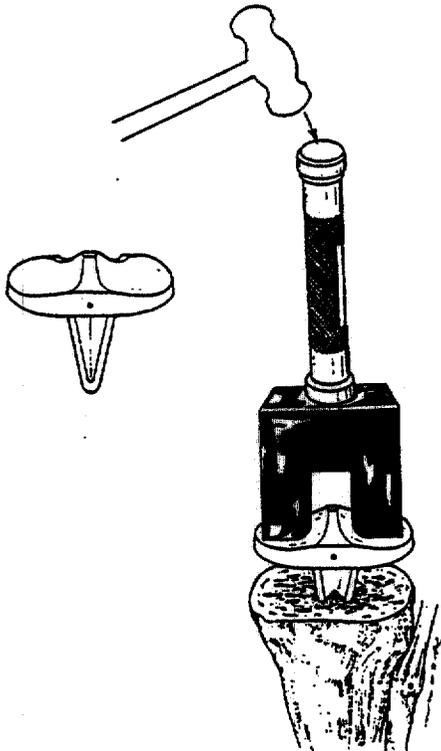


Figure 79

88

Soft Tissue Balancing

Varus Deformity

A varus deformity is easier to correct than a valgus deformity because most of the soft tissue balancing is done with the usual surgical approach to the knee. When the knee is exposed and being prepared for arthroplasty, the medial soft tissue must be released back to the posteromedial corner. This usually releases enough soft tissue initially so that the cuts of the femur, tibia and patella can be made and the final soft tissue balancing done with the trial components. Typically, if the knee has less than 10 degrees of varus deformity, the normal medial release done to expose the tibia is enough to correct the deformity. A slight amount of lateral laxity is acceptable since a varus knee will frequently have a stretched-out lateral soft tissue sleeve. This is of no clinical consequence because of the dynamic nature of the lateral side. This includes the biceps and iliotibial band for dynamic lateral stability. With the posterior cruciate ligament (PCL) intact, the knee should come to full extension. Check this by placing a hand on the greater trochanter. Medial/lateral stability in full extension should have 1mm of laxity. Remember, the normal knee has 7 degrees of varus/valgus play. Always test the competence of the PCL by performing a forced posterior draw maneuver. If excessive femoral roll-back

in flexion is present, the PCL should be progressively released from the tibia.

In the case of a varus knee which has a significant flexion contracture (greater than 15 degrees), the PCL most likely will require resection. If the PCL is resected, the knee is balanced so that the collateral ligaments have no laxity and the knee rests with 5 degrees to 10 degrees of spring short of full extension. One size/thickness larger tibial insert than the measured amount of bone resection, should be implanted. For example, if 9mm of tibia are resected this should be replaced with an 11mm insert. The posterior capsule will stretch out over the first 6 months. If the knee lacks full extension, but excessive roll-back is not present in flexion, one can alternatively resect more distal femur (or proximal tibia) by using the +2mm, -2mm, -4mm block (auxiliary distal femoral saw guide), rather than resecting the PCL. Approximately 1mm of bone resection is required for every 4 degrees of contracture.

Valgus Deformity

Valgus deformities are more difficult to balance properly than varus deformities. A valgus deformity frequently has a stretched-out medial collateral ligament which can be difficult to tighten. In many cases, it will be easier to balance between medial and lateral if the PCL is resected. This will allow overstuffing

the joint by one insert thickness, which will slightly tighten the medial side.

Valgus knees are a frequent indication for use of the ultracongruent insert, which provides increased anterior/posterior stability as well as rotational stability. Alternatively, if there is greater than 1cm of difference between varus and valgus laxity, the superficial medial collateral ligament is advanced distally on the tibia and stabilized with a ligament staple.

The lateral soft tissue releases are done in the following sequence: the popliteus tendon is taken at the time the lateral meniscus is removed. While removing posterior osteophytes, the posterior capsule is released from the femur, which should help with posterolateral tightness. Following this, the trials are placed and the other lateral structure palpated for tightness. If the knee is tight laterally in extension and not flexion, this is due to a tight iliotibial band. The iliotibial band is released from the inside by simply feeling the tight portion of the iliotibial band and transversely sectioning it with a knife with the knee in full extension. If care is taken to keep all of the release anterior to the head of the fibula, the peroneal nerve should be well protected.

If the knee is tight in both extension and flexion, the lateral collateral ligament is

usually tight. This can be confirmed by placing a finger in the lateral gutter of the knee and palpating the lateral collateral ligament to determine if it is too tight. The lateral collateral ligament is released with the knee in flexion by peeling the lateral collateral ligament subperiosteally off its origin on the femur to allow it to slide distally. The lateral collateral ligament can be released partially or completely in continuity with the lateral posterior capsule. Another option is to do a Z-lengthening of the fibular collateral or the iliotibial band. In extreme cases of valgus deformity, the biceps tendon may need to be released through a separate incision.

Ultracongruent Tibial Insert Indications

- (1) Marked valgus deformity - requiring PCL and lateral soft tissue release.
- (2) Prior high tibial osteotomies - soft tissue balancing is the same as for a valgus deformity with lateral soft tissue and PCL release.
- (3) Patellectomy - PCL incomplete or absent.
- (4) Most revision situations - PCL deficient or nonfunctional.

NOTE: The ultracongruent insert is contraindicated if the PCL is present.

The procedures contained herein are based upon techniques developed by Aaron A. Hofmann, MD, and are provided for informational purposes only. Members of the medical profession should determine the appropriateness of the surgical procedures and techniques herein based upon medical training, knowledge, and experience.

The Natural-Knee Primary Femoral, Resurfacing and Stemmed Tibial Baseplate, and Metal Backed Patellar Components with CSTi are approved for use with or without bone cement in the United States. Uncemented use of all other components in the Natural-Knee System is considered to be investigational in the United States. Intermedics Orthopedics, Natural-Knee, SinterLock CSTi and the logo are registered trademarks and Cancellous-Structured Titanium and CSTi are trademarks of Intermedics Orthopedics, Inc.

Intermedics Orthopedics products are distributed by:

Distributed in Japan by:

Sulzermedica Japan, Ltd.

Itopia Eitai Bldg. 7F

3-7 Saga 1-chome

Koto-ku

Tokyo, Japan 135

CS (3821) 7471

Distributed in Canada by:

Sulzer Canada, Inc.

295 Hymus Blvd.

Pointe Claire, Quebec H9R1C6

(514) 695-8320

Distributed in Australia by:

Sulzer Australia Medical

27 Salisbury Road

Hornsby, NSW 2077

(2) 476-4099

Distributed in Europe by:

Allo Pro AG

Grabenstrasse 25

CH-6340 Baar

(41) 42 34 32 32



Intermedics Orthopedics, Inc.

A company of **SULZERmedica**

Improved. Always. Driven by science.

9900 Topgum Drive

Austin, Texas 78717

512-412-4400 • 1-800-888-4676

Fax: 512-433-9014