

JAN - 4 2001

**510(k) SUMMARY**

K003269  
1 OF 4

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807, this is to serve as a Summary of Safety and Effectiveness for the Sulzer Orthopedics Unicondylar Interpositional Spacer.

**Submitter:** Sulzer Orthopedics Inc.  
9900 Spectrum Drive  
Austin, Texas 78717  
(512) 432-9900

**Date:** October 16, 2000

**Contact Person:** Mitchell A. Dhority  
Manager, Regulatory & Clinical Affairs

**Classification Name:** 21 CFR 888.3590 - Knee joint tibial (hemi-knee) metallic resurfacing uncemented prosthesis

**Common/Usual Name:** Hemi-knee prosthesis

**Trade/Proprietary Name:** Unicondylar Interpositional Spacer (UIS)

**PRODUCT DESCRIPTION**

Currently, arthroscopic debridements are performed regularly to address the pain and synovitis associated with early stage osteoarthritis; as many as half of those patients treated are estimated to have Grade III-IV chondromalacia. It is also estimated that failure occurs within 2 years in half of those treated. While the effectiveness of arthroscopic debridement is quite variable, it is clear that it does not address the mechanical alignment and laxity problems associated with the joint. Use of other options, such as knee arthroplasty and high tibial osteotomy (HTO), are more invasive, technically challenging and may compromise the joint to future treatment options. Anti-inflammatory medications have also been used to manage pain, but have limited effect on moderate arthritis and offer no solution in terms of repair to the joint.

The Unicondylar Interpositional Spacer was developed as an alternative to arthroscopy, HTO and knee arthroplasty treatments for those situations where limited degeneration/joint destruction exists. Instead of simply debriding soft tissues as in arthroscopy or resecting valuable unaffected bone and cartilage as in total knee replacement, this treatment allows for placement of a metallic "spacer" device into the joint space above the affected medial tibial plateau. The femur then articulates against the polished, curved surface of device. The device is intended to be used without cement and is held in place by its geometry and the surrounding soft tissue structures.

The device will be manufactured from either wrought cobalt chromium alloy (ASTM F1537) or forged cobalt chrome alloy (ASTM F799). The design is kidney shaped to mimic that of the medial tibial condyle; the shallow "dished" geometry allows for articulation with the femur. It is asymmetric (left and right components) and is available in seven sizes (30-54mm) and five thicknesses (1-5mm) to better restore joint alignment, tension and stability.

The surgical procedure to place the device is carried out in two stages. First, the posterior horn of the meniscus is debrided and resected arthroscopically. The device may then be inserted into the joint space above the affected medial tibial plateau via open surgical implantation.

Use of this device raises no new issues relative to safety or effectiveness and provides several potential advantages over other surgical options, including:

- Technically easier to implant than a unicompartmental total knee, high tibial osteotomy or meniscal transplant.
- Facilitates future conversion to total knee arthroplasty by eliminating the need for bone resections.
- Is surgically less invasive (e.g. unicompartmental treatment, smaller incision, fewer implant components required, no bone resection required).

### SPECIFIC DIAGNOSTIC INDICATIONS

The Unicondylar Interpositional Spacer is intended for uncemented use in treatment of the following:

- Moderate degeneration of the medial compartment of the knee (grade III-IV chondromalacia) with no more than minimal degeneration (grade I-II chondromalacia, no loss of joint space) in the lateral condyle and patellofemoral compartments.

### SUBSTANTIAL EQUIVALENCE

Substantial equivalence is based on comparison to the following preamendment devices:

- McKeever Hemiarthroplasty Prosthesis
- MacIntosh Hemiarthroplasty Prosthesis
- Sbarbaro Tibia Plateau Prosthesis

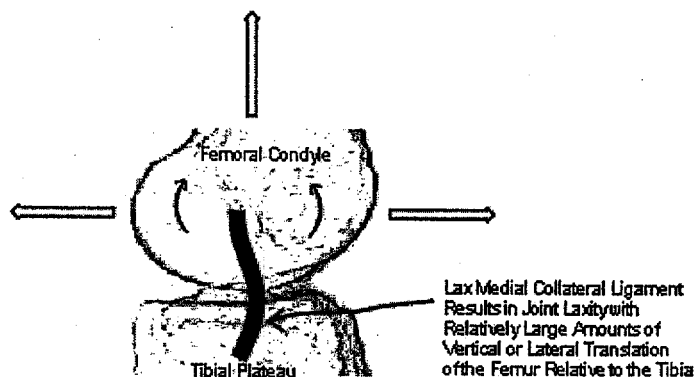
### Design Features

The subject and predicate devices are similar in terms of design features. All of these designs are unicondylar in nature and generally incorporate a metallic tibial resurfacing component of various sizes/thicknesses. The femoral condyle articulates against the curved upper surface of the implant.

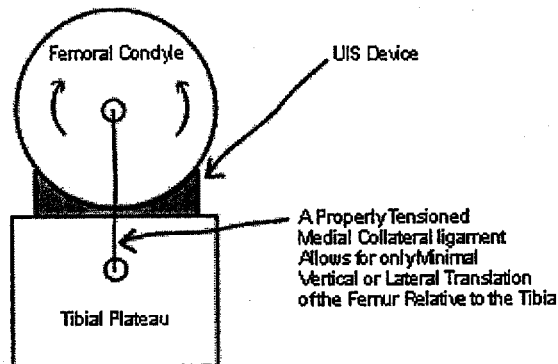
### Stability

Like the MacIntosh tibial prosthesis, the Unicondylar Interpositional Spacer has no obvious means of attachment.

In the osteoarthritic knee, substantial amounts of articular cartilage have been lost as a result of the disease. The knee compartment suffers a subsequent closing of the joint spacing as seen on X-ray. This joint closing allows the collateral ligament to become lax and the joint to become unstable and off-axis (varus deformity). Whereas normal motion of the femoral condyle is largely rotational, if ligament laxity is present, there will be increased translational motion of the femur relative to the tibia



Filling the joint space that was once occupied by the now missing articular cartilage can restore the correct tension of the collateral ligament. When the proper thickness of the Unicondylar Interpositional Spacer is chosen, the tightening of the collateral ligament prevents any excessive translational motion of the femoral condyle. Thus, almost all of the forces against the Unicondylar Interpositional Spacer now become rotational and the Unicondylar Interpositional Spacer will have no forces acting on it that would cause it to "spit" from the joint space. The stability of the joint is restored.



The surface geometry of the Unicondylar Interpositional Spacer also plays a significant role in its inherent stability.

MacIntosh states "The collateral ligaments usually maintain their own length...and that the stability is maintained by a prosthesis that is thick enough to correct the deformity and take up the slack in the collateral ligaments". He further states that "The prosthesis is held in position by the anatomy of the knee joint, and stability depends on taut collateral ligaments. The top of the prosthesis has a contoured surface with rounded edges to provide the condyle with a permanent low friction area."

The Unicondylar Interpositional Spacer has a femoral surface geometry that imitates that of the tibial plateau including an intact meniscus. On the other side, the tibial surface of the Unicondylar Interpositional Spacer imitates the surface of the tibial plateau without the meniscus.

When the Unicondylar Interpositional Spacer is properly placed into the knee compartment, it rests inside the boundaries of the resected meniscus. It has substantially intimate contact with the tibial plateau throughout the entire range of motion. The femoral side of the Unicondylar Interpositional Spacer also has substantially full contact with the femoral condyle when the knee is in full extension.

Thus, when the knee is in full extension, the Unicondylar Interpositional Spacer can only be located in one position in the joint space as determined by the relative position of the femoral condyle to the tibial plateau.

As the knee is flexed and the femoral condyle begins to rotate, since the collateral ligaments remain under tension, the posterior aspect of the femoral condyle remains in contact with the central weight-bearing surface of the UIS

Materials

The subject and predicate devices are similar in terms of materials used. All of these designs use cobalt chrome alloy.

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Intended Use

Additionally, the subject and predicate devices share similar indications for use. The subject device, like the predicate devices, are used generically in the treatment of unicompartmental tibial arthritis where total knee replacement is not warranted.

Clinical Safety & Effectiveness

Based on review of the published clinical literature on this type of device, the known potential risks associated with these devices are essentially of the same type and frequency as unicompartmental or total knee replacement, arthroscopy and others. As shown in the publications associated with the predicate devices, these risks include hematoma, infection, nerve palsy, embolus, dislocation, fracture and need for revision. The less invasive nature of the device also lends itself to ease of conversion to the more conventional surgical treatments.

The history with the predicate devices also indicates that the effectiveness of this treatment is at least equal to that obtained with tibial osteotomy in terms of pain relief, correction of deformity and restoration of stability. Furthermore, it provides some added benefits which cannot be recognized with current treatments (e.g., ease of implantation, ease of conversion to other treatments, less invasive).

Testing did not raise any new issues of safety or effectiveness and indicated that this device should provide performance equivalent to commercially marketed products.





DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JAN - 4 2001

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Mitchell Dhority  
Manager, Regulatory & Clinical Affairs  
Sulzer Orthopedics, Inc.  
9900 Spectrum Drive  
Austin, Texas 78717

Re: K003269

Trade Name: Unicondylar Interpositional Spacer (UIS)  
Regulatory Class: II  
Product Code: HSH  
Dated: October 17, 2000  
Received: October 18, 2000

Dear Mr. Dhority:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

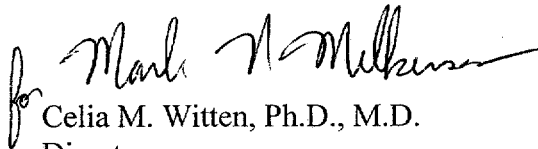
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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

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

Page 2 - Mr. Mitchell Dhority

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

Sincerely yours,

A handwritten signature in black ink, appearing to read "for Mark N. Milburn". The signature is written in a cursive style and is positioned above the typed name of the signatory.

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

Enclosure

510(k) Number (if known): 003269

Device Name: Unicondylar Interpositional Spacer

### Indications for Use:

The Unicondylar Interpositional Spacer is intended for uncemented use in treatment of the following:

- Moderate degeneration of the medial compartment of the knee (grade III-IV chondromalacia) with no more than minimal degeneration (grade I-II chondromalacia, no loss of joint space) in the lateral condyle and patellofemoral compartments.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

*for Mark A. Melkerson*

(Division Sign-Off)  
Division of General Restorative Device

510(k) Number K003269 1/4/01

Prescription Use \_\_\_\_\_

OR

Over-The-Counter Use \_\_\_\_\_

(Optional Format 1-2-96)



JAN - 4 2001

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Mitchell Dhority  
Manager, Regulatory & Clinical Affairs  
Sulzer Orthopedics, Inc.  
9900 Spectrum Drive  
Austin, Texas 78717

Re: K003269  
Trade Name: Unicondylar Interpositional Spacer (UIS)  
Regulatory Class: II  
Product Code: HSH  
Dated: October 17, 2000  
Received: October 18, 2000

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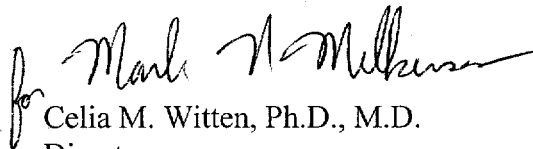
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Page 2 - Mr. Mitchell Dhority

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Sincerely yours,



Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative and  
Neurological Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure



510(k) Number (if known): 003269

Device Name: Unicondylar Interpositional Spacer

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

*for Mark A. Melkerson*

(Division Sign-Off)  
Division of General Restorative Device

510(k) Number K003269 1/9/01

Prescription Use \_\_\_\_\_

OR

Over-The-Counter Use \_\_\_\_\_

(Optional Format 1-2-96)

3

Memorandum

From: Reviewer(s) - Name(s) Peter Allen

Subject: 510(k) Number 1C 00 3269

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

- Refused to accept.
- Requires additional information (other than refuse to accept).
- Is substantially equivalent to marketed devices.
- NOT substantially equivalent to marketed devices.

De Novo Classification Candidate?  YES  NO

Other (e.g., exempt by regulation, not a device, duplicate, etc.)

- |   |   |  |
|---|---|--|
| Is this device subject to Postmarket Surveillance?                | <input type="checkbox"/> YES            | <input checked="" type="checkbox"/> NO |
| Is this device subject to the Tracking Regulation?                | <input type="checkbox"/> YES            | <input checked="" type="checkbox"/> NO |
| Was clinical data necessary to support the review of this 510(k)? | <input type="checkbox"/> YES            | <input checked="" type="checkbox"/> NO |
| Is this a prescription device?                                    | <input checked="" type="checkbox"/> YES | <input type="checkbox"/> NO            |
| Was this 510(k) reviewed by a Third Party?                        | <input type="checkbox"/> YES            | <input checked="" type="checkbox"/> NO |
| Special 510(k)?   | <input type="checkbox"/> YES            | <input checked="" type="checkbox"/> NO |
| Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers  | <input type="checkbox"/> YES            | <input checked="" type="checkbox"/> NO |

This 510(k) contains:

- Truthful and Accurate Statement  Requested  Enclosed  
(required for originals received 3-14-95 and after)
- A 510(k) summary OR  A 510(k) statement
- The required certification and summary for class III devices
- The indication for use form (required for originals received 1-1-96 and after)
- Material of Biological Origin  YES  NO

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

- No Confidentiality  Confidentiality for 90 days  Continued Confidentiality exceeding 90 days

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

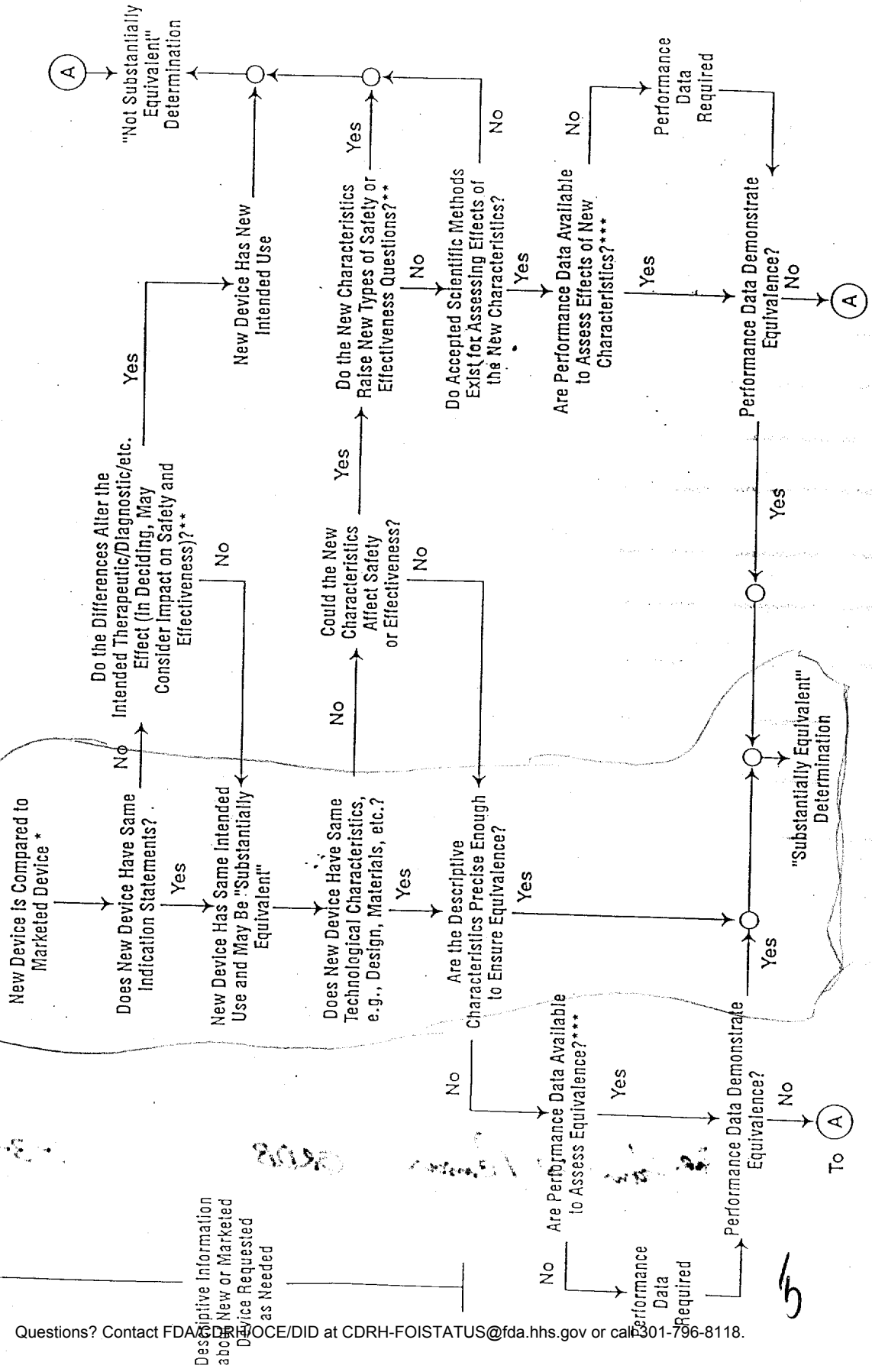
HSH, II

Review: for Harry W. Penner GRDB 1-3-01  
 (Branch Chief) (Branch Code) (Date)

Final Review: Mark N. Melkers 1/4/01  
 (Division Director) (Date)

Revised: 8/17/99

# 510(k) "Substantial Equivalence" Decision-Making Process (Detailed)



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 800-796-8118.

\* 510(k) Submissions Compare New Devices to Marketed Devices. FDA Requests Additional Information on the Relationship Between Marketed and "Predicate" (Pre-Amendment or Reclassified Post-Amendments) Devices is Unclear.  
 \*\* This Decision is Normally Based on Descriptive Information Alone, But Limited Information is Sometimes Required.  
 \*\*\* Data May be the 510(k), Other 510(k)s, The Center's Classification Files, or the Literature.



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510(k) MEMORANDUM

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**TO:** K003269  
**FROM:** Peter G. Allen, Biomedical Engineer, M.S.  
FDA/CDRH/ODE/DGRND/Orthopedic Devices Branch  
**DATE:** December 8, 2000  
**SUBJ:** **Unicondylar Interpositional Spacer**  
Product Code: HSH, 87; 21 CFR 888.3590; Class II  
**Company: Sulzer Orthopedics, Inc.**  
Contact: Mitchell Dhority, Manager or Regulatory & Clinical Affairs  
Phone: (512) 432-9202 Fax: (512) 432-9291

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**Recommendation:**

Based on similarities in design, materials, method of fixation, and intended use, I recommend that this device be found substantially equivalent (SE) to other legally marketed pre-amendments predicate devices.

**Review:**

1. **Administrative Requirements:**

Notification contains a 510(k) Summary, Indications for Use page, and a Truthful and Accuracy statement.

**EXPLANATIONS OF "YES" ANSWERS TO QUESTIONS 4, 6, 8, and 11 AND EVERY NO RESPONSE ON "SE" DECISION MAKING CHECKLIST AS NEEDED:**

Questions 4, 6, 8, and 11 are not applicable. See the SE Decision Making Checklist. There were no "No" responses.

2. **Device Description:**

The Unicondylar Interpositional Spacer (UIS) is intended to be placed in the medial joint space between the femoral and tibial condyles in patients with moderate chondromalacia. It was developed as an alternative to medication therapies, arthroscopy, high tibial osteotomy, and knee arthroplasty treatments for those situations where limited degeneration/joint destruction exists. The ability to provide 5, 10, or 15 years of non-total knee joint replacement that does not interfere with the subsequent conversion to a total knee implant is ideal. The UIS is designed to fill this interim therapeutic option. This device provides for a progressive approach to therapy. The UIS can be revised in its own right by using progressively thicker inserts and at any subsequent time can be converted to a primary total knee prosthesis when indicated. The UIS does not require any bone resection, even upon revision to a thicker version. This facilitates the eventual conversion to a primary total knee and enhances the potential for success of that treatment.

The surgical objective of the UIS is to:

- correct varus malalignment by filling the void created by lost articular cartilage
- redistribute load off of the damaged articular cartilage by recreating a conformal articular surface
- divorce the femoral and tibial surfaces and essentially eliminate motion against the tibial plateau
- eliminate the mechanical instability of the joint by reestablishing the proper tension in and the alignment of the medial collateral ligament (MCL)

The device will be manufactured from either wrought cobalt chrome alloy (ASTM F1537) or forged cobalt chrome alloy (ASTM F799). The design is kidney shaped to mimic that of the medial tibial condyle, which allows it to nest within the remaining meniscus. The shallow dish geometry allows for articulation with the femur. It is asymmetric (left and right components) and is available in seven sizes (30 -54mm) and five thicknesses (1 - 5mm) to better restore joint alignment, tension and stability.

The UIS is placed into the joint space above the affected medial tibial plateau. The femur then articulates against the polished, curved surface of the device. The device is intended to be used without cement and is held in place by its geometry, the compressive force between the femur and tibia, and the surrounding soft tissue structures.

3. **Intended Use:**

The Unicondylar Interpositional Spacer is intended for uncemented use in treatment of the following:

- Moderate degeneration of the medial compartment of the knee (grade III-IV chondromalacia) with no more than minimal degeneration (grade I-II chondromalacia, no loss of joint space) in the lateral condyle and patellofemoral compartments.

**4. Sterilization:**

All components are provided sterile.

Method: minimum of 25 kGy (range 25 – 35) of gamma radiation

Sterility Validation Method: AAMI/ISO TIR No. 13409-1996, "Sterilization of Health Care Products – Radiation Sterilization – Substantiation of 25 kGy as a Sterilization Dose for Small or Infrequent Production Batches".

Sterility Assurance Level:  $10^{-6}$

Description of packaging: The packaging consists of two nesting PETG plastic trays. Each tray is heat-sealed with a Tyvek lid. ARO burst tests are performed. The trays are inserted into a box and shrink wrapped.

Pyrogenicity: Products are not labeled as "pyrogen free" and orthopedic implants are not required to be nonpyrogenic.

Recommended re-sterilization method: not recommended (see package insert)

**5. Labeling:**

Appropriate representative package labels and a package insert were provided for the components in exhibits 9 and 8, respectively.

**6. Testing:**

Fatigue testing was conducted using worst-case conditions (e.g., combination of size and in-vivo load that results in earliest failure). (b)(4) Confidential [redacted] previously determined by FEA, was subjected to a condylar (b)(4) Confidential and Proprietary [redacted]. The spacers were mounted such that only perimeter support was provided. The spacers were then fatigue tested for ten million cycles similar to the method described in ASTM F1800-97. All six spacers survived the fatigue load without fracture of failure. Component fracture is not expected to be a problem. (b)(4) Confidential and Proprietary Information [redacted]

(b)(4) Confidential and Proprietary Information [redacted]

**7. Sponsor's information in support of SE:**

McKeever Hemiarthroplasty Prosthesis, Pre-amendments, Howmedica  
MacIntosh Hemiarthroplasty Prosthesis, Pre-amendments, Howmedica  
Sbarbaro Tibial Plateau Prosthesis, Pre-amendments, Zimmer Inc.

**8. Review of 510(k)s for SE:**

None.

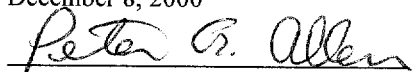
**9. Summary:**

The subject and predicate devices are similar in terms of design, materials, and indication for use. All designs are unicondylar and incorporate a semicircular metallic tibial resurfacing component in varying thicknesses and sizes. These devices are all intended for use without bone cement. Like the MacIntosh prosthesis the UIS is held in place mainly by its geometry and surrounding musculature. Filling the joint space restores joint alignment, stability, and the correct tension to the collateral ligament. Published clinical literature on the predicate devices is included in Exhibits 11 – 16 and 19. I recommend that the subject device be found substantially equivalent to the pre-amendments predicate devices.

**10. Contact History/Requests for More Information:**

None.

Peter G. Allen, Biomedical Engineer  
FDA/CDRH/DGRND/ORDB  
December 8, 2000



## Screening Checklist

### For all Premarket Notification 510(k) Submissions

<b>Device Name:</b> <i>Unicondylar Interpositional Spacer</i>						K003269					
<b>Submitter (Company):</b> <i>Sulzer Orthopedics, Inc.</i>											
<b>Items which should be included</b> <i>(circle missing &amp; needed information)</i>						<b>S P E C I A L</b>	<b>A B B R E V I A T E D</b>		<b>T R A D I T I O N A L</b>	<b>✓ IF ITEM IS NEEDED AND IS MISSING</b>	
						YES	NO	YES	NO	YES	NO
<b>1. Cover Letter clearly identifies Submission as:</b>											
a) "Special 510(k): Device Modification"										<input checked="" type="checkbox"/>	
b) "Abbreviated 510(k)"											
c) Traditional 510(k)						GO TO # 2,3		GO TO # 2,4,5		GO TO #2, 5	
<b>2. GENERAL INFORMATION: REQUIRED IN ALL 510(K) SUBMISSIONS</b>											
✓ IF ITEM IS NEEDED											
<b>Financial Certification or Disclosure Statement for 510(k)s with a Clinical Study 807.87(i)</b>						NA		YES		NO	
						SPECIALS		ABBREVIATED		TRADITIONAL	
						YES	NO	YES	NO	YES	NO
a) trade name, classification name, establishment registration number, device class											
b) OR a statement that the device is not yet classified						FDA-may be a classification request; see coordinator					
c) identification of legally marketed equivalent device						NA					
d) compliance with Section 514 - performance standards						NA					
e) address of manufacturer											
f) Truthful and Accurate Statement											
g) Indications for Use enclosure											
h) SMDA Summary or Statement (FOR ALL DEVICE CLASSES)											
i) Class III Certification & Summary (FOR ALL CLASS III DEVICES)											
j) Description of device (or modification) including diagrams, engineering drawings, photographs, service manuals											
k) Proposed Labeling:											
i) package labeling (user info)											
ii) statement of intended use											
iii) advertisements or promotional materials											
i) MRI compatibility (if claimed)											
l) Comparison Information (similarities and differences) to named legally marketed equivalent device (table preferred) should include:											
i) Labeling											
ii) intended use											
iii) physical characteristics											
iv) anatomical sites of use											
v) performance (bench, animal, clinical) testing						NA					
vi) safety characteristics						NA					
m) If kit, kit certification											
<b>3. "SPECIALS" - ONLY FOR MODIFICATIONS TO MANUFACTURER'S OWN CLASS II, III OR RESERVED CLASS I DEVICE</b>											
a) Name & 510(k) number of legally marketed (unmodified) predicate device											
b) STATEMENT - INTENDED USE AND INDICATIONS FOR											* If no - STOP not a special

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<b>USE OF MODIFIED DEVICE AS DESCRIBED IN ITS LABELING HAVE NOT CHANGED*</b>				
<b>c) STATEMENT - FUNDAMENTAL SCIENTIFIC TECHNOLOGY OF THE MODIFIED DEVICE HAS NOT CHANGED*</b>			* If no - STOP not a special	
<b>d) Design Control Activities Summary</b>				
i) Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis				
ii) Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria to be applied				
iii) A declaration of conformity with design controls. The declaration of conformity should include:				
1) A statement signed by the individual responsible, that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met				
2) A statement signed by the individual responsible, that manufacturing facility is in conformance with design control procedure Requirements as specified in 21 CFR 820.30 and the records are available for review.				

	SPECIALS		ABBREVIATED		TRADITIONAL		✓ IF ITEM IS NEEDED AND IS MISSING
	YES	NO	YES	NO	YES	NO	
<b>4. ABBREVIATED 510(K): SPECIAL CONTROLS/CONFORMANCE TO RECOGNIZED STANDARDS - PLEASE FILL OUT THE STANDARDS ABBREVIATED FORM ON THE H DRIVE</b>							
a) For a submission, which relies on a guidance document and/or special control(s), a summary report that describes how the guidance and/or special control(s) was used to address the risks associated with the particular device type							
b) If a manufacturer elects to use an alternate approach to address a particular risk, sufficient detail should be provided to justify that approach.							
c) For a submission, which relies on a recognized standard, a declaration of conformity to the standard. The declaration should include the following:							
i) An identification of the applicable recognized consensus standards that were met							
ii) A specification, for each consensus standard, that all requirements were met, except for							

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inapplicable requirements or deviations noted below			
iii) An identification, for each consensus standard, of any way(s) in which the standard may have been adapted for application to the device under review, e.g., an identification of an alternative series of tests that were performed			
iv) An identification, for each consensus standard, of any requirements that were not applicable to the device			
v) A specification of any deviations from each applicable standard that were applied			
vi) A specification of the differences that may exist, if any, between the tested device and the device to be marketed and a justification of the test results in these areas of difference			
vii) Name/address of test laboratory/certification body involved in determining the conformance of the device with applicable consensus standards and a reference to any accreditations for those organizations			
d) Data/information to address issues not covered by guidance documents, special controls, and/or recognized standards			

5. Additional Considerations: (may be covered by Design Controls)							
a) Biocompatibility data for all patient-contacting materials, OR certification of identical material/formulation:							
i) component & material							
ii) identify patient-contacting materials							
iii) biocompatibility of final sterilized product							
b) Sterilization and expiration dating information:							
i) sterilization method							
ii) SAL							
iii) packaging							
iv) specify pyrogen free							
v) ETO residues							
vi) radiation dose							
c) Software validation & verification:							
i) hazard analysis							
ii) level of concern							
iii) development documentation							
iv) certification							

Items shaded under "NO" are necessary for that type of submission. Circled items and items with checks in the "Needed & Missing" column must be submitted before acceptance of the document.

Passed Screening  Yes  No  
 Date: 12/7/00

Reviewer: Patricia G. Allen  
 Concurrence by Review Branch: [Signature]

10

REVISED:3/14/95

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

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

Reviewer: K003269  
Peter Allen  
 Division/Branch: DGRND/ORDB  
 Device Name: Unicondylar Interpositional Spacer  
 Product To Which Compared (510(K) Number If Known): Pre-amendments

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

Note: In addition to completing the form on the LAN, "yes" responses to questions 4, 6, 8, and 11, and every "no" response requires an explanation. Questions 4, 6, 8, and 11 are not applicable, see above. There were no "No" responses.

//

1. Intended Use:

*See Memo*

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

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

1. Explain why not a device:
2. Explain why not subject to 510(k):
3. How does the new indication differ from the predicate device's indication:
4. Explain why there is or is not a new effect or safety or effectiveness issue:
5. Describe the new technological characteristics:
6. Explain how new characteristics could or could not affect safety or effectiveness:
7. Explain how descriptive characteristics are not precise enough:
8. Explain new types of safety or effectiveness questions raised or why the questions are not new:
9. Explain why existing scientific methods can not be used:
10. Explain what performance data is needed:
11. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

**ATTACH ADDITIONAL SUPPORTING INFORMATION**

## Internal Administrative Form

	YES	NO
1. Did the firm request expedited review?		X
2. Did we grant expedited review?		X
3. Have you verified that the Document is labeled Class III for GMP purposes?	N/A	A
4. If, not, has POS been notified?		
5. Is the product a device?	X	
6. Is the device exempt from 510(k) by regulation or policy?		X
7. Is the device subject to review by CDRH?	X	
8. Are you aware that this device has been the subject of a previous NSE decision?		X
9. If yes, does this new 510(k) address the NSE issue(s), (e.g., performance data)?	N/A	A
10. Are you aware of the submitter being the subject of an integrity investigation?		X
11. If, yes, consult the ODE Integrity Officer.		
12. Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #I91-2 and Federal Register 90N0332, September 10, 1991.	N/A	A



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

October 18, 2000

SULZER ORTHOPEDICS, INC.  
9900 SPECTRUM DR.  
AUSTIN, TX 78717  
ATTN: MITCHELL A. DHORITY

510(k) Number: K003269  
Received: 18-OCT-2000  
Product: UNICONDYLAR  
INTERPOSITIONAL  
SPACER

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

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

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

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

Sincerely yours,

Marjorie Shulman  
Consumer Safety Officer  
Premarket Notification Staff  
Office of Device Evaluation

K003369

# SULZERMEDICA

Sulzer Orthopedics Inc.

9900 Spectrum Drive  
Austin, Texas 78717

Phone 512 432 9900  
Clinical Affairs Fax 512 432 9251  
Regulatory Affairs Fax 512 432 9291

October 17, 2000

Office of Device Evaluation  
510(k) Document Mail Center (HFZ-401)  
Center for Devices and Radiological Health  
Food and Drug Administration  
9200 Corporate Boulevard  
Rockville, MD 20850

Subject: 510(k) Notification  
Unicondylar Interpositional Spacer

SK-2-D  
RECEIVED  
18 Oct 00 11 00  
FDA/CDRH/OCE/DID

Dear Sir/Madam:

In accordance with Section 510(k) of the Federal Food, Drug and Cosmetic Act, and in conformance with Title 21 of the Code of Federal Regulations Part 807 (21 CFR 807), Subpart E, this premarket notification is submitted for substantial equivalence determination for the Unicondylar Interpositional Spacer.

The information provided in this 510(k) supports the substantial equivalence to similar previously marketed devices. In addition, the information provided in this 510(k) conforms to the requirements specified in the FDA's guidance document of March 28, 1995, entitled, "Draft Guidance Document for the Preparation of Premarket Notification [510(k)] Application for Orthopaedic Devices."

A Truthful and Accurate Statement, a 510(k) Summary and the Indications for Use form have also been provided in the enclosed information.

### Confidentiality Statement

- Sulzer Orthopedics regards its intent to market this device as confidential commercial information and requests that the FDA not disclose the existence of this device or any subsequent supplements or amendments to this application.
- Sulzer Orthopedics has not disclosed its intent to market the device to scientists, market analysts, exporters or other individuals who are not paid consultants to Sulzer Orthopedics Inc.
- Neither the undersigned nor, to the best of his knowledge, anyone else has disclosed the company's intent to market the device to anyone except employees of Sulzer Orthopedics Inc.

OK  
H

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510(k) Notification  
Food and Drug Administration  
October 17, 2000  
Page L-2

- Sulzer Orthopedics has taken all reasonable and prudent precautions to protect the confidentiality of its intent to market the above-mentioned device.

We believe that this, along with the following information, fulfills your requirements for submission and would appreciate your earliest attention to this 510(k) notification.

Please do not hesitate to contact us if you have any questions regarding this matter.

Sincerely,



Mitchell A. Dhority, RAC  
Manager, Regulatory & Clinical Affairs

MD/ca

Enclosure

cc: Chris Peterson

# 510(k) NOTIFICATION

## UNICONDYLAR INTERPOSITIONAL SPACER

21 CFR Part 888.3590  
CLASS II

SUBMITTED BY:  
SULZER ORTHOPEDICS INC.

OCTOBER 17, 2000

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## EXHIBITS

### EXHIBIT CONTENTS

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- 2 Indications for Use Form
- 3 Design Rationale - Inherent Stability of Device Design
- 4 Draft Surgical Technique
- 5 Table of Component Sizes/Catalog Numbers
- 6 Engineering Prints
- 7 Photograph
- 8 Draft Physicians Insert
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- 10 Test Report - Fatigue Performance
- 11 Literature Article - T. Potter et al.: "Arthroplasty of the Knee in Rheumatoid Arthritis and Osteoarthritis"
- 12 Literature Article - A. Swanson et al.: "Unicompartmental and Bicompartmental Arthroplasty of the Knee with a Finned Metal Tibial-Plateau Implant"
- 13 Literature Article - R. Scott et al.: "McKeever Metallic Hemiarthroplasty of the Knee in Unicompartmental Degenerative Arthritis"
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- 15 Literature Article - D. McKeever: "Tibial Plateau Prosthesis"
- 16 Literature Article - D. MacIntosh et al.: "The Use of the Hemiarthroplasty Prosthesis for Advanced Osteoarthritis and Rheumatoid Arthritis of the Knee"
- 17 Advertisement - Zimmer Sbarbaro Tibial Plateau Prosthesis
- 18 Subject/Predicate Device Comparison Table
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**I. Truthful and Accurate Statement**

The Truthful and Accurate Statement is provided as Exhibit 1.

**II. Administrative Information**

**A. Sponsor/Manufacturer Information**

Sulzer Orthopedics Inc.  
9900 Spectrum Drive  
Austin, TX 78717

**B. Establishment Registration No.**

2935620

**C. Official Contact Person**

Name: Mitchell A. Dhority  
Telephone number: 512-432-9202  
Fax Number: 512-432-9291

**D. Device Identification**

1. Trade/Proprietary Name

Unicondylar Interpositional Spacer

2. Common/Usual Name

Hemi-knee prosthesis

3. Classification Name

21 CFR 888.3590 - Knee joint tibial (hemi-knee) metallic resurfacing uncemented prosthesis

4. Device Classification

Class II



5. Device Product Code

87 HSH

**III. Intended Use**

**A. *Specific Diagnostic Indications***

The Unicondylar Interpositional Spacer is intended for uncemented use in treatment of the following:

- Moderate degeneration of the medial compartment of the knee (grade III-IV chondromalacia) with no more than minimal degeneration (grade I-II chondromalacia, no loss of joint space) in the lateral condyle and patellofemoral compartments.

The Indications for Use form is provided in Exhibit 2.

**B. *Single Use/Reusable***

This device is intended for single use only.

**C. *Use with Other Cleared Devices***

This device is not intended to be used in combination with other cleared devices.

**IV. Device Description**

**A. *Background***

Clinically, there has always existed a need to address the special considerations of the arthritic knee. An erect bipedal posture imposes bio-mechanically complex motion and stress distribution on the knee joint. The high load condition and complex motion requirements of the normal knee place extraordinary stresses on this critical joint. Aging, disease and traumatic conditions dramatically alter the ability of the knee to withstand these otherwise normal physiologic requirements.

The knee is a complex compound joint capable of limited rotational movement and a constantly variable radius of rotation. The weight of the body is transmitted downward through the lower extremities to the ground. The knee passes the majority of this force through the medial condyle and medial portion of the tibial plateau. Thus, wear of the knee's articular surfaces is not uniform. Loss of hydration, disease, trauma and wear of the articular surfaces continually narrow the joint space of the knee. As the joint space narrows, laxity of the stabilizing ligaments supporting the knee occurs. Loss of stability leads to

additional wear and inflammation in a non-uniform fashion. A sequence is established that results in progressive successive cycles of degeneration and loss of function. Over time, significant deformity, severe pain and near complete loss of ambulatory ability result.

Historically, treatment for this progressive disability centered on rest, splinting, bracing, casting, anti-inflammatory agents, surgery and ultimately arthrodesis. This was the case until approximately 45 years ago.

The advent of modern high strength orthopedic implant materials altered the therapeutic approach to treating troublesome degenerative knee conditions. In the United States, three progressive surgeons (McKeever, MacIntosh and Sbarbaro) began implanting specially designed hemiarthroplasty knee prostheses. All three implant designs shared the common concepts of improved articular surfaces, restoration of proper joint spacing and attendant re-tensioning of the formerly lax knee ligaments. Two of the devices (McKeever & Sbarbaro) were stabilized by a keel or key inserted into a surgically created tibial plateau groove or notch. The remaining MacIntosh device was centered within a prepared tibial plateau bed. The geometry of the MacIntosh implant's articulating surface and dynamic re-tensioning of the knee ligaments stabilized the device in the joint.

All three devices predated the use of PMMA bone cement and effective total knee joint replacement devices.

The procedure to implant the keyed devices was exacting and relatively time consuming. If the keyway or notch was incorrect, even slightly, the articulating surfaces did not match optimally. Early device failure and re-operation resulted. The "keyless" MacIntosh device, though constrained, was capable of limited realignment of the articular surfaces during flexion and extension. Failure to establish ideal dynamic re-tensioning of the knee ligaments during implantation could lead to dislocation of the device and subsequent re-operation, including arthrodesis.

The patient population most in need of these devices was elderly with a significant degree of disability and deformity. Because the disease process was so advanced in many patients, maximum potential benefit was seldom realized. In fact, most of these patients were perhaps better suited to a total knee replacement, had one existed. Therapy was pointed primarily at the relief of pain and restoration of modest daily activities.

The advent of PMMA bone cement combined with modern implant materials changed this situation dramatically. For the first time, total joint replacement of the knee became a real alternative. Almost overnight, total joint replacement became the treatment of choice for this long-suffering patient population. The use of the hemiarthroplasty knee device essentially ceased in the early to mid 1970's.

The present patient population in need of knee restoration surgery has changed significantly. Today's knee patient is younger and more active with many patients suffering athletic related arthritic knee conditions. Even the finest total knee prostheses currently available are sometimes unable to withstand the demands of this patient population. Revision after 5-10 years of use is not uncommon. Many of these patients are under age 50, some much younger. With such highly active lifestyles, such patients face two or even three total knee replacement revision surgeries during the remainder of their lives. For most patients, repeated revision surgery on this scale is unlikely due to progressive bone loss at each additional surgery.

The need for the hemiarthroplasty knee implant has therefore come full circle. The ability to provide 5, 10, 15 or more years of non-total knee joint therapy that does not interfere with subsequent conversion to a total knee implant is ideal.

The Unicondylar Interpositional Spacer (UIS) is a device designed to fill this interim therapeutic option. Use of this device provides a progressive approach to therapy. The UIS implant can be revised in it's own right by using progressively thicker inserts. At any subsequent time, the UIS can be converted to a primary total knee prosthesis when and if indicated.

**B. *Subject Device Description***

Arthroscopic debridements have now become the routine treatment to address the pain and synovitis associated with early stage osteoarthritis with approximately half of the patients treated presenting with Grade III-IV chondromalacia. It is estimated that symptoms recur within 2 years in half of those patients who receive this form of treatment. While the effectiveness of arthroscopic debridement is quite variable, it is clear that it does not address the mechanical alignment and laxity problems associated with the joint.

Anti-inflammatory medication has also been used to manage joint pain, but has limited effectiveness on moderate arthritis and offers no solution in terms of repair to the joint structure.

As described previously, the use of other surgical options such as knee arthroplasty and high tibial osteotomy (HTO) are more invasive, technically challenging and may compromise the joint to future treatment options.

The Unicondylar Interpositional Spacer was developed as an alternative to medication therapies, arthroscopy, HTO and knee arthroplasty treatments for those situations where limited degeneration/joint destruction exists. Instead of simply debriding soft tissues as in arthroscopy or resecting valuable unaffected bone and cartilage as in total knee replacement, this treatment allows for placement of a metallic "spacer" device into the joint space above the affected medial tibial plateau. The femur then articulates against the polished, curved surface of device.

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The device is intended to be used without cement and is held in place by its geometry and the surrounding soft tissue structures. Further discussion lending to the inherent stability achieved with this design is provided in Exhibit 3.

The device will be manufactured from either wrought cobalt chromium alloy (ASTM F1537) or forged cobalt chrome alloy (ASTM F799). The design is kidney shaped to mimic that of the medial tibial condyle; the shallow "dished" geometry allows for articulation with the femur. It is asymmetric (left and right components) and is available in seven sizes (30-54mm) and five thicknesses (1-5mm) to better restore joint alignment, tension and stability.

The surgical procedure to place the device is carried out in two stages. First, the posterior horn of the meniscus is debrided and resected arthroscopically. The device may then be inserted into the joint space above the affected medial tibial plateau via open surgical implantation. A copy of the draft surgical technique is provided as Exhibit 4.

Use of this device provides several potential advantages over other surgical options, including:

- Technically easier to implant than a unicompartmental total knee, high tibial osteotomy or meniscal transplant.
- Facilitates future conversion to total knee arthroplasty by eliminating the need for bone resections.
- Is surgically less invasive (e.g. unicompartmental treatment, smaller incision, fewer implant components required, no bone resection required, no cement used).

**C. *Sizes***

The device is available in seven sizes (30-54mm) and five thicknesses (1-5mm) to better restore joint alignment, tension and stability. A list of sizes and catalog numbers is included as Exhibit 5.

**D. *References to Drawings***

Engineering drawings are included as Exhibit 6.

**E. *References to Photos***

Photos are provided as Exhibit 7.

**F. *Instrumentation***

Instrumentation to be included with this system includes an implant holder, trial prosthesis holder, depth/thickness gauges, and an extractor instrument.

**V. Materials**

**A. *Material Composition of Device***

The Unicondylar Interpositional Spacer will be manufactured from either wrought cobalt chromium alloy or forged cobalt chromium alloy.

**B. *Applicable Voluntary Standards***

- ASTM F799 Standard Specification for Cobalt-28 Chromium-6 Molybdenum Alloy Forgings for Surgical Implants
- ASTM F1537 Specification for Wrought Cobalt-28 Chromium-6 Molybdenum Alloy for Surgical Implants

**VI. Labeling/Promotional Materials**

**A. *Draft Physicians Insert***

A copy of the draft Physicians Inserts is included as Exhibit 8.

**B. *Draft Product Labeling***

A copy of the draft product labeling is included as Exhibit 9.

**VII. Additional Information**

**A. *Mechanical Testing - Fatigue Analysis***

Fatigue testing was conducted using worst-case conditions (e.g., combination of size and in-vivo load that results in earliest failure). The spacers were mounted such that only perimeter support was provided. The spacers were then fatigue tested for ten million cycles similar to the method described in ASTM F1800-97. All six spacers survived the fatigue load without fracture or failure. A copy of this report is provided as Exhibit 10.

**VIII. Sterility Information**

**A. *Sterilization Status***

This device will be provided sterile.

**B. Sterilization Method**

1. Sterilization Method

The component will be sterilized by a minimum of 25 kGy (range 25-35) of gamma radiation.

2. Sterilization Validation Method

Sterilization cycles are validated using AAMI/ISO TIR No. 13409-1996, "Sterilization of Health Care Products - Radiation Sterilization - Substantiation of 25 kGy as a Sterilization Dose for Small or Infrequent Production Batches".

3. SAL

Cycles are validated as stated above for a SAL of  $10^{-6}$ .

4. Pyrogenicity Statement

Product will not be labeled "pyrogen free".

**IX. Packaging Description**

Products are packaged using two nesting PETG plastic trays. Each tray is heat-sealed with Tyvek<sup>®</sup> inner lidding. A heat-sealed outer Tyvek lid follows the inner lidding process. Seal integrity is verified visually as well as by performing ARO burst tests. The packaged product is then placed inside a box and shrink-wrapped.

**X. Substantial Equivalence Determination**

**A. Predicate Comparison**

Substantial equivalence is based on comparison to the following devices relative to similarities in design, materials, intended use, and published clinical results pertaining to their safety and effectiveness:

- McKeever Hemiarthroplasty Prosthesis (Exhibit 11, 12, 13, 14, 15)
- MacIntosh Hemiarthroplasty Prosthesis (Exhibit 16)
- Sbarbaro Tibial Plateau Prosthesis (Exhibit 17)

A table comparing the design features of the subject and predicate devices is provided as Exhibit 18.

Design Features

The subject and predicate devices are similar in terms of design features. In general, all of these designs are unicondylar and incorporate a semicircular metallic

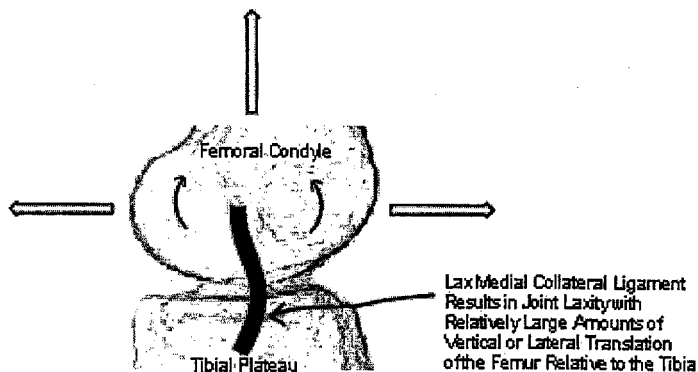
27

tibial resurfacing component in varying thicknesses and sizes. In each design, the femoral condyle articulates against the curved upper surface of the implant. These devices are intended for use without bone cement. The Unicompartmental Interpositional Spacer is similar to the MacIntosh prosthesis in that it does not rely on a fin for additional stabilization; the prosthesis is held in place mainly by its geometry and the surrounding musculature. The Unicompartmental Interpositional Spacer is similar to the McKeever prosthesis in that they both have a convex tibial surface.

### Stability

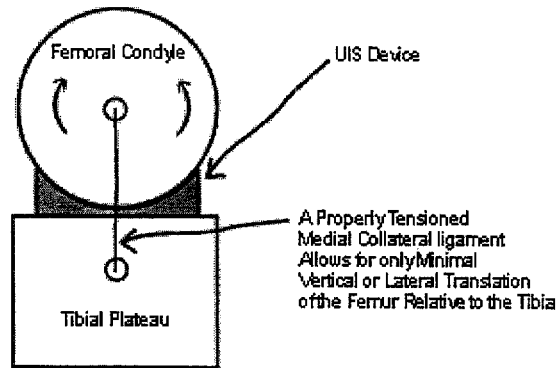
Like the MacIntosh tibial prosthesis, the Unicondylar Interpositional Spacer has no obvious means of attachment.

In the osteoarthritic knee, substantial amounts of articular cartilage have been lost as a result of the disease. The knee compartment suffers a subsequent closing of the joint spacing as seen on X-ray. This joint closing allows the collateral ligament to become lax and the joint to become unstable and off-axis (varus deformity). Whereas normal motion of the femoral condyle is largely rotational, if ligament laxity is present, there will be increased translational motion of the femur relative to the tibia



Filling the joint space that was once occupied by the now missing articular cartilage can restore the correct tension of the collateral ligament. When the proper thickness of the Unicondylar Interpositional Spacer is chosen, the tightening of the collateral ligament prevents any excessive translational motion of the femoral condyle. Thus, almost all of the forces against the Unicondylar Interpositional Spacer now become rotational and the Unicondylar Interpositional Spacer will have no forces acting on it that would cause it to "spit" from the joint space. The stability of the joint is restored.

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The surface geometry of the Unicondylar Interpositional Spacer also plays a significant role in its inherent stability.

MacIntosh (Exhibit 16) states "The collateral ligaments usually maintain their own length...and that the stability is maintained by a prosthesis that is thick enough to correct the deformity and take up the slack in the collateral ligaments". He further states that "The prosthesis is held in position by the anatomy of the knee joint, and stability depends on taut collateral ligaments. The top of the prosthesis has a contoured surface with rounded edges to provide the condyle with a permanent low friction area."

The Unicondylar Interpositional Spacer has a femoral surface geometry that imitates that of the tibial plateau including an intact meniscus. On the other side, the tibial surface of the Unicondylar Interpositional Spacer imitates the surface of the tibial plateau without the meniscus.

When the Unicondylar Interpositional Spacer is properly placed into the knee compartment, it rests inside the boundaries of the resected meniscus. It has substantially intimate contact with the tibial plateau throughout the entire range of motion. The femoral side of the Unicondylar Interpositional Spacer also has substantially full contact with the femoral condyle when the knee is in full extension.

Thus, when the knee is in full extension, the Unicondylar Interpositional Spacer can only be located in one position in the joint space as determined by the relative position of the femoral condyle to the tibial plateau.

As the knee is flexed and the femoral condyle begins to rotate, since the collateral ligaments remain under tension, the posterior aspect of the femoral condyle remains in contact with the central weight-bearing surface of the UIS

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Materials

The subject and predicate devices are similar in terms of materials used. All of these designs use cobalt chrome alloy.

Intended Use

Additionally, the subject and predicate devices share similar indications for use. The subject device, like the predicate devices, are used generically in the treatment of moderate/severe unicompartmental tibial arthritis to relieve pain, restore stability and correct deformity in cases where total knee replacement is not warranted.

Clinical Safety & Effectiveness

The published clinical literature on the predicate devices (Exhibits 11-16) was reviewed and tabulated (Exhibit 19).

As indicated in the proposed labeling/Physicians Insert, the known potential risks associated with these devices are essentially of the same type and frequency as unicompartmental or total knee replacement, arthroscopy and others. As shown in the publications associated with the predicate devices, these risks include hematoma, infection, nerve palsy, embolus, dislocation, fracture and need for revision. As with the other orthopedic options, these risks are mitigated through appropriate warnings in the labeling as well as through proper training for the surgeon.

The history with the predicate devices also indicates that the effectiveness of this treatment is at least equal to that obtained with osteotomy or arthroplasty in terms of pain relief, correction of deformity and restoration of stability. Furthermore, it provides some added benefits, which cannot be recognized with these current treatments (e.g., ease of implantation, ease of conversion to other treatments, less invasive).

**XI. 510(k) Summary**

The 510(k) summary is included as Exhibit 20.

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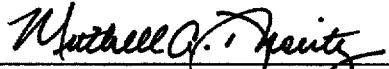
# EXHIBIT 1

**PREMARKET NOTIFICATION**

**TRUTHFUL AND ACCURATE STATEMENT**

**(As Required By 21 CFR 807.87(j))**

I certify that, in my capacity as Manager of Regulatory & Clinical Affairs at Sulzer Orthopedics Inc., to the best of my knowledge that reasonable efforts have been made to ensure that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

  
\_\_\_\_\_  
Mitchell A. Dhority, RAC

  
\_\_\_\_\_  
Dated

\_\_\_\_\_  
[Premarket Notification (510(k)) Number]

# EXHIBIT 2

510(k) Number (if known): 003269

Device Name: Unicondylar Interpositional Spacer

### Indications for Use:

The Unicondylar Interpositional Spacer is intended for uncemented use in treatment of the following:

- Moderate degeneration of the medial compartment of the knee (grade III-IV chondromalacia) with no more than minimal degeneration (grade I-II chondromalacia, no loss of joint space) in the lateral condyle and patellofemoral compartments.

---

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use \_\_\_\_\_

OR

Over-The-Counter Use \_\_\_\_\_

(Optional Format 1-2-96)

# EXHIBIT 3







# EXHIBIT 4

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**DRAFT - DRAFT - DRAFT**

**OPERATIVE TECHNIQUE FOR THE UNICONDYLAR INTERPOSITIONAL SPACER**

Currently, there is a void in options used to treat relatively young patients with **moderate to severe chondromalacia** involving mainly the **medial compartment** of the knee.

Articular cartilage and meniscal cartilage provides the mobile weight bearing surfaces of the knee joint. Damage to these surfaces is generally due to

- Genetic predisposition,
- Trauma,
- And/or aging.

The result of such damage is usually the

- Development of chondromalacia,
- Thinning and softening of the articular cartilage, and
- Degenerative tearing of the meniscal cartilage.
- Secondary osteophyte formation along the femoral condyle and tibial plateau that functionally shortens the medial collateral ligament.
  - These combined changes in the medial compartment result in varus malalignment with alteration in joint loading. (Figures 1, 1A)

Various methods of treatment are available to treat these disease processes. Each option usually has specific indications and is accompanied by a list of benefits and deficiencies that may be compared to other options.

- Some patients cannot tolerate or do not want the risk or potential side effects of NSAIDs.
- Repeated cortisone injections actually weaken articular cartilage after a long period of time.
- Arthroscopic debridement alone frequently does not provide long-lasting relief of symptoms.
- High tibial osteotomy (HTO) corrects the varus malalignment between the tibia and femur but since it is performed below the joint line, it does not fill the cartilage void or re-tension the medial collateral ligament (MCL). Removing bone and changing the joint line does not complicate the conversion to TKA. However, a HTO does leave a hard sclerotic region of bone which is difficult to penetrate making conversion to a total knee replacement (TKR) technically challenging.
- Unicompartmental and bi-compartment total knee replacements resect significant amounts of bone and, if performed on younger patients, will likely require revision surgery as they age.
- Revision total knee replacement surgery is usually extensive and results in predictably diminished mechanical life expectancy.
  - Therefore, it is best to delay this type of bone resecting surgery as long as possible.

**The surgical objective** of UNICONDYLAR INTERPOSITIONAL SPACER (UIS) is to

- Correct the varus malalignment by filling the void created by lost articular cartilage,
- Redistribute load off of the damaged articular cartilage by recreating a conformal articular surface,
- Divorces the femoral and tibial surfaces and essentially eliminates motion against the tibial plateau and
- Eliminate the mechanical instability of the joint by reestablishing the proper tension in and the alignment of the medial collateral ligament (MCL)

It accomplishes this **without resecting bone or attaching the device** with screws, keels, or methyl-methacrylate adhesive.

**The procedure** outlined below **will describe how the major problems** associated with knee joint degeneration **are corrected with the UIS** without creating some of the concerns associated with previously described alternative medication and surgical solutions.

## **OPERATIVE PROCEDURE**

**The operative procedure** begins with an initial arthroscopic evaluation followed by insertion of the Unicondylar Interpositional Spacer (UIS) via a small median parapatellar arthrotomy.

- After routine preoperative preparation the patient is brought into the operating room and placed on a standard operating table in the supine position. A knee post may be used to aid in exerting a valgus stress during the procedure.
- Preoperative prophylactic antibiotic treatment should precede inflation of a tourniquet or, if a tourniquet is not used, initiation of the surgical procedure.
- The patient is prepped and draped in a routine fashion for a standard arthroscopy and arthrotomy.
- The planned arthroscopy portals, the planned arthrotomy incision, and the intra-articular space are all infiltrated with Marcaine with epinephrine.
- Initial arthroscopic evaluation and debridement is performed prior to insertion of the UIS.
  - Standard arthroscopic portals are used for introduction of the arthroscope into the knee.
  - An initial inspection of the whole joint is followed by the arthroscopic debridement.
  - Particular attention to the femoral condyles, menisci, and weight-bearing surface of the tibial plateau is necessary to assess the knee for appropriate indications for use of the UIS. The indications and contraindications are located in the Physicians Insert included with the component packaging; a copy is also provided at the end of this technique for reference (Figure 2)
  - Resection of the leading edge of the posterior and middle thirds of the meniscus is necessary to allow proper seating of the implant on the tibial plateau. (Figures 3, 4)

- Resection of degenerative tears of the meniscus, arthroscopic debridement of the femoral condyle and tibial plateau can also be performed to prepare the knee for insertion of the UIS.
- There is one instrument (that functions as two instruments) in the set that can now be used for assessment of implant size and thickness.
  - The **Thickness Gauge** (Figure 5) is made of a semi-rigid Delrin and comes in various thicknesses that correspond to the available thicknesses of the UIS. The device is inserted while the knee is in flexion, through the anterior arthroscopy portal between the weight bearing surfaces of the tibial and the femoral condyle. While the gauge remains in position, the knee is gently brought into extension. A snug fit without undo force on the gauge determines the best fit. This instrument allows the surgeon to select one of the offered thicknesses.
  - The **Sizing Gauge**, (Figure 6) etched onto the surface of the thickness gauge, is demarcated into divisions representative of the various length sizes of the UIS. It is also placed through the anterior portal and is gently pushed up against the posterior rim of the meniscus, while maintaining its course under the most distal portion of the femoral condyle. The gauge is then measured against the anterior, leading edge of the meniscus. This anterior-posterior measurement is used to select the correct implant size. These two measurements together are used to select the initial trial implant. See Figure.
- Our research has shown a definitive correlation of the radius of curvature of the femoral condyle to the length and width of the device. Thus, **only an intra-operative length and thickness measurement are required for proper sizing of the UIS.**
- **After the arthroscopic portion of the procedure is completed, a standard median parapatellar arthrotomy is necessary to insert the implant.** For any surgeon who trained or practiced before 1980, this portion of the procedure will be a walk down memory lane.
  - A longitudinal incision three to four centimeters long is placed parallel to the patellar tendon. If there is a previous open menisectomy scar from one of our older colleagues, this could be used for placement of the incision. The subcutaneous tissue is dissected down to the joint capsule, which is incised along the same axis as the incision.
  - A knee retractor can then be placed into the incision. This should provide stable visualization of the medial compartment of the knee.
  - Osteophytes should then be removed from the medial femoral condyle and from the medial tibial plateau.
    - This allows the medial collateral ligament to return to its original length. The combination of loss of articular cartilage thickness and restoration of MCL length will produce instability and allow shear stress on the articular surface of the joint. If there is contracture of the MCL, a recession of the collateral ligament can be performed to release the contracture and ease the insertion of the UIS.
- **Trial sizing**, once adequate exposure has been obtained, can be performed prior to insertion of the actual device. The best-fit selection can be confirmed by sizing up or down from the preoperatively preselected size. **The same instruments are used for insertion and removal of the trials and the final implant.** The insertion handle fits over the **non-removable peg** on

the anterior edge of the **trial**. The handle comes off the peg at a 60-degree angle and may be rotated 360 degrees on the axis of the peg. This feature allows the surgeon to insert or remove the trial from any angle, which is especially important when previously existing scars must be utilized, as is often the case.

- **Insertion of the trial UIS** is quite simple.
  - The knee is **flexed** to approximately **50 degrees** and opened medially with the application of a **slight valgus** stress.
  - The trial is then placed as far into the knee as possible, **up against the posterior rim of the meniscus, adjacent to the femoral condyle**.
  - **While holding the trial in position against the femoral condyle apply an increasing amount of valgus stress as the knee is brought into extension.**
    - With a palpable release the posterior edge of the trial seats behind the femoral condyle.
    - Remove the insertion tool by loosening the clamping knob.
- Fit and stability are confirmed by placing the knee in flexion and extension with varus, valgus, and rotational forces applied to the joint.
  - Properly fitted, the knee will be able to **easily achieve** full extension through 120 degrees of flexion with minimal movement of the UIS
    - Inability to easily achieve full extension could indicate that the trial is too thick or that there are still osteophytes present which need to be removed.
    - Significant translation (>1mm) of the UIS through the range of motion indicates too thin a UIS or too small a length
    - Overhang of the UIS over the anterior portion of the meniscus indicates too long a UIS selection, insufficient removal of the posterior meniscus or meniscal or articular cartilage fragments present in the joint space.
  - The **lateral stability** of the joint should now approximate that of a normal, healthy Knee (Figure 7)
  - The femur should now have a neutral to slightly valgus relationship to the tibia (Figure 8)
  - To insure the **proper length** of the UIS, a **C-arm** is used to radiographically inspect the size in relation to the bony landmarks. A **true lateral image with femoral condyles superimposed** is the best view to assess anterior-posterior length. See Figure. **It is very difficult to assess proper length of implant by visual inspection.**
    - Proper length sizing will ensure that the UIS sits inside the boundaries of the trimmed meniscus and does not overhang the medial boundary of the tibial plateau. (Figure 9, 10)

- To **remove the trial**,
  - Reattach the insertion handle to the peg of the trial,
  - Reapply the valgus stress with the knee in extension, and,
  - While maintaining the valgus stress, flex the knee to approximately 50 degrees and remove the trial with continuous, gentle pulling
- **Insertion of the actual UIS implant**
  - Once the correct size and thickness have been confirmed, the UIS is now inserted in a similar fashion.
    - The **peg** on the anterior aspect of the actual UIS implant is **removable** and it **MUST** be removed.
    - An additional instrument that is similar to the insertion tool is used to unscrew the peg from the device and remove it from the knee. The peg removal instrument, slips over the peg and removes it from the UIS implant in a ratcheting fashion. The tool captures the peg during this motion and minimizes the risk of dropping the removed peg into the operative area.
    - Properly fitted, the knee will be able to **easily achieve** full extension through 120 degrees of flexion with minimal movement of the UIS
      - Inability to easily achieve full extension could indicate that the trial is too thick or that there are still osteophytes present which need to be removed.
      - Significant translation (>1mm) of the UIS through the range of motion indicates too thin a UIS or too small a length
      - Overhang of the UIS over the anterior portion of the meniscus indicates too long a UIS selection, insufficient removal of the posterior meniscus or meniscal or articular cartilage fragments present in the joint space.
    - The **lateral stability** of the joint should now approximate that of a normal, healthy Knee (Figure 7)
    - The femur should be now have a neutral to slightly valgus relationship to the tibia (Figure 8)
    - To insure the **proper length** of the UIS, a **C-arm** is used to radiographically inspect the size in relation to the bony landmarks. A **true lateral image with femoral condyles superimposed** is the best view to assess anterior-posterior length. See Figure. **It is very difficult to assess proper length of implant by visual inspection.**
      - Proper length sizing will ensure that the UIS sits inside the boundaries of the trimmed meniscus and does not overhang the medial boundary of the tibial plateau. (Figure 9, 10)
  - **Closure** of the arthrotomy involves closing the capsule, subcutaneous tissue, and skin in layers using routine technique. A Hemovac drain may be placed into the knee prior to wound closure. The leg is then placed in a large cotton dressing and the tourniquet is deflated.

## **POSTOPERATIVE PROTOCOL**

The postoperative care for the UIS will be very similar to that for any arthrotomy of the Knee.

- Prophylactic antibiotics should be used for approximately 24 hours.
- The Hemovac drain can be removed at any point in the first 24 hours when drainage subsides.
- A leg immobilizer should be used until the bulky cotton dressing is removed
- Physical therapy can be initiated for crutch training with toe touch weight bearing.
- Quadriceps setting exercises and straight leg lifts should be started while the bulky cotton dressing is in place.
- The bulky cotton dressing can be removed after 24-48 hours.
- Once this is off, the patient may begin range of motion exercise.
- Cold therapy should also begin after the bulky cotton dressing is removed.
- Oral analgesic medication can be used for pain control.
- There is no contra indication to the use of nonsteroidal anti-inflammatory medication as well.

# EXHIBIT 5

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**UNICOMPARTMENTAL INTERPOSITIONAL SPACER  
SIZES/CATALOG NUMBERS**

Size	Thickness	Side	Catalog No.
30mm	1mm	L	6200-20-301
		R	6200-30-301
	2mm	L	6200-20-302
		R	6200-30-302
	3mm	L	6200-20-303
		R	6200-30-303
	4mm	L	6200-20-304
		R	6200-30-304
	5mm	L	6200-20-305
		R	6200-30-305
34mm	1mm	L	6200-20-341
		R	6200-30-341
	2mm	L	6200-20-342
		R	6200-30-342
	3mm	L	6200-20-343
		R	6200-30-343
	4mm	L	6200-20-344
		R	6200-30-344
	5mm	L	6200-20-345
		R	6200-30-345
38mm	1mm	L	6200-20-381
		R	6200-30-381
	2mm	L	6200-20-382
		R	6200-30-382
	3mm	L	6200-20-383
		R	6200-30-383
	4mm	L	6200-20-384
		R	6200-30-384
	5mm	L	6200-20-385
		R	6200-30-385
42mm	1mm	L	6200-20-421
		R	6200-30-421
	2mm	L	6200-20-422
		R	6200-30-422
	3mm	L	6200-20-423
		R	6200-30-423
	4mm	L	6200-20-424
		R	6200-30-424
	5mm	L	6200-20-425
		R	6200-30-425

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46mm	1mm	L	6200-20-461
		R	6200-30-461
	2mm	L	6200-20-462
		R	6200-30-462
	3mm	L	6200-20-463
		R	6200-30-463
	4mm	L	6200-20-464
		R	6200-30-464
	5mm	L	6200-20-465
		R	6200-30-465
50mm	1mm	L	6200-20-501
		R	6200-30-501
	2mm	L	6200-20-502
		R	6200-30-502
	3mm	L	6200-20-503
		R	6200-30-503
	4mm	L	6200-20-504
		R	6200-30-504
	5mm	L	6200-20-505
		R	6200-30-505
54mm	1mm	L	6200-20-541
		R	6200-30-541
	2mm	L	6200-20-542
		R	6200-30-542
	3mm	L	6200-20-543
		R	6200-30-543
	4mm	L	6200-20-544
		R	6200-30-544
	5mm	L	6200-20-545
		R	6200-30-545

# EXHIBIT 6

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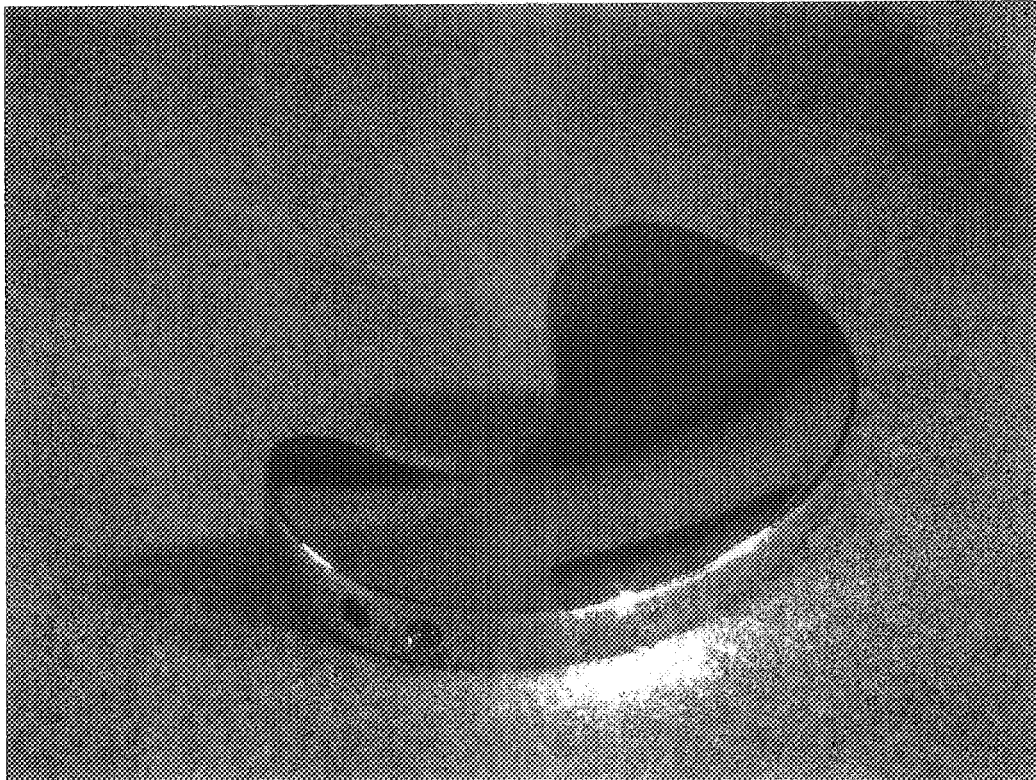




# EXHIBIT 7



**Sulzer Orthopedics  
Unicondylar Interpositional Spacer**



# EXHIBIT 8

2700??

**SULZER MEDICA**  
Sulzer Orthopedics Inc.

CE 0123

<b>Manufacturer:</b>	<b>Distributor:</b>	<b>Authorized EC Representative</b>
9900 Spectrum Drive	Sulzer Orthopedics Ltd.	Sulzer Orthopädie Ges.m.b.H.
Austin, Texas 78717	Grabenstrasse 25	Enzersdorferstrasse 12a
(512) 432-9900	CH-6341 Baar, Switzerland	A-2340 Mödling b. Wien, Austria
Toll Free 800-888-4676	+41(0)41-768-3232	

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

## UNICONDYLAR INTERPOSITIONAL SPACER

### Description of Prosthesis

The Interpositional Spacer is a unicondylar device intended to be placed in the medial joint space between the femoral and tibial condyles in patients with moderate chondromalacia. The component is kidney shaped to allow it to nest within the remaining meniscus. The device articulates directly with the existing tibiofemoral anatomy. Stability is achieved without mechanical fixation via the geometry of the device as well as the surrounding soft tissue structures. The component is available in a variety of sizes and thicknesses and is manufactured from forged cobalt-chrome alloy (CoCr, ASTM F799 or ISO 5832-12).

### Information for Use

The advancement of orthopedic surgery has provided the surgeon numerous means of restoring mobility and reducing pain for many patients. While these treatments are largely successful in attaining these goals, they should not be expected to replace or fully restore that seen with the normal joint.

In using this device, the surgeon should be aware that the following factors can be of extreme importance to the eventual success of the procedure:

- This device requires careful insertion, placement, and adequate surrounding structures (e.g., bone, muscle, ligaments, etc) for stability and should be restricted to limited functional stress.
- In selecting patients, the following factors can be of extreme importance to the eventual success of the procedure:
  - The patient's weight:** An overweight or obese patient can produce loads on the prosthesis that can lead to failure.
  - The patient's occupation or activity:** If the patient is involved in an occupation or activity, that involves significant levels of walking, running, lifting and/or muscle strain, the resultant forces can cause failure of the device.
  - 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.
  - 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.
  - Foreign body sensitivity:** Where material sensitivity is suspected, appropriate tests should be made prior to material selection or implantation.
  - Infection:** Local infection, recent or chronic, may be a contraindication for the use of this device. Extreme care should be used in patient selection in the event of recent or chronic infection.

### Indications and Contraindications

Indications and contraindications for the use may be relative or absolute and must be carefully weighed against the patient's entire evaluation and the prognosis for possible alternative procedures such as nonoperative treatment, arthroscopy, arthroplasty and others.

Patient selection will be largely dependent on patient's age, general health, conditions of available bone and tissue stock, prior surgery and anticipated further surgeries.

#### A. Indications

- Moderate degeneration of the medial compartment of the knee (grade III-IV chondromalacia) with no more than minimal degeneration (grade I-II chondromalacia, no loss of joint space) in the lateral condyle and patellofemoral compartments.

#### B. Contraindications

- Degeneration greater than Grade I-II chondromalacia, loss of joint space or moderate osteophyte formation in the lateral condyle or patellofemoral compartment.
- Greater than 5 degrees of varus (as determined by AP erect radiograph of both knees).
- Bone loss, large areas of avascular necrosis or large subchondral bone cysts of the femoral condyle or tibial plateau.
- Flattening of the femoral condyle over a large radius (area).
- Ipsilateral hip with poor/limited rotation, severe degenerative arthritis or contracture.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

- Conditions that will require use of bone cement or mechanical fixation.
- Patient physical conditions that would eliminate or tend to eliminate adequate support or prevent the use of an appropriately sized implant, e.g., insufficient quality or quantity of bone resulting from conditions such as cancer or congenital dislocation, osteoporosis, osteomyelitis, neuromuscular compromise or vascular deficiency in the affected limb in sufficient degree to render the procedure unjustifiable (e.g., absence of musculoligamentous supporting structures, joint neuropathy), or other conditions that may lead to inadequate stability.
- Active old or remote infection. This may be an absolute or relative contraindication. Every effort should be undertaken to rule out preoperative infection in a patient with suspicious symptoms, such as a history of, or when there are signs of, local inflammation, abscesses, fever, increased blood sedimentation rate, evidence of rapid joint destruction or bone resorption.
- Severe instability secondary to advanced loss of muscle, ligament or soft tissue integrity.
- Other conditions that will place excessive demands on the joint:
  - Charcot's joints
  - muscle deficiencies
  - multiple joint disabilities
  - refusal to modify postoperative physical activities
  - obesity
- Conditions that tend to impose severe loading on the affected extremity include, but are not limited to, the following:
  - obesity
  - heavy labor
  - active sports
  - history of falls
  - general neurological abnormalities or neurological conditions including mental conditions (e.g., mental illness, senility, drug use, alcoholism) that tend to preempt the patient's ability or willingness to follow the surgeon's postoperative instructions.
- Physical conditions that tend to adversely affect the stability of the implant includes, but is not limited to, the following:
  - marked osteoporosis
  - systemic and metabolic disorders leading to progressive deterioration of bone, (e.g., cortisone therapies, immunosuppressive therapies)
  - tumors and/or cysts of the supporting bone structure
  - suspected allergic reactions to metals
  - other joint disabilities (i.e., hips or ankles)

### Warnings and Precautions

#### A. Preoperative

- The preoperative planning and surgical technique for implantation of the device represents principles that are basic to sound surgical management. 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. 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.
- When this device 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 surgery, limitations particular to the patient, the possible consequences resulting from these limitations and, therefore, the necessity of following preoperative instructions.
- Allergies and other reactions to implant materials, although rare, should be considered and ruled out preoperatively.
- X-ray templates should be used to estimate size and placement. An adequate inventory of 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).
- The correct handling of the implant is extremely important. The implant should be used without nicks, scratches, or other alterations; these can produce defects and stresses that may become the focal point for eventual failure of the implant.
- 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 that may lead to failure. Only new implants may be used.**
- The safety and effectiveness of the use of this device in bilateral applications have not been established.

#### B. 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.
- Proper preparation of the joint is important in enhancing prosthesis success. Soft tissue excision should be limited to the amount necessary to accommodate the

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implant. Excessive removal may result in subsequent failure of the procedure due to degenerative changes, increased pain, loss of stability or deformation of the implant. When preparing and positioning the components, proper placement, soft tissue tension and alignment must be ensured.

3. Prior to closure, the surgical site should be thoroughly cleansed. Presence of third body structures may lead to dislocation or painful and restricted motion. Range of motion should be thoroughly checked for soft tissue balance and instability.

#### C. 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.

1. Early postoperative care should be carefully structured to maintain range of motion, and to prevent dislocation.
2. 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 soft tissue quality may necessitate extending the period of limited weight bearing.
3. 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 instability and evidence of device failure (e.g. breakage, bending, etc.).
4. The patient should be encouraged to promptly report any unusual changes in the operative extremity to his physician.

#### D. Adverse Events

The potential adverse effects are similar to those occurring with any orthopedic procedure. These effects are often attributable to factors listed under "Warnings and Precautions" and commonly include:

1. Changing position of the prosthesis (dislocation, bending or fracture of component) with or without instability or clinical symptoms.
2. Subluxation, dislocation, decreased range of motion, and shortening or lengthening of the extremity.
3. Fractures of the bone.
4. Ectopic ossification.
5. Early or late infection.

6. Cardiovascular disorders, including damage to blood vessels, wound hematoma, venous thrombosis, pulmonary embolism, and myocardial infarction.
7. Temporary or permanent neuropathies.
8. Pulmonary disorders including pneumonia and atelectasis.
9. Aggravated conditions in other joints or back due to intraoperative trauma, leg length discrepancy, or muscular deficiencies.
10. Excessive wear of the component or surrounding anatomy from damage to mating wear surfaces or debris particles.
11. Tissue reactions and allergies to corrosion or wear products.
12. Urological complications, especially urinary retention and infection.
13. Other complications associated with general surgery, drugs, or ancillary devices used, blood, etc.

#### 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 Unicompartmental Interpositional Spacer may be obtained from Sulzer Orthopedics Inc.

**THE UNICONDYLAR INTERPOSITIONAL SPACER IS INTENDED FOR USE WITHOUT BONE CEMENT.**

# EXHIBIT 9

**SULZER MEDICA**  
Sulzer Orthopedics Inc.  
CAT NO. 6200-20-341  
LOT NO. XXXXXXXXXX QTY. (1)  
MATL: CoCr STERILE



<b>LEFT</b>	<b>34MM X 1MM</b>	<b>SPACER</b>
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**UNICOMPARTMENTAL INTERPOSITIONAL SPACER**



CAUTION: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.  
SULZER ORTHOPEDICS INC. 9900 SPECTRUM DRIVE, AUSTIN, TX 78717

**SULZER MEDICA**  
Sulzer Orthopedics Inc.  
**REF** 6200-20-341 **LOT** XXXXXXXXXX QTY. (1)  
MATL: CoCr



<b>UNICOMPARTMENTAL INTERPOSITIONAL</b>	<b>34MM X 1MM</b>
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**STERILE R**

**CE 0197**

SULZER ORTHOPEDICS INC. 9900 SPECTRUM DRIVE, AUSTIN, TX 78717

**SULZER MEDICA**  
Sulzer Orthopedics Inc.  
**STERILE CE 0197**  
UNICOMPARTMENTAL INTERPOSITIONAL SPACER  
CAT NO. 6200-20-341  
LOT NO. XXXXXXXXXX  
MATL: CoCr

**SULZER MEDICA**  
Sulzer Orthopedics Inc.  
CAT NO. 6200-20-341 LOT NO. XXXXXXXXXX  

<b>LEFT</b>	<b>34MM X 1MM</b>	<b>SPACER</b>
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UNICOMPARTMENTAL INTERPOSITIONAL SPACER

<b>LEFT</b>	<b>34MM X 1MM</b>	<b>SPACER</b>
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# EXHIBIT 10

















# EXHIBIT 11

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## Arthroplasty of the Knee in Rheumatoid Arthritis and Osteoarthritis

A FOLLOW-UP STUDY AFTER IMPLANTATION OF THE MCKEEVER  
AND MACINTOSH PROSTHESES \*

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Relief of pain and restoration of function in arthritic joints have challenged surgeons for over a century. Credit for one of the first operative procedures performed to accomplish these ends belongs to John Rhea Barton who, in 1826, did an osteotomy adjacent to an ankylosed temporomandibular joint in an attempt to produce a pseudarthrosis. Rodgers subsequently performed several similar procedures but re-ankylosis was a persistent problem. After the advent of aseptic technique, more extensive procedures were developed, and in 1860 Verneuil suggested interposition of soft tissue between the exposed bone ends after the joint was resected. After several successful procedures on the temporomandibular joint using this method, he attempted arthroplasty of the knee in 1863 and used the joint capsule as the interposing membrane. In 1886, Ollier proposed the use of muscle as a covering to prevent re-ankylosis, and in 1894 Helferich reported a successful arthroplasty of the knee using this tissue. Gluck later covered the new joint surfaces with skin but reported no consistently good results.

Knee arthroplasties were first performed in this country by Murphy who used fat and fascia to provide a lining for the joint and, in 1913, recorded five ankylosed knees which were treated successfully by this method. Baer tried covering the exposed bone surfaces with chromicized pig bladder and, in 1918, reported on twenty-three knee arthroplasties of which seven resulted in motion in excess of 40 degrees. In the same year, Henderson reviewed 117 knee arthroplasties collected from a number of centers, and added four of his own. He concluded that only eighteen of the 121 could be considered successful. Several years later Campbell<sup>5</sup> discussed his experience with twenty-four arthroplasties in which fascial flaps (ten cases), chromicized pig bladders (nine cases), and free fascia lata (two cases) were used. Of these twenty-four knees, only thirteen were followed long enough for evaluation, and of these only five obtained useful motion. Ryerson, in his discussion of this paper, added eleven cases in which there was one good result. In spite of the discouraging reports from previous surgeons, Putt, in 1921 strongly advocated knee arthro-

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plasty as a procedure "which can give great satisfaction both to the patient and the surgeon."

In 1923 MacAusland reviewed the literature and described his own operative technique. He cited instability of the knee as the most significant postoperative complication, but did not report his findings or estimate the incidence of instability. To improve the stability of the joint, Albee fashioned the distal end of the femur into the shape of a shallow V and in 1928 reported good results in ten cases in which this technique was used.

Campbell in 1940 first reported on the use of metal in the reconstruction of the human knee. He inserted a curved Vitallium plate which covered the femoral condyles and was fixed to the distal end of the femur with a screw. His first two operations resulted in failure, and the procedure was abandoned. Smith-Petersen, in 1942, attempted two knee arthroplasties using a movable Vitallium mold over the femoral condyles, but the results in both cases were disappointing.

In 1949 Speed and Trout revived interest in fascial arthroplasty when they reported 44.6 per cent good results in sixty-five cases, but they excluded patients with multiple joint involvement, infection, obesity, or osteoporosis.

Samson in his review of fifty fascial arthroplasties found that twenty-six were stable and painless with 45 to 90 degrees of motion. Miller and Friedman in their review of thirty-seven fascial arthroplasties, including twenty cases of rheumatoid arthritis, found that only eleven (30 per cent) had more than 45 degrees of stable, painless motion.

In 1950 Kuhns and Potter<sup>13</sup> reported encouraging results after twenty-five knee arthroplasties performed with nylon as the interposing membrane, but later<sup>11</sup> noted deterioration of the nylon and recurrence of the deformity.

The Smith-Petersen mold for the femoral condyles was modified in 1952 to include an intramedullary stem, and the results using this prosthesis were presented by Jones in 1967.

In the past fifteen years various joint replacement prostheses have been proposed by Majnoni d'Intignano, Moeys, Shiers<sup>31</sup>, Anstett, Walldius, von Hellens, and Young. These prostheses are basically hinged joints with intramedullary fixation in the femur and the tibia by means of proximal and distal stems. These authors reported good to excellent results in from 42 to 74 per cent of the knees.

Townley in 1964 described a procedure in which the articular surfaces of the tibial plateaus were covered with a curved stainless-steel plate fixed to the tibia by two screws. His findings in nineteen knees, which were evaluated more than two years after surgery, were fourteen (74 per cent) good to excellent; two (10 per cent) fair, and three (16 per cent) poor.

In the late 1950's McKeever began to replace each tibial plateau with a metallic implant. He died before he could report his findings, but Elliott<sup>19</sup> reviewed his cases in 1960 and found good results in thirty-nine of forty knees.

MacIntosh<sup>17</sup> designed a tibial plateau prosthesis which was made first of acrylic and later of Vitallium. In 1967 he reported on his experience with 103 knees followed for more than six months. Seventy-two were rated good; five fair, and twenty-six poor. Murray in the same year found sixteen good to excellent results after twenty knee arthroplasties in which the MacIntosh prosthesis was used.

Knee arthroplasties have been performed at the Robert B. Brigham Hospital in Boston, Massachusetts, for many years. Osgood and Wilson performed approximately forty fascial arthroplasties in the 1920's, but abandoned the procedure because of the high rate of failure. Over a hundred arthroplasties, using nylon as the interposing membrane, were performed by Kuhns and associates<sup>12</sup> from 1944 to 1958 but a high rate of recurrent deformity prompted the discontinuation of this procedure.

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From 1958 to 1967, 142 arthroplasties, using metallic implants to replace the tibial plateaus, were performed on 119 patients. Ninety-five of these patients had rheumatoid arthritis; the other twenty-four had findings consistent with osteoarthritis. This study being reported here was undertaken to evaluate the results of these procedures after follow-ups of from one to nine years.

### Indications and Contraindications

Relief of pain and maintenance or restoration of function in the severely damaged arthritic knee constitute the prime indication for arthroplasty. Pain in an arthritic knee is usually due to loss of cartilage on the articular surface of the tibia and femur. Loss of cartilage can be detected by applying varus and valgus stress to the knee as it is moved through a passive range of motion. When the cartilage is absent, a dry grinding crepitus is noted as the bone on the surface of the tibial plateau slides over the exposed bone of the femoral condyle. This is the most significant clinical finding and is a more accurate diagnostic sign of loss of articular cartilage than roentgenographic evidence of joint narrowing. Arthroplasty is not necessary if non-narcotic medication and use of a cane for longer walks are sufficient to relieve discomfort.

Varus or valgus deformities and instability of the knee may be produced by either arthritis or injury. Correction of these conditions by using plateau prostheses of appropriate thickness is the second indication for arthroplasty. Roentgenograms made while corrective forces are applied permit an estimate of the amount of correction which can be obtained by arthroplasty. Use of plateau prostheses of appropriate height will improve stability in most instances, provided the capsular and ligamentous structures are intact. If the corrective forces do not eliminate the deformity, osteotomy may be required. When valgus or varus deformity of the knee has been present for a long time, the tibia will often be subluxated medially or laterally on the femur. Arthroplasty cannot be expected to correct medial or lateral subluxation and should not be performed when subluxation is present. Complete loss of integrity of the collateral ligaments was not observed in any of the knees in this series. The anterior cruciate ligament was frequently destroyed or attenuated in the rheumatoid knees, but the posterior cruciate was intact in every instance. Loss of the anterior cruciate is not a contraindication to arthroplasty.

Flexion contractures of the knee may result from either incongruous joint surfaces or contracture of the soft tissues. Traction, exercises, and a series of bivalved plaster casts, each applied with the knee in maximum extension, should be used prior to surgery in an effort to minimize this deformity. If the flexion contracture is primarily due to incongruous joint surfaces, much of the deformity may be corrected as a result of the arthroplasty. When the preoperative flexion contracture cannot be corrected to less than 30 degrees, a posterior capsulotomy or osteotomy of the distal end of the femur may be required. These procedures should be considered if a postoperative knee flexion contracture is greater than 20 degrees or if knee function is significantly impaired by the contracture.

Quadriceps power is difficult to evaluate accurately in the severe arthritic knee, since pain inhibits normal contraction of the muscle. By relieving the pain, strength at a functional level can be achieved. If there is quadriceps weakness because of a neural deficit, arthroplasty should not be performed.

Typical roentgenographic findings in rheumatoid arthritis (Fig. 5) of the knee are demineralization, cyst formation, soft-tissue swelling, and narrowing of the cartilage space. Narrowing of the cartilage space may be overlooked unless either weight-bearing or varus stress and valgus stress roentgenograms are made. Roentgenographic findings in osteoarthritis are similar to those mentioned previously ex-

cept that there is sclerosis rather than demineralization and the subchondral cysts are likely to be much smaller or absent. Hypertrophic spurs on both the tibia and the femur are also more frequently observed in the osteoarthritic knee. If subchondral cysts in the tibia are visible on roentgenograms, the possibility of the prosthesis sinking into the cysts must be carefully considered. If the cysts are too large, arthroplasty is contraindicated. Large cysts in the weight-bearing area of the femoral condyles also constitute a contraindication to arthroplasty with plateau prostheses.

### The Implants

Vitallium prostheses of both the McKeever (Fig. 1) and the MacIntosh (Fig. 2) design were used in this series. The McKeever prosthesis is semicircular with a smooth concave superior surface, and on the inferior surface, a T-shaped fin with the transverse limb of the T anteriorly. Five thicknesses of the prosthesis, ranging from three to fifteen millimeters, are available for the correction of varus and valgus deformities (Fig. 3). Medial and lateral components (according to the orientation of the fins) are used.

When McKeever described the design of his prosthesis he emphasized the importance of the following features. The area of contact between the prosthesis and bone should be as large as possible, fixation of the prosthesis should be ensured by its shape and in a joint in which there is reciprocating motion, the stress should be continuous and of the same type so far as possible. In the normal knee the amount of the joint surface in contact varies with the position of the joint. The area of contact is maximum in the extended position when the concave tibial plateaus approximate the convex femoral condyles. McKeever measured forty tibial condyles, and found considerable variation in total surface area but little variation in the central weight-bearing area. He concluded that only one size of prosthesis is needed to conform to

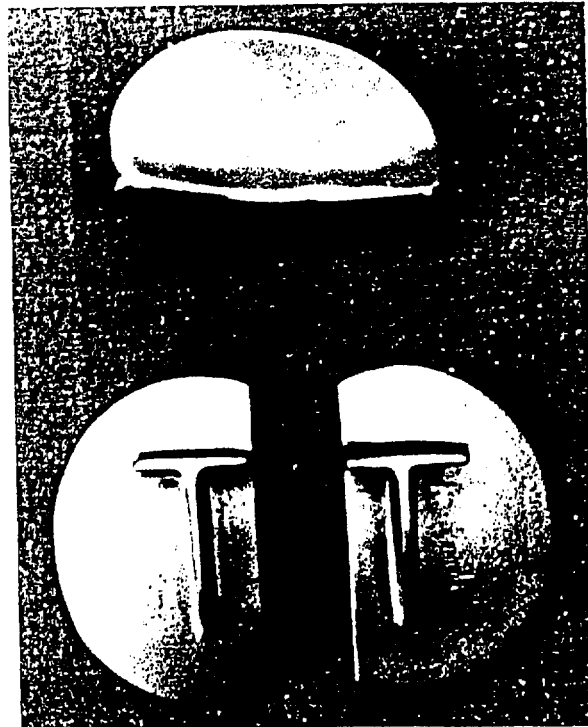


FIG. 1

McKeever prostheses. Upper surface (above) smooth and concave; inferior surface (below) with T-shaped fin.

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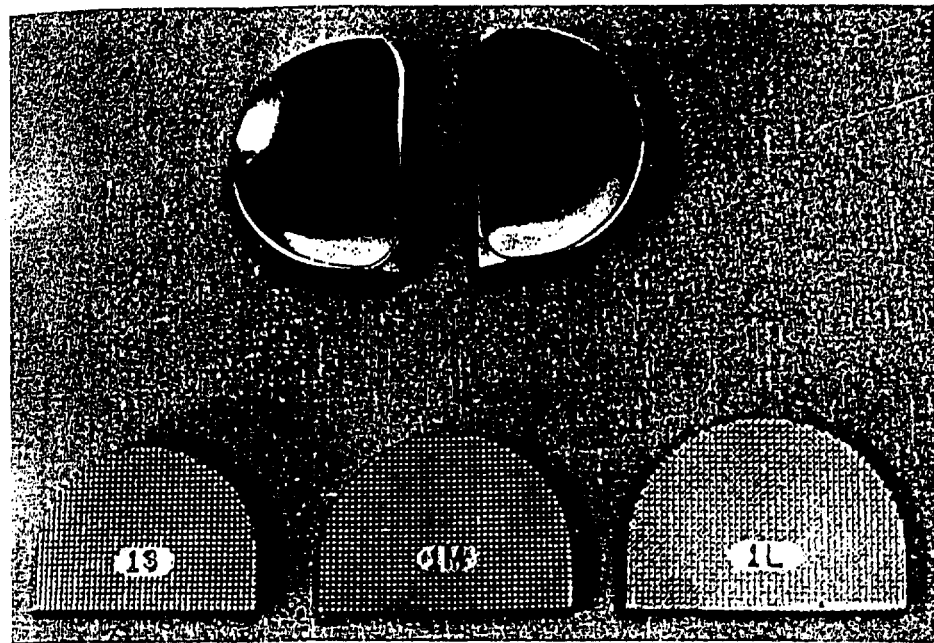


FIG. 2

MacIntosh prostheses. Upper surface (above) smooth and concave, lower surface (below) with serrated surface showing small, medium and large (left to right) prostheses.

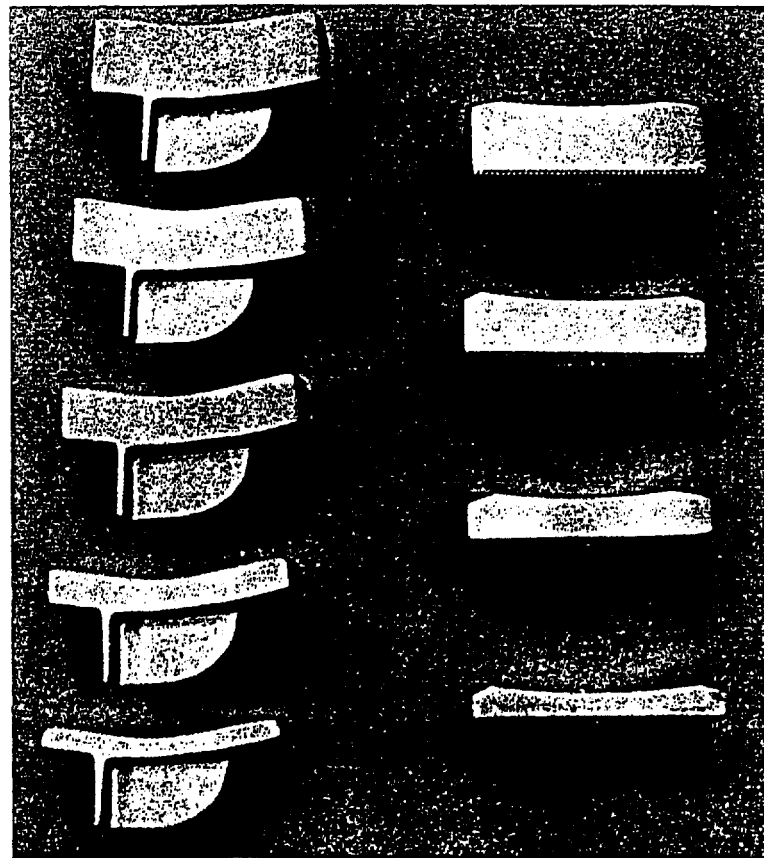


FIG. 3

McKeever (left) and MacIntosh (right) prostheses, showing variety of available thicknesses.

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this central area and, therefore, his prostheses are all the same size with respect to surface area. Fixation is provided in part by the T-shaped fin which maintains the alignment of the prosthesis, but fixation for the most part is dependent on the forces acting on the joint during function. The stress produced by these forces at the prosthesis-bone interface is primarily compression in the direction of the axis of the tibia in all positions of the knee, due to the flat configuration of the implant. When a prosthesis is attached to the femur it must be convex and hence the stress produced by forces on the knee must vary as the position of the knee changes.

The MacIntosh (Fig. 2) prosthesis has a similar design except that its inferior surface is flat with multiple serrations. The stability of the MacIntosh prosthesis depends on the difference in the coefficient of friction of the serrated inferior surface resting on the tibial plateau and that of the polished superior surface of the prosthesis in contact with the femoral condyle. This implant is made in three sizes to conform as closely as possible to the total surface area of the tibial plateau. The same prosthesis can be used in either the medial or the lateral compartment of the joint, and prostheses are available in four basic thicknesses ranging from three to twelve millimeters with additional thicknesses up to twenty-one millimeters obtainable on request (Fig. 3).



FIG. 4

Operative view of femoral condyles of left knee of forty-five-year-old woman with rheumatoid arthritis showing complete loss of articular cartilage over the weight-bearing area and a ridge of bone and cartilage on the anterior part of medial femoral condyle.

#### Operative Technique

The operation is usually performed using a tourniquet and a long medial parapatellar incision. The vastus medialis with a narrow strip of its tendinous attachment is reflected medially to expose the capsule. After opening the joint, it is thoroughly examined to evaluate the extent of destruction of the articular surfaces of the tibia, femur, and patella. In every case, the operative findings (Fig. 4) showed more extensive destruction than had been anticipated from either the appearance of the joint on the roentgenograms (Fig. 5) or the clinical findings during the preoperative examination.

Initially a synovectomy (Fig. 6) is performed, starting in the suprapatellar re-

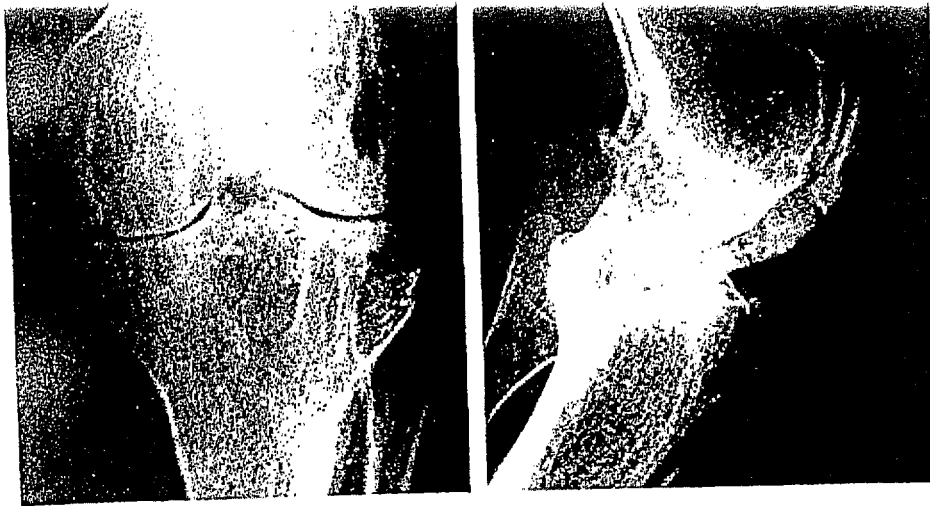


FIG. 5

Anteroposterior and lateral roentgenograms of the same knee as the one shown in Fig. 4. Note narrowing of the joint space in both medial and lateral compartments and the marked cyst formation in both tibia and femur.



FIG. 6

Excision of hypertrophic synovium beginning in supracondylar area and dissecting distally along the sides of the condyles to the menisci.

gion and removing all visible synovium including that in the posterior part of the joint. In cases of osteoarthritis, a synovectomy is performed only when there is marked hypertrophy or proliferation of the synovium. The menisci are also excised, since they are generally involved by the arthritic process. The anterior cruciate ligament is often absent or attenuated. If it is markedly involved by the synovitis, it may be removed since loss of the anterior cruciate ligament in these patients does not noticeably interfere with joint function.

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Large marginal spurs along the femoral condyle are excised, but since the resulting raw bone surfaces provide potential sites for adhesions, smaller spurs and those which do not interfere with motion are left intact. There is usually a transverse ridge along the anterior aspect of both femoral condyles which appears to be the result of repeated impingement of the anterior margin of the tibia against the femoral condyles. This bone ridge is excised in order to improve knee extension. A bone rasp is used to smooth each femoral condyle and provide it with a rounded contour. Multiple parallel straight cuts three millimeters apart are made with a thin straight osteotome in the areas of exposed eburnated bone on the femoral condyles. Then by directing additional parallel cuts at right angles to the first set of cuts, a crosshatched appearance is produced. We believe that cutting through the eburnated cortical bone facilitates vascularization and the formation of fibrocartilage on the femoral condyles.

#### McKeever Prosthesis

A slotted template (Fig. 7) is used to determine the appropriate site of insertion of the McKeever prostheses. Each component should be placed so that it forms a posteriorly opening angle of about 10 degrees with the mid-sagittal plane (Fig. 8) to conform to the angulation of the femoral condyles (Fig. 9). The curved outer margins of each prosthesis should not protrude beyond the outer margin of the corresponding tibial plateau or impinge on the collateral ligaments. The inner margins of the medial and lateral prostheses when properly placed should outline on the tibia a wedge-shaped area which encompasses the tibial spines and is pointed anteriorly. An osteotome is used to mark the tibial surface along the straight side of the template which is placed in one side of the joint. A vertical cut is then made along this mark to form a buttress against which the straight side of the prosthesis will impinge. A horizontal anteroposterior cut is then made with a slightly curved 12.7 millimeter osteotome so that it joins the vertical cut. This cut surface should be slightly concave paralleling the surface of the tibial plateau and conforming to the shape of the under-

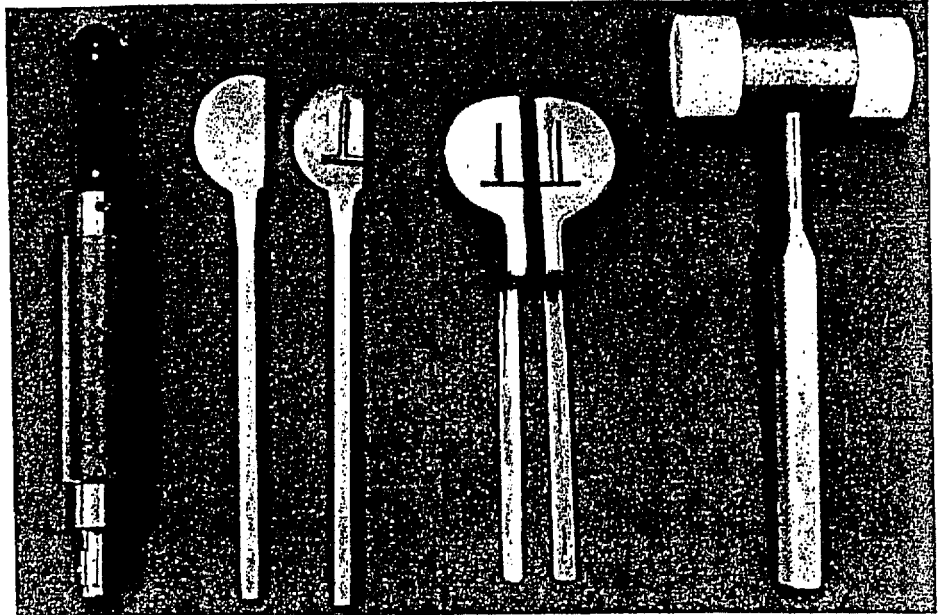


FIG. 7

Special instruments used in knee arthroplasties (left to right): sagittal saw, template with raised fin in location of McKeever fin, template with slots in similar orientation, and nylon headed hammer to prevent damage of prosthesis (see text).

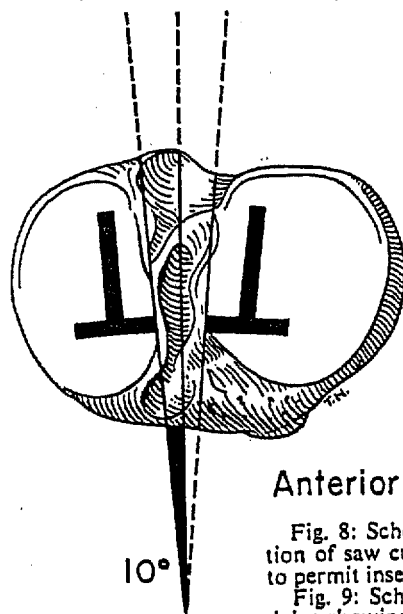


FIG. 8

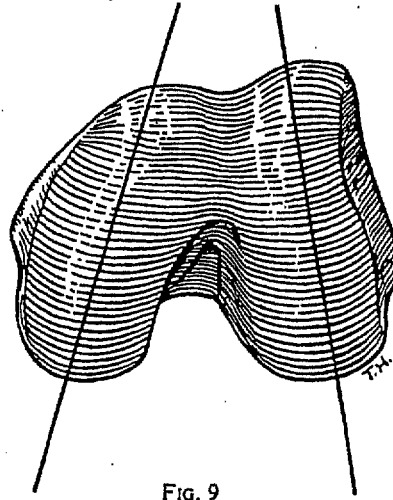


FIG. 9

Fig. 8: Schematic view of tibial plateaus showing proper orientation of saw cuts made to outline the tibial bone fragments removed to permit insertion of the prosthesis.

Fig. 9: Schematic view of weight-bearing surface of femoral condyles showing normal alignment (distal femoral condyles of a right knee).

surface of the prosthesis. In making the horizontal cut an effort should be made to preserve the subchondral bone. After the fragment formed by the osteotomies is removed a similar fragment is removed from the opposite joint compartment using the same technique. The template is then reinserted to determine the sites of the slots for the fins of the medial and lateral prosthesis. The longitudinal (sagittal) slots are six millimeters from the corresponding inner vertical buttress near the base of the tibial spines while the transverse (frontal) slots are twelve millimeters behind the anterior margin of the tibial plateaus. A small reciprocating saw (Fig. 7) is useful to cut these T-shaped slots to prevent fracture of the tibial plateaus; however, a thin osteotome can be used if a saw is not available. The cuts should extend through the subchondral cortex into cancellous bone.

With the knee in maximum flexion the longitudinal fin of the McKeever prosthesis is inserted into the appropriate longitudinal slot in the tibia. The prosthesis is then tamped in a posterior direction using a nylon hammer (Fig. 7). When the transverse fin overlies its tibial slot, the knee is gently extended to seat the prosthesis firmly in place. A similar procedure is carried out in the other compartment. To correct a valgus deformity, the medial prosthesis should be inserted first. The lateral prosthesis, which should be sufficiently thick to correct the deformity yet still permit full knee motion, is then inserted in the same manner. If there is difficulty inserting the implant due to a narrow joint space, a few millimeters of bone may be removed from the posterior non-weight-bearing portion of the corresponding femoral condyle. Similarly, if the anterior tibial spine impinges against the femur in the intercondylar notch, full extension of the knee is prevented. Under these circumstances a rectangular block of bone should be removed from the femoral intercondylar area to create a sufficient space to accommodate the tibial spines when the knee is in full extension.

Once inserted (Fig. 10) the prosthesis should be stable and not move as the knee is flexed and extended through an arc of at least 90 degrees. The anterior edge of the implant may project just beyond the edge of the tibial plateau. If this edge of the implant is too far posteriorly, it will abut against the femoral condyle and block full extension. The prosthesis must be inserted correctly the first time. A new set of slots should not be made because the prosthesis may then be unstable.





FIG. 10

Medial and lateral McKeever prostheses in proper position following synovectomy and excision of hypertrophic spurs from femoral condyles. Note slight toeing-in of prostheses.

#### MacIntosh Prosthesis

For insertion of the MacIntosh prosthesis, the buttresses along the tibial spines are cut initially in the same manner as for the McKeever device. Bone is then removed from each tibial plateau to provide flat surfaces. These cuts should not be made so deeply that they extend entirely into cancellous bone. It is important to remove the posterior lip of each tibial plateau so that the prosthesis can be seated far enough posteriorly to prevent anterior displacement of the implant during knee flexion.

A patelloplasty is performed when there is loss of patellar articular cartilage and extensive marginal osteophytes. To do this the soft tissues are dissected subperiosteally away from the periphery of the patella, and using a reciprocating saw, the posterior two-thirds of the patella is removed, leaving a slight central ridge, corresponding to the femoral intercondylar groove. The cancellous surface of the patella is usually covered with fascia lata. However, the infrapatellar fat pad or articularis genu muscle has also been used. The layers of the wound are then closed with interrupted silk sutures, and the extremity is immobilized in a long plaster cast with the knee in maximum extension. The cast is bivalved on the day of surgery.

#### Postoperative Regimen

The patient is started on quadriceps setting exercises on the first postoperative day. The bivalved cast is removed for active assisted exercises two or three days after operation. The cast is then lined and used as a night cast for eight to twelve weeks. If there is a residual flexion contracture, or the quadriceps is weak, the bivalved cast holding the knee in maximum extension is worn intermittently during the day. Additional casts to maintain the knee in maximum extension are made as the flexion contracture diminishes. If the patient does not attain 60 degrees of flexion by two weeks, a gentle manipulation to 90 degrees is carried out under general anesthesia. During the third week, the patient begins limited weight-bearing, using two crutches. Use of crutches is continued with a gradual increase in weight-bearing for a minimum of three months. At that time, crutches may be discontinued provided the patient has smooth painless motion to more than 70 degrees of flexion, adequate stability, good

quadriceps power, and no residual deformity. If these criteria have not been met, some form of support should be continued.

#### Method of Evaluation

The evaluation of postoperative results is difficult under any circumstances, especially when there is progression of the disease process or recurrence of disease activity. Any bias caused by the enthusiasm of the surgeon for the procedure or by the loyalty of the patient to his surgeon must be minimized if accurate reproducible assessments of the results are to be obtained. We have devised a system for the evaluation of knee arthroplasties which attempts to diminish subjective factors, and to provide a reproducible numerical score which accurately reflects the success of the procedure. The scoring system is based on demerits which are assigned in seven categories: pain, motion, flexion contracture, varus or valgus deformity, medial-lateral instability, quadriceps power, and need for support (Table I). The final rating is determined by adding up the demerit points assigned in each of the categories and rating the result as excellent, good, fair, or poor according to the total demerit scores as shown in Table I.

The one subjective factor which cannot be eliminated from the final result rating is pain. Since relief of pain is a primary goal of the procedure, the method of scoring must weigh heavily any residual pain, considering at the same time the well known tremendous individual variation in the tolerance of pain. The severity of the pain, of course, can be evaluated to some extent by determining how much the pain limits the patient's activities. If the patient has pain only after prolonged walking and otherwise has no limitation of his usual activities, one demerit is assigned. If the patient occasionally limits his ordinary activity due to pain or has pain after walking short distances, he is assigned three demerits and eliminated from the excellent group. For the occasional use of narcotics to relieve pain, six demerits are assigned which would still qualify the patient for the good category if there were no other demerits. However, such a patient would be advised to use support and the added demerits would place the result in a lower category.

Range of motion, deformity, and instability can be measured in degrees in a reproducible fashion and hence are objective factors which aid in the quantitative assessment of the results. Demerit values are assigned according to the severity of the deformity and the amount of limitation of motion.

The measurement of quadriceps strength provides a reliable assessment of knee function. If no motion is present, quadriceps power cannot be measured, and six demerits are assigned in both the quadriceps-power and knee-motion categories so that the ankylosed knee falls in the poor category. In assigning demerits for the use of support, the reason for the use of support is disregarded. Thus, even if crutches are required because of disability in the hip of the opposite extremity, demerits are assigned in the rating of the result of the knee arthroplasty.

In this study an excellent result denoted a virtually painless knee that enabled the individual to perform most of his activities without the need for support. This rating does not imply, however, that an excellent knee is normal and able to withstand all the forms of stress tolerated by a normal knee.

The roentgenographic findings are important and cannot be disregarded in the evaluation of the results after arthroplasty, since they indicate how the bone has reacted to the presence of the prosthesis and also show if there has been any loosening or displacement of the prostheses. However, for the numerical grading of the results we decided that a system based only on function and the clinical findings would be more meaningful and more practical to use. Accordingly, the numerical rating system makes no allowance for the roentgenographic findings.

TABLE I  
 KNEE ARTHROPLASTY EVALUATION

	Demerit Points
<b>Pain</b>	
None; no limitation of activity	0
Occasionally with prolonged walking; no limitation of usual activity	1
Pain after walking short distances; some limitation of usual activity	3
Pain, sufficient to require narcotics for relief; marked limitation of activity	6
Pain at rest; patient incapacitated	7
<b>Knee Motion</b>	
80 degrees or more	0
60 to 80 degrees	1
30 to 60 degrees	3
Less than 30 degrees	6
<b>Flexion Contracture</b>	
None to 5 degrees	0
5 to 15 degrees	1
15 to 30 degrees	2
30 to 45 degrees	4
More than 45 degrees	6
<b>Varus or Valgus Deformity</b>	
Less than 10 degrees	0
10 to 20 degrees	2
20 to 30 degrees	3
More than 30 degrees	4
<b>Medial-Lateral Instability</b>	
Less than 10 degrees	0
10 to 20 degrees	2
More than 20 degrees	4
<b>Quadriceps Power</b>	
Normal to good	0
Good minus to fair plus	1
Fair	2
Poor	4
No motion	6
<b>Support</b>	
None	0
Occasionally uses cane	
Cane all the time	2
Crutches	4
<b>Final Rating</b>	
Excellent	0 to 2
Good	3 to 6
Fair	7 to 10
Poor	11+

Roentgenograms were made in the immediate postoperative period prior to discharge from the hospital, and after approximately three months, when an increase in weight-bearing was anticipated. Subsequent examinations were made at six months, one year, and annually thereafter unless the clinical condition warranted additional studies. The roentgenograms made in the immediate postoperative period permitted evaluation of the placement of the prostheses. When properly placed, the prostheses should not extend medially or laterally beyond the margins of the tibial condyles on the anteroposterior roentgenogram (Fig. 11) but should extend to or slightly beyond the anterior margins of the tibial condyles. Correction of valgus or varus deformity by prostheses of appropriate thickness was evident on the postoperative roentgenograms. Roentgenograms made later showed reactive changes in the bone in contact

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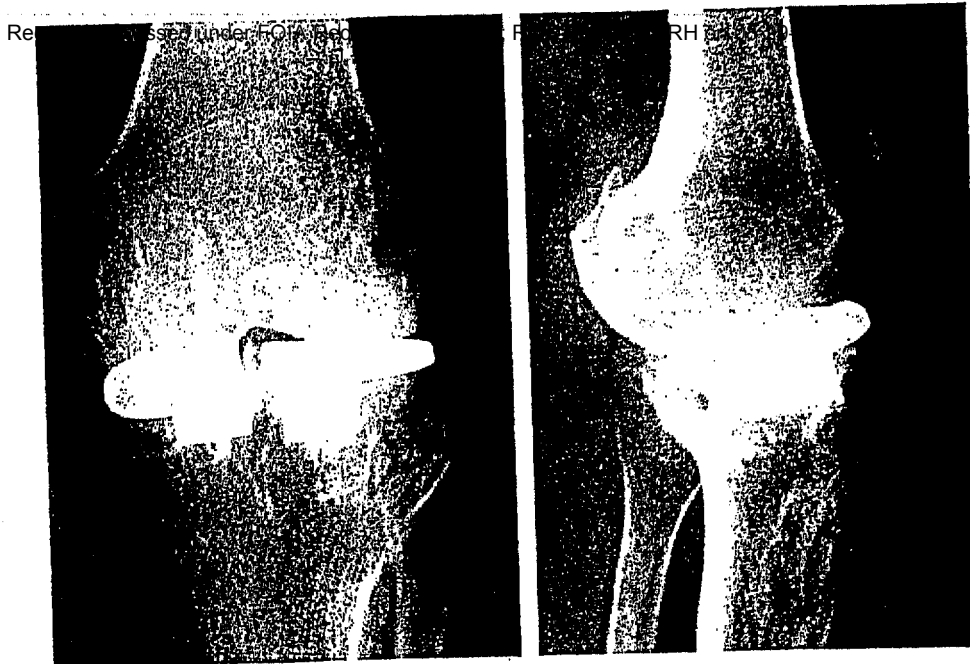


Fig. 11

Anteroposterior and lateral roentgenograms of same patient as in Figs. 4, 5, and 6, eight years following knee arthroplasty with McKeever prostheses. Note area of sclerosis beneath fins and prostheses. This patient had an excellent result by the rating system described.

with the prosthesis. With the McKeever prosthesis the observed changes were a line of sclerosis about the fins and along the undersurface of the prosthesis.

None of the McKeever prostheses in this study migrated distally more than one to two millimeters into the tibial plateau. It is impossible to assess minute changes in angulation of the prostheses due to the technical difficulty of reproducing exactly comparable roentgenograms. No gross changes in the position of the prostheses were noted except for two MacIntosh and one McKeever prosthesis which are discussed in the section on complications. Significant progressive changes were also noted in the lateral femoral condyle of one patient whose clinical course is discussed in the section on results.

#### Material

Since 1958, 142 knee arthroplasties have been performed on 119 patients who have been followed for from one to nine years after surgery. Twenty-three of these patients had a bilateral procedure. Ninety-five patients fulfilled the accepted criteria for the diagnosis of rheumatoid arthritis, and the remaining twenty-four had pathological changes consistent with degenerative joint disease. Included in the latter group were one case each of ochronosis, pseudogout, and traumatic arthritis, secondary to a gunshot wound. The age (Chart I) of the patients at the time of surgery ranged from twenty-two to seventy-six years for the rheumatoid group with a median age of fifty-three, and from twenty-nine to eighty-one years for the osteoarthritic group with a median age of sixty-four. The sex distributions were sixty-nine women and thirteen men in the rheumatoid group and twelve women and five men in the osteoarthritic group. All patients had some form of medical therapy prior to knee surgery. The use of anti-inflammatory drugs did not adversely affect the postoperative course of any patient with one exception to be described.

Of the total group of 142 knee arthroplasties, 118 (ninety-nine rheumatoid and nineteen osteoarthritic) in ninety-nine patients (eighty-two rheumatoid and seventeen

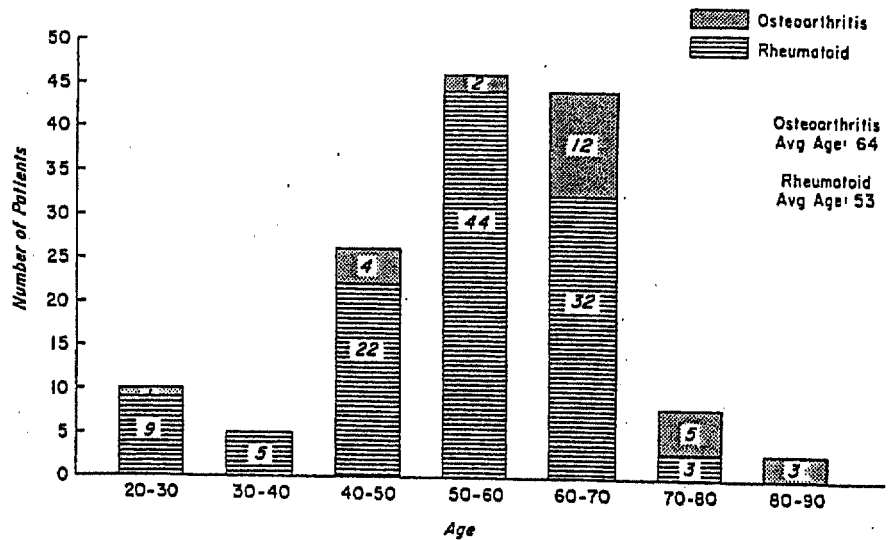


CHART I  
Age at operation.

osteoarthritic) were evaluated one to nine years after operation. Seven patients with eight knee arthroplasties died before this study was carried out and thirteen patients with sixteen operations were not available for follow-up. The average follow-up was three years; the range, from one to nine years. All of the knees evaluated had been examined by one of the authors within six months of the time of writing.

Many of the patients had extensive involvement. Forty of the ninety-nine patients with rheumatoid arthritis had operations on the opposite knee. These included synovectomy and débridement in ten, arthroplasty with metallic implants in twenty, arthrodesis in eight, and meniscectomy and arthroplasty using nylon in one each. Four of the nineteen patients with osteoarthritis also had contralateral knee operations. These were arthroplasties with metallic implants in three and an arthrodesis in one.

In addition, many patients also had involvement of one or both hips. The resulting disability was sufficient to necessitate surgical treatment in thirteen patients with rheumatoid arthritis and in one with osteoarthritis. Vitallium mold arthroplasties were performed in thirteen patients: on both hips in two of the thirteen rheumatoid patients and in the contralateral hip of the patient with osteoarthritis. One patient had a bilateral Moore arthroplasty for rheumatoid arthritis.

### Results

The results were analyzed in three ways:

1. The over-all results were assessed comparing the postoperative status with that before operation by means of the rating system described;
2. The preoperative and postoperative status were compared in terms of some of the rating categories; and
3. The influence of specific factors on the results was explored by appropriate correlations.

#### Over-All Results

By the described method of evaluation (Table I) the postoperative ratings in the ninety-nine rheumatoid knees were excellent in thirty-six, good in twenty, fair in sixteen, and poor in twenty-seven. The preoperative ratings for these same knees were

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eight good, twenty-three fair, and sixty-five poor, leaving three unrated before operation because of insufficient preoperative information. (The postoperative results in these three were two good and one poor.) The postoperative ratings in the nineteen osteoarthritic knees were fourteen excellent, three good, one fair, and one poor, in contrast to their preoperative ratings that were eight good, six fair, and five poor (Table II). Thus, 70 per cent of the rheumatoid knees and 89 per cent of the osteoarthritic knees were improved according to this method of evaluation.

TABLE II  
RATING BEFORE AND AFTER ARTHROPLASTY

Rating	Rheumatoid		Osteoarthritic	
	Preoperative	Postoperative	Preoperative	Postoperative
Excellent	-	36	-	14
Good	8	20	8	3
Fair	23	16	6	1
Poor	65	27	5	1
	<u>96*</u>	<u>99</u>	<u>19</u>	<u>19</u>

\* For three rheumatoid knees there was insufficient preoperative information. Their postoperative results were two good and one poor.

Of the ninety-six knees in the rheumatoid group, two-thirds were in the poor category preoperatively, while postoperatively only slightly more than one-fourth were in this category, 28 per cent remained unchanged, and 2 per cent were made worse. Of the nineteen osteoarthritic knees, 89 per cent were improved and 11 per cent were unchanged. The changes in rating as a result of arthroplasty according to preoperative ratings are shown in Table III. Considering the rheumatoid and osteoarthritic knees together, eighty-four of 115 knees were improved, two were made worse dropping from a fair to a poor rating, and twenty-nine were not changed, twenty-five remaining at a poor rating, three at a fair rating, and one at a good rating.

TABLE III  
CHANGE IN RATING AS RESULT OF ARTHROPLASTY

Ratings	Rheumatoid	Osteoarthritic
Poor to Poor	24	1
Poor to Fair	13	1
Poor to Good	13	
Poor to Excellent	15	3
Fair to Poor	2	
Fair to Fair	3	
Fair to Good	5	2
Fair to Excellent	13	4
Good to Poor		
Good to Fair		
Good to Good		1
Good to Excellent	8	7
Totals	<u>96*</u>	<u>19</u>

\* Three knees of the ninety-nine rheumatoid knees were not evaluated because of insufficient preoperative information. The postoperative results in these knees were two good and one poor.

Of the eighty-four knees that improved, twenty improved from poor or fair to good, and thirty-five from poor or fair to excellent, while fifteen improved from good to excellent. The remaining fourteen (thirteen rheumatoid and one osteoarthritic)

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knees improved only from poor to fair. Of these fourteen knees, twelve (eleven of the rheumatoid and the one osteoarthritic knee) were assigned four of their demerit points because support was used. Nine of these twelve knees were in limbs with only fair quadriceps power. In the other two knees (of the fourteen which improved only from poor to fair) the slight improvement was due to an increase in motion and quadriceps power.



FIG. 12

Anteroposterior roentgenograms of the left knee of rheumatoid patient preoperatively (left) and nine years following lateral McKeever arthroplasty (right). At the time of evaluation this patient had a good result by the rating system.

Of the two patients whose ratings dropped from fair to poor following knee arthroplasty, one had large (1.5 centimeter) cystic defects in both the lateral femoral condyle and the lateral tibial plateau. An attempt was made to fill these defects with bone grafts but further collapse of the femoral condyle led to instability and pain necessitating the use of crutches. The other patient who dropped from fair to poor had a 30-degree flexion contracture following arthroplasty and a supracondylar osteotomy was performed two months postoperatively. Although the deformity was corrected, the knee was painful after prolonged walking. In addition the patient had little knee motion and poor quadriceps power, and required crutches for ambulation.

Of the twenty-five knees which were poor preoperatively and remained so after operation, nine had complications. These were: two supracondylar fractures as the result of manipulation, four postoperative infections, one varus and one valgus deformity both of which were corrected by reoperation and insertion of a thicker prosthesis but without improvement in rating, and one torn medial capsule, the result of a fall four weeks after arthroplasty. The torn medial capsule in this knee was repaired but quadriceps power remained poor and residual instability necessitated the use of crutches.

Thirteen more of the twenty-five knees with poor ratings preoperatively had severely limited motion (less than 45 degrees) before operation. They gained no motion following arthroplasty and, indeed, none of the knees in this series with severe limitation of motion preoperatively gained satisfactory motion after arthroplasty.

The three remaining knees (of the twenty-five which continued to have a poor

ARTHROPLASTY OF THE KNEE

rating) were distributed as follows: One was in a patient with spasticity; another, in a patient with Wernicke's encephalopathy and the third, in a patient in whom no explanation for the poor result was apparent.

Of the three knees which rated fair both before and after operation, the first had a poor quadriceps both preoperatively and postoperatively and continued to require a cane for support, the patient with bilateral arthroplasty had less pain but continued to have only fair quadriceps power bilaterally and hence required two crutches.

The one patient whose rating was good before operation and remained so postoperatively was improved in regard to the knee but required two crutches for progressive hip symptoms.

Sixteen knees (eight rheumatoid and eight osteoarthritic) had good ratings preoperatively. All of the eight rheumatoid and six of the eight osteoarthritic knees had arthroplasties because of pain which came on after short walks (three demerit points in the pain category). The other two osteoarthritic knees were operated on because of valgus deformity in one knee and increasing pain, although still in the 0 to 1 category, requiring continual use of a cane in walking. Of the fourteen knees, thirteen had sufficient improvement to be placed in the excellent category postoperatively. The remaining patient had decreased pain but required two crutches in walking after a Vitallium-mold hip arthroplasty, maintaining the result in the good category.

*Comparison of Preoperative and Postoperative Status*

The result categories used for this comparison were pain, range of motion, flexion contracture, varus or valgus deformity, need for support, and stability.

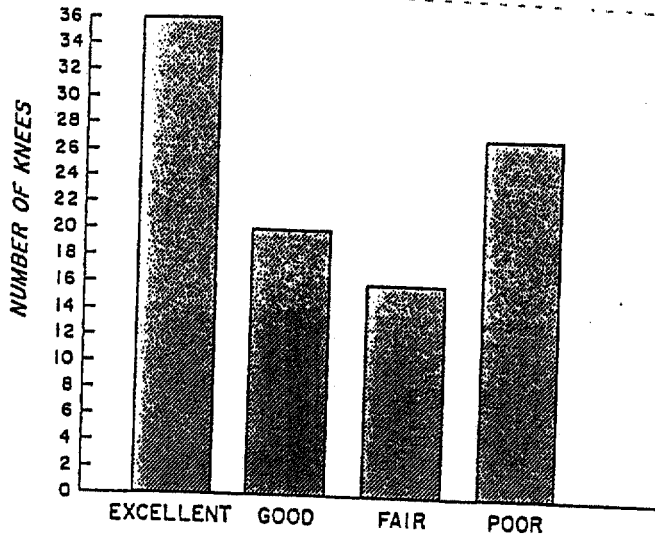


CHART II

End results of knee arthroplasty in rheumatoid arthritis.

*Rheumatoid Group (Eighty-two Patients with Ninety-nine Arthroplasties)*

Prior to arthroplasty, four patients with six knees had a rating for pain of 0 to 1, whereas at follow-up sixty-eight patients with eighty-one knees had this rating. The results in the four patients with a preoperative pain rating of 0 to 1 were as follows: The first with bilateral fibrous ankylosis in 45 degrees of flexion before operation had fibrous ankylosis in 20 degrees of flexion and no change in the poor rating of both knees. The second with flexion contractures of 45 degrees, only 35 degrees of knee motion, and poor quadriceps power, had bilateral arthroplasty and posterior capsulotomy with reduction of both flexion contractures to 20 degrees but insufficient



gain in motion or quadriceps power to change the over-all ratings. The third had a flexion contracture of 30 degrees, a valgus deformity of 15 degrees, limited motion, and fair quadriceps power, and walked with two crutches preoperatively. At follow-up this knee had no demerit points and an excellent rating. The fourth patient with increasing pain (still at the 0 to 1 level), quadriceps weakness following a nylon arthroplasty on one knee six years earlier, and using two crutches in walking had sufficient improvement in these categories to attain an excellent rating.

Before operation fifty-two knees had 80 degrees of motion or more; postoperatively seventy-one had this range of motion.

Preoperatively the flexion contractures were less than 5 degrees in twenty-one knees, 5 to 15 degrees in thirty-four, and 15 degrees or more in forty-one. Postoperatively, the contractures were less than 5 degrees in sixty-one knees, 5 to 15 degrees in fourteen, and more than 15 degrees in twenty-four.

Before arthroplasty varus or valgus deformity of more than 10 degrees was present in thirty-five knees; postoperatively, nine knees had deformities of this severity.

Preoperatively fifty-three knees were given four demerit points for required external support (two crutches); postoperatively, forty-two knees were so rated.

Preoperatively sixteen knees showed medial-lateral instability greater than 10 degrees; postoperatively, nine knees had instability of this severity.

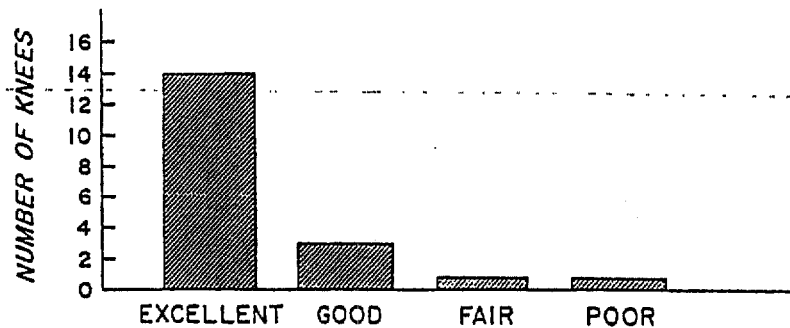


CHART III

End results of knee arthroplasty in osteoarthritis.

#### *Osteoarthritic Group (Seventeen Patients with Nineteen Arthroplasties)*

Before arthroplasty two patients with two knees had pain ratings of 0 to 1, while postoperatively all seventeen patients (nineteen knees) had this rating.

Preoperatively seventeen knees had motion of 80 degrees or more, whereas after arthroplasty sixteen had this amount of motion. The one that lost motion was a patient with chronic spasticity whose over-all rating of poor did not improve after arthroplasty. The two knees with less than 80 degrees of motion preoperatively had increased motion after operation. They improved from fair to one good and one excellent rating.

Initially the flexion contractures were less than 5 degrees in nine knees, 5 to 15 degrees in seven knees, and more than 15 degrees in three. Postoperatively the contractures were less than 5 degrees in fourteen knees, 5 to 15 degrees in two, and more than 15 degrees in three.

Before arthroplasty, varus or valgus deformity of more than 10 degrees was present in ten knees; postoperatively, one knee had such a deformity.

Preoperatively seven knees were given four demerit points for required external support; postoperatively, three knees were so rated.

None of the knees in this group was unstable either before or after operation.

### *Influence of Specific Factors*

The results of knee arthroplasty were correlated with whether prior surgery had been performed in the same knee, the type of knee prosthesis used, and whether a patelloplasty had been performed at the time of arthroplasty. Other factors investigated were bilateral arthroplasty, fusion of the contralateral knee, hip involvement, and the patient's age at the time of operation.

Twenty-seven of the 142 knees studied had been operated on prior to their arthroplasty with tibial plateau prostheses. These operations were: synovectomy and débridement in ten rheumatoid and two osteoarthritic knees, arthroplasty with nylon membrane in one rheumatoid and one osteoarthritic knee, arthrotomy with or without meniscectomy in four rheumatoid and three osteoarthritic knees, posterior capsulotomy in five rheumatoid knees, and supracondylar osteotomy in one rheumatoid knee. Twenty-one of the twenty-seven knees which had had previous operations were available for evaluation. The other six were lost to follow-up for reasons previously noted. The results were four excellent, four fair, and eight poor in the rheumatoid group, and two excellent and three good in the osteoarthritic group. Prior surgery, therefore, did not appear to have an adverse effect on the results of arthroplasty for the osteoarthritic group. In the rheumatoid knees, on the other hand, prior surgery did seem more likely to be associated with a poor result after tibial plateau arthroplasty.

The results with the McKeever and MacIntosh prostheses were also compared. Of the ninety-nine rheumatoid knees, sixty-three were treated with the McKeever, twenty-nine with the MacIntosh, and seven with a medial McKeever and a lateral MacIntosh prosthesis. Both types of prosthesis were used in the same knee before McKeever prostheses of varying heights were available. The ratings with the McKeever prostheses were: twenty-four excellent, twelve good, eleven fair, and sixteen poor, and with the MacIntosh, ten excellent, six good, three fair, and ten poor. With the medial McKeever and lateral MacIntosh the ratings were two excellent, two good, two fair, and one poor. Of the nineteen osteoarthritic knees, eleven were treated with the McKeever and eight with the MacIntosh. With the McKeever the ratings were nine excellent and two good, and with the MacIntosh, five excellent, one good, one fair, and one poor. There was, therefore, no significant difference in the results with the two prostheses although the incidence of poor results was slightly higher when the MacIntosh prosthesis was used.

The results in the twenty-one patients who had patelloplasty were analyzed separately to determine the effect of this additional procedure. There were eighteen rheumatoid and three osteoarthritic knees in which this procedure was performed. In the rheumatoid knees the ratings were five excellent, three good, six fair, and four poor. In the osteoarthritic knees the results were excellent in all three. Patelloplasty, therefore, did not appear to influence the final rating.

Of the twenty-three patients who had bilateral arthroplasty with a McKeever or MacIntosh prosthesis, nineteen could be evaluated: seventeen with rheumatoid arthritis and two with osteoarthritis. The results of the thirty-four knee arthroplasties in the seventeen patients with rheumatoid arthritis were good to excellent in sixteen knees (47 per cent), while the results of the four arthroplasties in the two patients with osteoarthritis were excellent. The results in the bilateral cases were therefore essentially the same as those in the whole group.

Nine patients had an arthroplasty in one knee and an arthrodesis in the other. Of these nine arthroplasties, two were rated excellent, two good, two fair, and three poor, after follow-ups ranging from one to seven years. The findings in these nine patients suggest that arthrodesis of the opposite knee, although not desirable, is not a definite contraindication to arthroplasty.

Fifteen knee arthroplasties were performed on thirteen patients who had Vitallium-mold arthroplasty of the hip. The ratings of these knees were: one excellent, three good, four fair, and seven poor. One patient had bilateral Moore arthroplasties for her hips and bilateral knee arthroplasties, which were both poor.

One knee arthroplasty was performed on the same extremity as the Vitallium-mold arthroplasty, and eight on the contralateral side. Two patients had bilateral knee arthroplasty and two had bilateral hip arthroplasties with one knee arthroplasty.

Fourteen of these seventeen knees had a significant diminution in pain. Of the three in which pain was not decreased, two had postoperative infections, and there was no explanation for the lack of improvement in the third patient. All fourteen patients were using crutches at the time of evaluation.

Age at the time of surgery did not appear to influence the results significantly in either group. For the patients with rheumatoid arthritis, the ratings of the thirty-four, less than fifty years old, were twelve excellent, four good, five fair, and thirteen poor, while the ratings of the sixty-five patients, fifty-one years old or more, were twenty-four excellent, sixteen good, eleven fair, and fourteen poor. For the patients with osteoarthritis, the ratings of the six, less than sixty years old, were two excellent, three good, and one poor, while the ratings of thirteen patients, sixty-one years old or more, were twelve excellent and one fair.

### Complications

Manipulation under anesthesia after arthroplasty was performed on forty-one (36 per cent) of the 118 knees and was considered a second stage of the procedure rather than treatment of a complication. Two manipulations performed more than three weeks following arthroplasty resulted in supracondylar fractures necessitating prolonged immobilization. Both of these knees had a poor result. Otherwise the knees which were manipulated had the same over-all ratings as those which were not.

Four wounds became infected with *Staphylococcus aureus*. Two of these were treated by débridement, drainage, and antibiotics without removal of the implants. Both of these knees showed no evidence, clinical or roentgenographic, of recurrent infection but both were in the poor category at follow-up, one and three years, respectively, after arthroplasty.

The two other wound infections were treated by removal of the prosthesis and arthrodesis of the knee. One of these infections followed a secondary procedure necessitated by a tibial plateau fracture in a patient with a McKeever prosthesis. This patient fell from her bed two weeks after arthroplasty and surgical elevation of the plateau using an autogenous bone graft was followed by a wound infection. After removal of the prosthesis and débridement the wound healed and arthrodesis of the knee occurred.

The other knee treated by removal of the prosthesis and arthrodesis was operated on early in the series. A MacIntosh prosthesis thick enough to correct the valgus deformity was not available and an iliac graft was inserted beneath the implant. A postoperative infection developed followed by resorption of the graft and dislocation of the prosthesis. After removal of the implant the wound healed and the patient was left with a fibrous ankylosis and a poor result.

In recent years we have routinely administered a single dose of parenteral antibiotics (streptomycin one gram and oxacillin one gram) immediately prior to surgery, unless the patient is allergic to these medications. A bacitracin solution (twenty-five units per milliliter) is used to irrigate the wound prior to closure. Only one of the four patients with infections had received preoperative antibiotics.

Four arthroplasties, which were performed before prostheses of different heights were available, had to be revised to correct residual varus or valgus deformities. One

of these patients was lost to follow-up; the other three had one fair and two poor results.

Three patients had re-explorations of their knees for lysis of adhesions after closed manipulations had failed to increase knee motion. Their results were one excellent, one good, and one poor.

One patient had a transient peroneal palsy first noted one week postoperatively and presumably caused by pressure from the plaster cast. Peroneal function returned spontaneously and the patient had a good result when last seen one year after arthroplasty.

There was one postoperative death. This patient had been on large doses of steroid prior to arthroplasty and death was attributed to adrenal insufficiency and gram negative septicemia. No organisms were cultured from the knee.

### Discussion

Comparison of our results with those from other centers is difficult. In many studies the criteria used for evaluation are not well defined and in very few are the results in rheumatoid and osteoarthritic knees separated. In those studies in which arthroplasties on rheumatoid knees were analyzed separately it was generally found that the results in the rheumatoid knees were less satisfactory. The results in some of the recent studies warrant consideration. In 1960 Shiers<sup>30,32</sup> reviewed the world literature pertaining to knee arthroplasty and found an over-all incidence of 42.7 per cent good results in the 831 cases collected. At that time he reported his own results after twenty-eight arthroplasties, in which a joint replacement prosthesis of his own design was used. He found good to excellent results in 42 per cent of the twenty-eight knees. In 1963 Young reported on eight cases of his own and on eleven supplied by other surgeons in which the Young prosthesis had been used. In these nineteen knees, the ratings were 42 per cent good and 37 per cent poor. Eleven of these nineteen patients had rheumatoid arthritis, and only three of these eleven received a good rating. In 1960 Walldius reported his results in sixty-four knees treated with his total joint replacement. The results in 74 per cent of these knees were classified as good to very good with a maximum follow-up of eight years. Wilson in 1968 presented his preliminary findings in eleven patients treated with the Walldius prosthesis and found that seven had a satisfactory arthroplasty after a maximum follow-up of twenty-one months. When Young discussed Wilson's paper he noted that prolonged observation after joint replacement prosthesis revealed many complications due to mechanical failure, loosening of the prosthesis, or local tissue reaction.

In 1967 Jones reported the over-all results from the Massachusetts General Hospital where a Vitallium mold replacement for the femoral condyles had been used. Seventy-five per cent of the sixty-five patients evaluated had rheumatoid arthritis. The over-all results were 51 per cent good to very good and 30 per cent poor. In McKeever's posthumous report of results in forty patients, there was only one unsatisfactory result in a knee which had had a recurrence of an old infection. One other patient had moderate pain, but all others were walking without support and had at least 90 degrees of flexion. Murray found good to excellent results in sixteen of twenty rheumatoid knees (80 per cent) treated by tibial plateau replacement with the MacIntosh prosthesis, but the maximum follow-up in his series was three years.

In our series of ninety-six rheumatoid knees, the results (56 per cent good to excellent ratings) are only slightly better than the previously reported average results, and are not nearly as good as the results in some of the smaller series. Results in our osteoarthritic patients, on the other hand, compare quite favorably with those in previous studies. If our two groups are combined, the over-all results were good to excellent in 62 per cent.

Since the McKeever prosthesis has become available in different heights, we have seldom used the MacIntosh because we prefer the greater stability provided by the T-shaped fin. The MacIntosh prosthesis has been used when an extremely tight joint space has made it technically difficult to insert the McKeever prosthesis. For this reason all sizes of both implants should be available to the surgeon when arthroplasty is contemplated. It is advisable to insert prostheses in both the medial and the lateral compartment in rheumatoid knees.

Patelloplasty, done in twenty-one patients with severe changes in the patella (loss of cartilage and spur formation), did not have a deleterious effect on the results since the ratings in these knees were essentially the same as those in the entire group. Patelloplasty would therefore seem to be indicated whenever there is gross irregularity of the patellofemoral articulation.

Involvement of other joints in the rheumatoid group undoubtedly lowered the result ratings in some patients who used support because of the involvement of other joints and hence received demerits in the rating of their knee.

It is noteworthy that synovectomy and débridement preceded arthroplasty in ten rheumatoid patients and in two patients with osteoarthritis. In each of these, progressive joint destruction and pain necessitated arthroplasty. This finding should not be construed as a condemnation of synovectomy but it suggests that the stage of the disease at which synovectomy should be performed needs further study.

Prior surgery, including synovectomy and débridement, nylon arthroplasty, arthrotomy with or without meniscectomy, posterior capsulotomy, and supracondylar osteotomy did not appear to influence the results in this series. However, there were too few cases to permit definite conclusions.

Secondary surgical procedures were performed following knee arthroplasty in twenty-one of the knees evaluated. Twelve of these were necessitated by complications and were discussed in that section. The remaining nine included: posterior capsulotomies in five rheumatoid and one osteoarthritic knee, two supracondylar osteotomies in one rheumatoid and one osteoarthritic knee, and one arthrodesis in a rheumatoid knee with residual pain, limited motion, and marked flexion deformity.

Posterior capsulotomy or supracondylar osteotomy is likely to be required when the preoperative flexion deformity is more than 30 degrees despite non-operative measures to correct it. In this series surgical correction of flexion contractures was carried out both before and after arthroplasty. Flexion contractures are frequently improved as a result of knee arthroplasty after maximum correction has been obtained by conservative measures preoperatively. If the flexion contracture is greater than 45 degrees, however, it should be corrected surgically prior to arthroplasty. When there is a flexion contracture of 30 degrees or more following knee arthroplasty, a secondary surgical procedure will be required to correct the deformity. The secondary procedure should not be performed until the patient has regained good mobility and active control of his knee.

Arthrodesis of the contralateral knee did not seem to compromise the early or long-term result after arthroplasty. However, since the patients with bilateral arthroplasty in general did quite well, arthrodesis of one knee would not seem to be indicated if both knees are favorable for arthroplasty.

Hip disease had a definite deleterious effect on the results of knee arthroplasty as evaluated by our rating system. However, despite these less satisfactory results the diminution of knee pain after arthroplasty was sufficient to justify arthroplasty.

### Summary

The literature related to arthroplasty of the knee is reviewed and the surgical technique and postoperative management for knee arthroplasty using the McKeever

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and MacIntosh prostheses are described. The results after follow-ups ranging from one to nine years in eighty-two patients with rheumatoid arthritis and seventeen patients with osteoarthritis are presented using a method of evaluation based on demerits assigned for pain, limitation of motion, deformity, instability, quadriceps weakness, and need for support.

Using the described method of evaluation, fifty-six of the ninety-nine rheumatoid knees and seventeen of the nineteen osteoarthritic knees which could be evaluated, had good or excellent results. From these findings it is concluded that knee arthroplasty of the type described when performed in properly selected patients is an effective method to relieve pain and restore function.

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## Unicompartmental and Bicompartamental Arthroplasty of the Knee with a Finned Metal Tibial-Plateau Implant\*

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**ABSTRACT:** We followed a series of ten patients (ten knees) who had a unicompartmental and twenty patients (twenty-two knees) who had a bicompartamental arthroplasty of the knee, in which a finned metal tibial-plateau implant had been used, for two to fourteen years (average, five years) postoperatively. According to the modified criteria of MacIntosh and Hunter, thirty knees (94 per cent) had a good result and two (6 per cent), a fair result. There were two complications: one intraoperative and one postoperative fracture of the tibial plateau. One patient with rheumatoid arthritis required a revision to a total knee arthroplasty at six months because of rapid progression of disease in the contralateral, untreated compartment. Our results suggest that with the proper indications this arthroplasty has a place in reconstructive surgery of the arthritic knee joint.

Prior to the advent of total arthroplasty for treatment of the arthritic knee, the senior one of us (A. B. S.) had used either the MacIntosh or McKeever tibial-plateau hemiarthroplasty in 112 patients. As in other published series<sup>2-8</sup>, the results were often good, but it was his experience that these implants were occasionally unstable or difficult to place.

In 1969, the senior one of us designed and first used a finned metal tibial-plateau implant (Howmedica; Rutherford, New Jersey) for hemiarthroplasty of the knee<sup>10-12</sup>. A short, sagittally directed fin on the undersurface of the metal implant, designed to fit into a slot in the tibial plateau, was provided for stabilization. With the single sagittal fin, this

was found to be easier to insert than the McKeever implant, with its T-shaped stem, and to be more stable than the stemless MacIntosh implant. It was designed in various thicknesses so that angular deformities or ligament loosening and instability could be corrected by selecting the appropriate height of the tibial plateau. We have found this relatively simple and limited arthroplasty to be of value in the treatment of the arthritic knee, especially in certain patients with rheumatoid arthritis and osteoarthritis and in younger patients when the bone stock of the tibial plateau and the femoral condyles are adequate. The procedure is salvageable in that it can be revised to a total knee arthroplasty if necessary.

### Materials and Methods

Between 1969 and 1983, a finned tibial-plateau implant was used in fifty-three knees in forty-nine patients. This report, however, deals with only thirty-two knees in thirty patients who were followed for two to fourteen years (average, five years). A total of fifty-four implants were used, as twenty-two knees (twenty patients) had bicompartamental implants. The patients ranged in age from thirty-two to seventy-two years (average, fifty-five years). Twenty-four patients (twenty-six knees) had rheumatoid arthritis and six patients (six knees) had osteoarthritis. In all of the patients with osteoarthritis a unicompartmental replacement was used.

### Design of the Implant

The implant is made of cobalt-chromium alloy. The surface of the tibial plateau is slightly concave, and there is a fifteen-millimeter vertical fin on the inferior surface that is offset slightly toward the straight intercondylar side of the implant. The implant is available in four diameters (forty-three, forty-six, forty-nine, and fifty-two millimeters) and four thicknesses (four, six, nine, and twelve millime-

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ters) (Fig. 1). The surgical instrumentation includes four templates, representing the available diameters of the implants, and they have a slot through which the tibial plateau can be marked for cutting. A guide with a detachable handle is used to determine the required thickness of the implant.

**Surgical Considerations**

The goals for the use of the finned tibial-plateau implant are pain relief, an increase in the functional range of motion of the knee, improvement of stability, and correction of angular deformity. The advantages of the implant include: (1) replacement of one or both surfaces of the tibial plateau without sacrifice of adequate femoral condyles, (2) minimum removal of bone, so that the procedure may be salvaged later if necessary, (3) less operative time than a total

**Contraindications**

The contraindications to the arthroplasty are: (1) previous sepsis or ankylosis; (2) extensive joint destruction including cystic and erosive changes, particularly of the femur, and poor bone stock at either the tibial or the femoral surface and associated with patellofemoral arthritis (these are indications for a total knee-arthroplasty procedure); (3) neuropathic arthritis; (4) poor motivation of the patient; and (5) angular deformity that cannot be corrected by passive stress testing, for which an associated osteotomy or total knee procedure is indicated.

**Surgical Technique**

The procedure is carried out under tourniquet control. The extremity is draped to expose the entire circumference

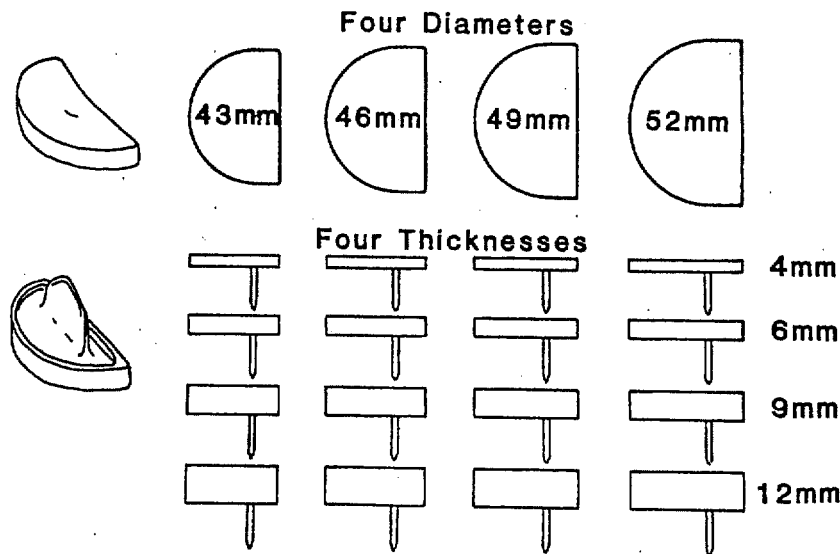


FIG. 1  
The finned metal tibial-plateau implant.

knee procedure and minimum blood loss, (4) the feasibility of use in the young adult, and (5) simple postoperative rehabilitation.

**Indications**

A unilateral or bilateral finned tibial-plateau arthroplasty can be indicated when the disability is due to rheumatoid arthritis, osteoarthritis, or post-traumatic arthritis, providing there is adequate bone stock without erosive or cystic changes in either the tibial or the femoral surface. When these conditions are met, it can be done: (1) after synovectomy in the rheumatoid arthritic knee when joint-space narrowing from degeneration of the tibial or femoral articular cartilage is present (a bicompartamental replacement is preferred, to preclude symptoms from the later development of degenerative change on the other side), and (2) in knees with unicompartamental osteoarthritis when there is loss or depression of the bone of the tibial articular surface, provided angular deformity can be corrected by passive stress testing.

of the distal part of the thigh, the knee, and the proximal part of the leg, so that the alignment of the lower limb can be visualized.

A fifteen to twenty-centimeter medial parapatellar skin incision is used for both the single and bilateral compartment replacements. The quadriceps muscle and patellar tendon are exposed. Starting proximally, a longitudinal incision is made on the medial aspect of the quadriceps tendon, extended into the suprapatellar pouch, and continued distally around the medial side of the patella and through the joint capsule of the knee to the tibial tubercle. The medial quadriceps mechanism is released so that lateral eversion of the patella can be obtained as the knee is flexed. The knee joint is then exposed and inspected. A subperiosteal dissection is carried to the level of the collateral ligaments. Any necessary débridement of the joint and condyles is then done, including trimming and smoothing of the patella, excision of osteophytes from the femur and tibia, and thorough synovectomy. Both tibial plateaus are evaluated. The meniscus, if present, is excised from either one or both compart-

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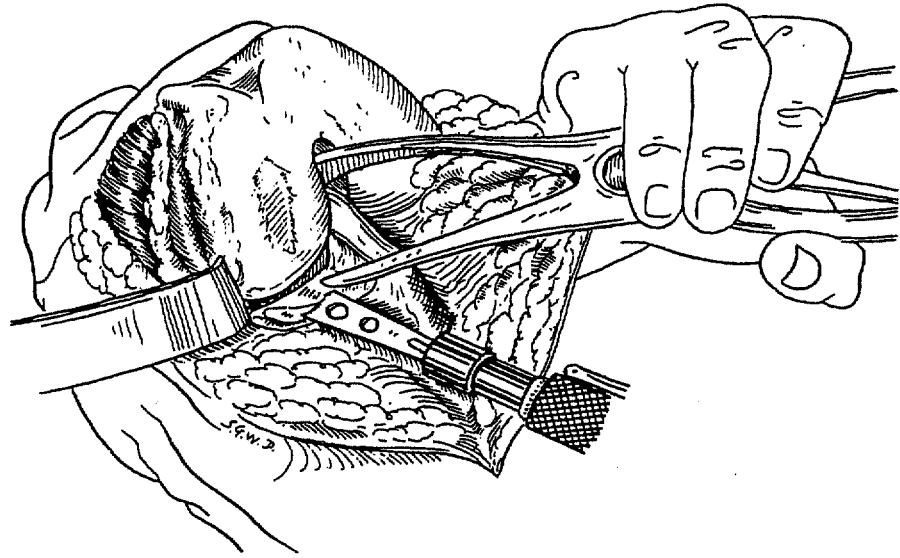


FIG. 2-A

Figs. 2-A through 2-E: The surgical technique.

Fig. 2-A: The surface of the tibial plateau is leveled, removing as little bone as possible. A laminar spreader can be used to improve the exposure.

ments, as indicated, and the stability and alignment of the joint are assessed. One or both tibial compartments, as indicated, are prepared to receive the implant. In patients with rheumatoid arthritis a bicompartamental reconstruction is recommended, with the lateral plateau being prepared first.

The first cut in bone is made vertically and parallel to the intercondylar eminence, which is carefully preserved. The second cut is made parallel to the tibial plateau, trimming osseous irregularities and removing as little cortical bone as possible along a plane at a right angle to the long axis of the tibia (Fig. 2-A). With the knee extended and the

wound edges retracted, one can determine how much joint space is necessary to obtain proper alignment of the knee by laterally stressing the knee into either a valgus or a varus position to visualize the joint space of the medial or lateral compartment. The optimum diameter and thickness of the implant are determined by using the diameter and thickness-sizing templates. The knee should be aligned in 3 to 5 degrees of valgus angulation, and this may require additional preparation of the joint space. Through the slot of the template, a third cut is marked on the surface of the tibial plateau, parallel to the intercondylar cut. This sagittally

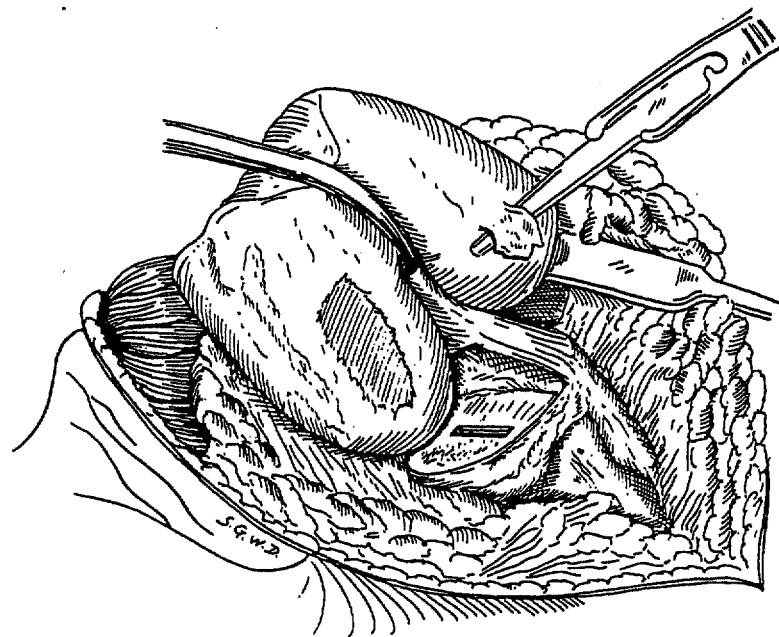


FIG. 2-B

The surface of the tibial plateau, in which a slot has been prepared to receive the fin of the implant. Synovectomy and joint débridement are done as necessary.

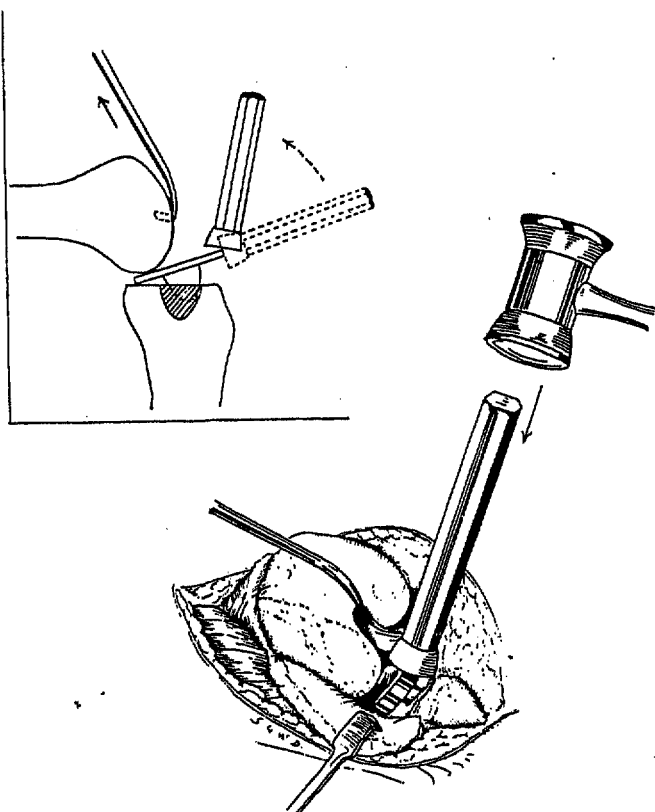


FIG. 2-C

Placement of the implant is facilitated by pulling the tibia anteriorly and lifting the femur vertically with a bone-hook inserted in the intercondylar notch while the knee is flexed. A fine-pointed impactor is used to start placement of the fin, and a blunt polyethylene-tipped impactor is used to complete placement of the implant.

oriented slot is fashioned with a side-cutting burr to receive the fin of the implant and it should be directed more toward the posterior aspect of the cortex to avoid fracturing the anterior aspect of the cortex (Fig. 2-B). With the knee

flexed, the tibia is pulled anteriorly by an assistant and the femur is lifted vertically with a bone-hook inserted in the intercondylar notch. The implant is then inserted with its fin resting in the sagittal slot and its edges on the cortical bone of the plateau. The diameter of the implant should be sufficient to cover the articular surface of the tibial compartment and its thickness should provide proper height of the tibial plateau to provide stability and correction of deformity. A fine-pointed impactor is applied to the fin to start the placement of the fin correctly, and a blunt polyethylene-tipped impactor is used to complete the placement of the implant (Fig. 2-C).

The passive range of motion of the joint, the stability of the implant, and the tracking of the femoral condyle on the implant are tested with the knee in both extension and flexion. If the implant is congruous without pistoning or tilting on movement and the joint is stable, the insertion is satisfactory (Figs. 2-D and 2-E). The wound is then thoroughly irrigated with normal saline solution and a triple antibiotic solution (bacitracin, 100,000 units; polymyxin B, 2.5 million units; and neomycin, one gram in 250 milliliters of normal saline solution) and is closed in layers. Suction drainage is routinely used. Blood transfusions are rarely needed.

Prophylactic intravenous antibiotics, preferably of the cephalosporin family, have been used routinely, administered one day preoperatively, intraoperatively, and one day postoperatively.

The bulky dressing is removed three days after the operation. The postoperative management includes early active and passive movements, which are usually started on the third postoperative day. The goal is to gain 90 degrees of flexion before the patient is discharged from the hospital. Very rarely, a postoperative manipulation under anesthesia is required to gain flexion. A muscle-strengthening program,

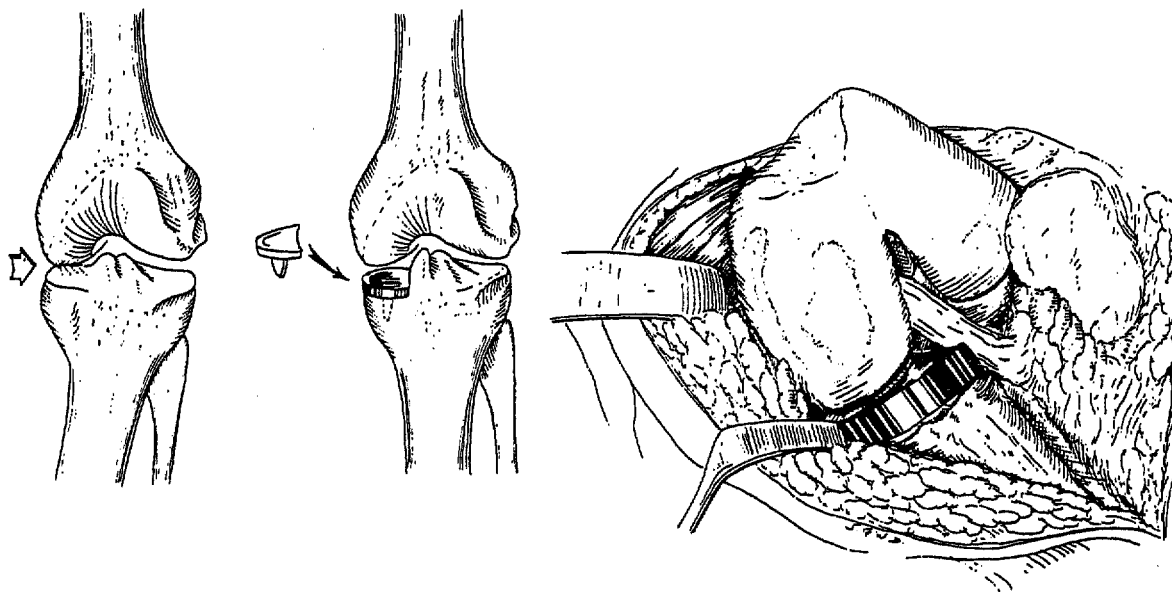


FIG. 2-D

Proper selection of the thickness of the implant will allow correction of alignment with minimum bone resection. A satisfactory insertion allows smooth flexion and extension without pistoning or tilting of the implant.

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emphasizing development of the quadriceps, and gait-training with aids such as crutches, a walker, or a cane, are used. The patients are allowed partial weight-bearing on the involved extremity as soon as tolerated, and they progress to full weight-bearing as tolerated over a period of four to six weeks postoperatively. Bracing of the knee in extension is used at night for six to eight weeks, especially for patients who had a knee-flexion contracture. As soon as the patient can walk without a limp, usually after two to three months, the assistive devices are discarded. Muscle-strengthening programs are continued until the knee has adequate flexion and extension power and its full range of motion. Similar postoperative management is used for both the unicompartmental and bicompartmental tibial-plateau replacements. As would be expected, the recovery period is slightly longer for the patients with bicompartmental tibial-plateau replacement.

A tibial wedge osteotomy had been done prior to this procedure to correct an angular deformity in two patients. In four patients, an osteotomy was done concomitantly with the tibial plateau arthroplasty. The postoperative therapy was compromised in those four patients because of the need for plaster-cast immobilization of the osteotomy site. Angular deformity in a rheumatoid knee that is not correctable by passive stress testing is an indication for total joint replacement.

The clinical factors of pain, motion, stability, angular deformity, and gait were recorded on a specially designed form preoperatively, six months postoperatively, and an-

TABLE I  
MODIFICATION OF THE SYSTEM OF MACINTOSH AND HUNTER<sup>5</sup> FOR  
EVALUATION OF THE RESULTS OF THE ARTHROPLASTY

Result	No. of Criteria Met*
Good	4
Fair	3
Poor	<3, or later revision required

\* The four criteria are: (1) no pain with activity or pain with only heavy activity, (2) extension to -15 degrees or less and flexion to 75 degrees or more, (3) no subjective or objective instability of the knee, and (4) 3 to 5 degrees of valgus alignment.

nally thereafter. At each visit standing anteroposterior and non-weight-bearing lateral radiographs of the knee were made. The results were classified as good, fair, and poor according to a modification of the method of MacIntosh and Hunter<sup>5</sup> (Table I).

### Results

#### Pain (Table II)

Pain was rated on a scale of five classes. Preoperatively, all patients had Class-III pain or greater. Postoperatively, twenty-eight knees (87.5 per cent) were not painful with activity; three knees were painful with heavy activity only (one was rheumatoid, with bicompartmental replacement, and two were osteoarthritic, with unicompartmental

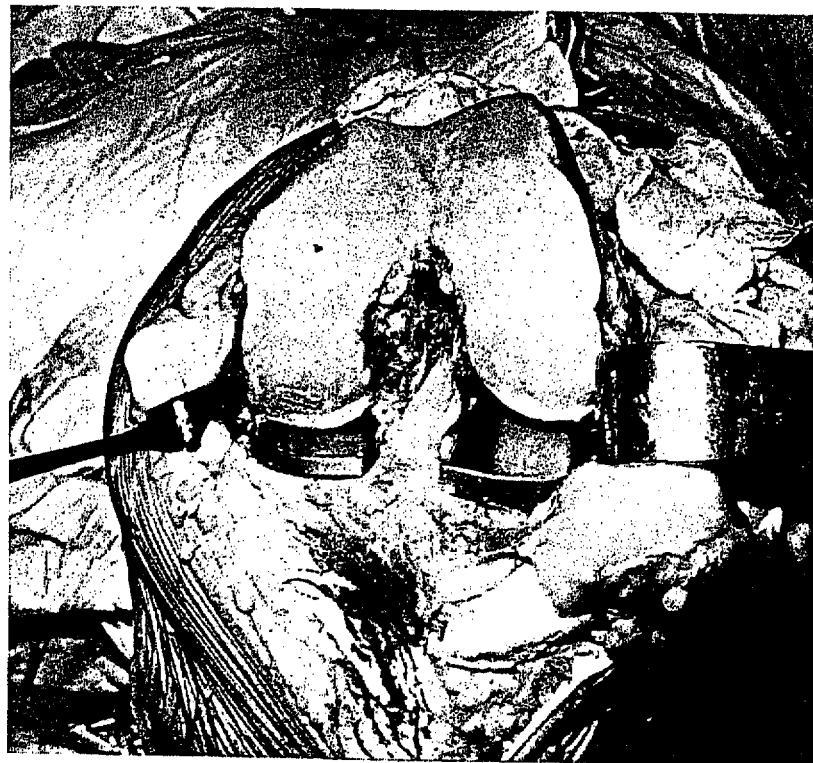


FIG. 2-E

The stability of the implant is tested in both extension and flexion of the joint and by evaluating the tracking of the femoral condyles on the implant. If the joint is stable, without pistoning or tilting of the implant on movement, the insertion is satisfactory.

TABLE II  
PREOPERATIVE AND POSTOPERATIVE PAIN RATINGS  
IN THE THIRTY-TWO KNEES

Class	Pain	No. of Knees	
		Preop.	Postop.
I	None with activity	0	28
II	With heavy activity only	0	3
III	With moderate activity	11	1
IV	With minimum activity	20	0
V	At rest	1	0

replacement); and one knee was painful with moderate activity (a rheumatoid knee, with bicompartamental replacement).

#### Range of Motion (Table III)

The range of motion (flexion and extension) was classified as good, fair, or poor. The average preoperative arc of motion was 91 degrees (-13 degrees of extension to 104 degrees of flexion). The average postoperative arc of motion was 95 degrees (-5 degrees of extension to 100 degrees of flexion).

#### Clinical Angulation Deformity

Good alignment of the knee was considered to be the normal anatomical range of 3 to 5 degrees of valgus angulation. An angulation deformity was present preopera-

tively in seventeen knees (53 per cent) and postoperatively in none. Preoperatively a valgus deformity ranging from 7 to 17 degrees (average, 12 degrees) was present in fifteen knees, twelve of which had rheumatoid arthritis and three, osteoarthritis. A tibial wedge osteotomy was carried out concomitantly with the arthroplasty in the three osteoarthritic knees and in one rheumatoid knee in which the valgus angle exceeded 15 degrees. A varus deformity of 10 degrees was present preoperatively in two osteoarthritic knees, both of which had a tibial wedge osteotomy prior to the unicompartmental arthroplasty. All of the tibial wedge osteotomies resulted in anatomical alignment postoperatively.

TABLE III  
PREOPERATIVE AND POSTOPERATIVE RANGE OF MOTION  
IN THE THIRTY-TWO KNEES

	No. of Knees	
	Preop.	Postop.
Extension		
Good (0 to -10 degrees)	17	29
Fair (-11 to -15 degrees)	3	2
Poor (> -15 degrees)	12	1
Flexion		
Good (>90 degrees)	30	25
Fair (75 to 89 degrees)	2	6
Poor (<75 degrees)	0	1
Average flexion/ extension (degrees)	-13/104	-5/100

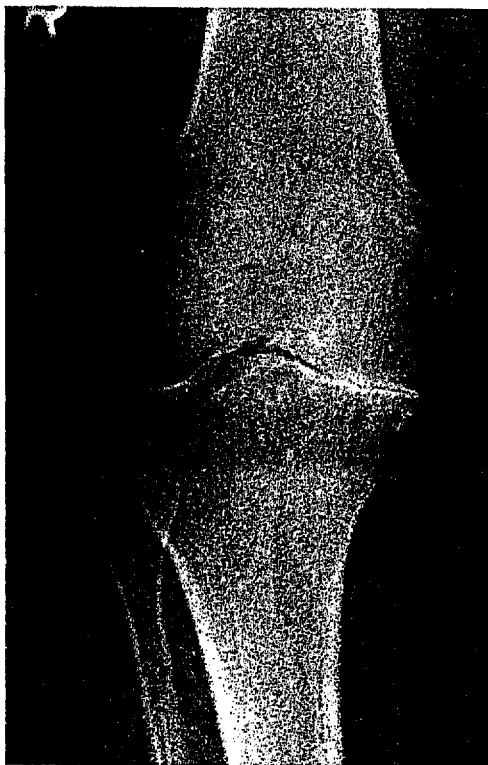


FIG. 3-A



FIG. 3-B

Fig. 3-A: Preoperative standing anteroposterior radiograph of an eighty-two-year-old woman with degenerative changes in the medial compartment, an 8-degree varus deformity, and Class-IV pain.

Fig. 3-B: Radiograph made two years postoperatively, showing tolerance of the underlying bone to the implant and no signs of loosening. The patient had no pain and the range of motion was from -5 degrees of extension to 100 degrees of flexion.

### Stability

Instability of the knee was tested medially, laterally, and anteroposteriorly. It was present in twenty-two (69 per cent) of the knees preoperatively but in none postoperatively.

### Gait

The patients were considered to have an independent gait if they did not require, in order to walk, aids such as a cane, crutches, or a walker because of the surgically treated knee. Our analysis did not include the use of assistive

lateral radiographs of two knees.

### Complications and Revision

No patient had an infection or wound breakdown. A non-displaced fracture of the tibial plateau occurred intraoperatively in one knee during insertion of the implant. This was treated with a bone staple and the patient had a good result. Because of this complication, the design of the implant was changed by shortening the fin and placing it closer to the medial edge of the implant, which is next to the intercondylar eminence. No further problems have occurred

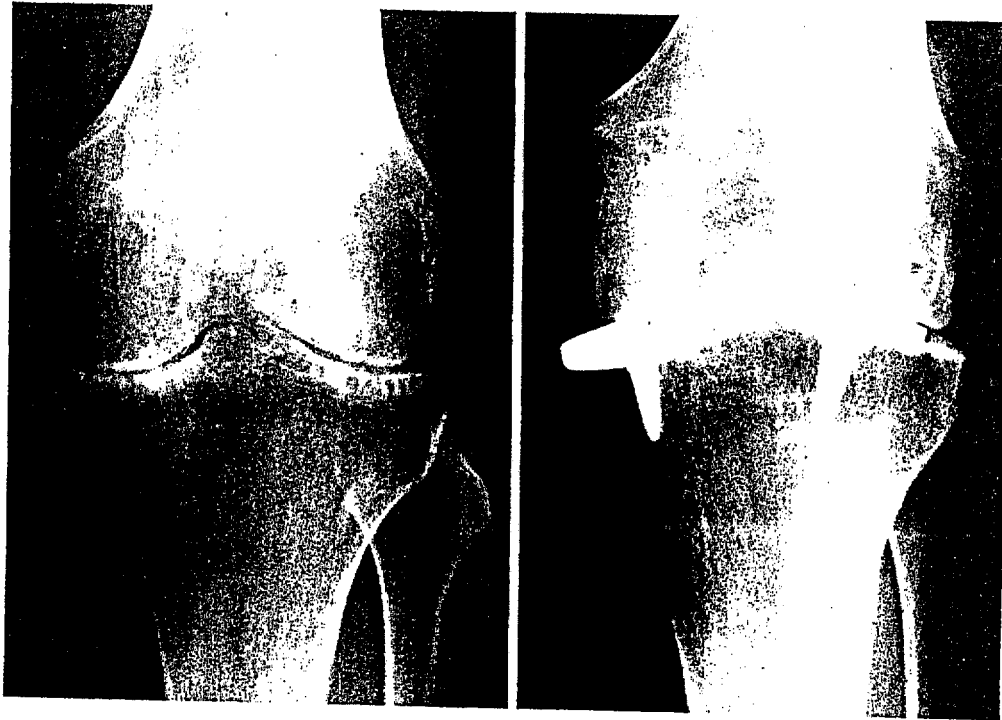


FIG. 4-A

FIG. 4-B

Fig. 4-A: Preoperative standing anteroposterior radiograph of the knee of a thirty-three-year-old man with rheumatoid arthritis. The range of motion was from -20 degrees of extension to 100 degrees of flexion and the pain was Class IV.

Fig. 4-B: Radiograph made fourteen years postoperatively, showing a continued satisfactory position of the implant as well as bone formation around the implant and stems, without signs of resorption. The range of motion was from -15 degrees of extension to 105 degrees of flexion and the knee was pain-free.

devices for problems not involving the surgically treated knee. Preoperatively twenty-four patients had an independent gait, while postoperatively twenty-nine (97 per cent) had an independent gait.

### Radiographic Findings

None of the tibial plateau implants showed radiographic evidence of fracture or displacement, and no absorption of bone was seen beneath the implant (Figs. 3-A through 4-B). No patient had collapse of the tibial plateau on the surgically treated side of the knee. A favorable bone-remodeling process, as evidenced by production of bone beneath the implant and around its fin, was noted in all patients, and we think that it was due to favorable force-loading of the bone on weight-bearing across the implant. The arthroplasty is contraindicated in the presence of poor cortical-bone stock and erosive or cystic changes. Asymptomatic flattening of the femoral condyle was noted on the

since this modification of the design was implemented. In one knee, a fracture of the medial plateau beneath the implant occurred six weeks after operation, and a high tibial osteotomy was done three years later to correct an 8-degree varus deformity, with a subsequent good late result.

A total replacement was required six months postoperatively in one rheumatoid arthritic knee with a unilateral tibial-plateau arthroplasty because of rapid progression of the disease in the untreated compartment. Although that patient was not followed for long enough to be included in our long-term series, the case illustrates that rheumatoid arthritis in the knee is a bicompartamental disease, and we now reconstruct both compartments in such patients.

In the thirty-two patients who were followed for two years or more, the results were graded using a modification of the criteria of MacIntosh and Hunter<sup>5</sup> (Table I). Thirty knees (94 per cent) were graded as having a good result and two (6 per cent) had a fair result. Both of the knees with a

fair result were rheumatoid and had bicompartamental replacement, with one having poor motion and the other, Class-III pain. The patient who had a total knee replacement at six months because of rheumatoid arthritis had a poor early result.

### Discussion

We think that the finned tibial-plateau arthroplasty of the knee is a useful procedure in selected patients with osteoarthritis or rheumatoid arthritis, cartilage degeneration, and adequate cortical-bone stock. When angular deformity is correctable by passive stress testing, this procedure can provide resurfacing of the tibial plateau and correct its level and height. A later total revision is feasible, as the bone of the tibial plateau is preserved and no cement is used. The most probable causes of early failure are poor selection of

patients (see Contraindications) and technical failures such as inadequate sizing of the implant and poor postoperative therapy. Late failures are likely to be due to progression of disease in the untreated contralateral compartment, especially in patients with rheumatoid arthritis.

Our review of a long-term follow-up of patients with an arthroplasty employing a tibial plateau implant has led us to re-evaluate the worth of this method. We think that both arthroplasty with a finned tibial-plateau implant and total knee-replacement procedures have a place in the care of the arthritic knee joint. When a tibial plateau arthroplasty is done in a rheumatoid patient, both compartments of the knee should be reconstructed. If the proper indications and recommended techniques are followed, tibial plateau arthroplasty should find its proper place in the orthopaedic armamentarium.

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# EXHIBIT 13

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# McKeever Metallic Hemiarthroplasty of the Knee in Unicompartamental Degenerative Arthritis

LONG-TERM CLINICAL FOLLOW-UP AND CURRENT INDICATIONS

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**ABSTRACT:** Forty patients with forty-four unicompartamental McKeever metallic uncemented hemiarthroplasties were followed for five to thirteen years (average, eight years). Thirty-nine knees had a medial and five, a lateral arthroplasty. The age at surgery ranged from thirty-two to eighty-two years (average, sixty-seven years). At the final follow-up, 70 per cent of the knees were rated as good or excellent. Seventy-nine per cent of the knees in patients who were less than sixty-five years old at the time of surgery were in these categories. Six knees (14 per cent) had required revision to either a unicompartamental or a bicompartamental total knee replacement. The average preoperative and postoperative knee flexion did not change, but knees with initially poor motion improved. The average preoperative flexion contracture of 10 degrees improved postoperatively to 5 degrees. Complications were rare and no cases of infection, peroneal palsy, or clinically detectable phlebitis occurred. Obesity did not seem to adversely affect the outcome. This study indicated that the McKeever unicompartamental metallic hemiarthroplasty can provide an attractive alternative in the treatment of unicompartamental degenerative arthritis when proximal tibial osteotomy is contraindicated or has failed or when the patient is too young, heavy, or active to consider total knee replacement.

The surgical options that currently are available for the treatment of advanced unicompartamental osteoarthritis of the knee include tibial osteotomy, metallic hemiarthroplasty, and metal-to-plastic unicompartamental, bicompartamental, or tricompartmental knee replacement. If tibial osteotomy is contraindicated or has failed, most surgeons do not consider metallic hemiarthroplasty but proceed directly to metal-to-plastic knee replacement.

In the late 1950's, McKeever introduced a metallic hemiarthroplasty to resurface the tibial plateau. He reported good initial results in thirty-nine of forty knees. MacIntosh designed a similar interpositional hemiarthroplasty and reported good initial results in seventy-two of 103 knees with

a minimum six-month follow-up<sup>5,6</sup>. Potter et al. followed nineteen osteoarthritic knees that had either a McKeever or a MacIntosh prosthesis for an average of three years (range, one to nine years) and noted good to excellent results in seventeen. Despite these early encouraging reports, metallic hemiarthroplasty never became popular, possibly because of the advent of metal-to-plastic cemented total knee replacement. However, as the rate of loosening of cemented prosthetic components increases with both time and higher stresses across the bone-cement interface, younger, heavier, and more active patients risk a higher failure rate than do older, lighter, and less active patients. Bone stock is compromised by the insertion of the total knee components and by the effects of loosening, which makes revision surgery difficult. The revised knee arthroplasty is then in turn subjected to the same risks of failure as the initial knee arthroplasty. "Bridges have been burned", and the opportunity to take advantage of subsequent technological advances with the second operation may have been compromised.

For this reason, we believe that metallic hemiarthroplasty should still be considered in a select group of patients before proceeding to total knee replacement. The purpose of this report is to review our long-term results with McKeever arthroplasty in unicompartamental degenerative arthritis and to suggest which patients may be candidates.

## Materials and Methods

At the Robert Breck Brigham Hospital (now Brigham and Women's Hospital), unicompartamental McKeever arthroplasty was performed on fifty-one patients (fifty-five knees) with degenerative arthritis between January 1968 and January 1976 by one of six staff surgeons. Eleven patients were lost to follow-up before the five-year examination could be performed. Two had died within two years after surgery, one had insufficient data to be included in the study, and eight were lost to follow-up within the first three years. This left forty patients (forty-four knees) who had been followed for five to thirteen years (average, eight years). Thirty-nine knees had had a medial and five, a lateral arthroplasty. Thirty-two of the knees were in thirty women and twelve, in ten men. The age at the time of surgery ranged from thirty-two to eighty-two years (average, sixty-seven years). Prior operative procedures had been performed on the ipsilateral knee in four patients, and consisted of

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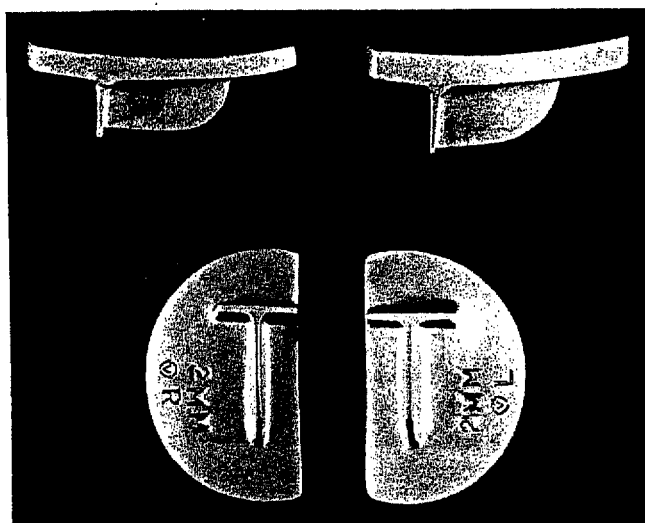


FIG. 1

The McKeever metallic prostheses. They are available in thicknesses ranging from two to fifteen millimeters.

three medial meniscectomies and one proximal tibial osteotomy. In two knees there had been a prior fracture of the tibial plateau. In nine knees the meniscus in the contralateral compartment was found at surgery to be torn and was removed. Eleven patients subsequently had had surgery on the contralateral knee. Four of them had had a contralateral unicompartmental McKeever arthroplasty; four, a unicompartmental metal-to-plastic knee replacement; two, a bicompartamental total knee replacement; and one, a proximal tibial osteotomy.

McKeever Vitallium prostheses were used in this series. Their shape roughly simulates that of a tibial plateau, with a slightly concave and a highly polished superior surface (Fig. 1). The inferior surface has a T-shaped fin that is inserted into a corresponding T-shaped slot made in the tibial plateau for fixation. The transverse limb of the T is anterior, for ease of insertion. The prostheses are designed as right and left mirror-images. A right prosthesis resurfaces either the right lateral or the left medial tibial plateau and a left prosthesis resurfaces either the left lateral or the right medial plateau. Varying thicknesses of the prostheses are available, ranging from two to fifteen millimeters. Three and four-millimeter prostheses were used in twenty-seven (61 per cent) of the knees in this series.

#### Operative Technique

We prefer a slightly median vertical parapatellar incision to expose the joint, such as is used for unicompartmental total joint replacement<sup>10</sup>. The details of the surgical approach and the technique for insertion of the prosthesis have been previously described<sup>8</sup>. An oscillating saw or burr is used to remove any irregularity on the opposing femoral condyle and to shape the tibial plateau so as to achieve maximum surface contact with the tibial prosthesis. It is not necessary to remove all remnants of articular cartilage, but only what is needed to properly shape the tibial plateau. Intercondylar osteophytes should be removed to relieve any

impingement with the tibial spine. All peripheral osteophytes that press against the collateral ligaments and capsule on the concave side of the knee deformity should be removed to assist passive correction of the deformity<sup>10</sup>. The correct thickness of the prosthesis is that which fills the joint space in the arthritic compartment but which is not so tight that it causes subluxation of the tibia on the femur or excessive pressure on the contralateral compartment. As a rule, the correct prosthesis in the medial compartment should allow the medial joint space to be opened approximately one millimeter when a valgus stress is applied with the knee in full extension. The knee must also be tested in flexion, as ex-

TABLE I\*  
KNEE ARTHROPLASTY EVALUATION

	Demerit Points
<b>Pain</b>	
None; no limitation of activity	0
Occasionally with prolonged walking; no limitation of usual activity	1
After walking short distances; some limitation of usual activity	3
Sufficient to require narcotics for relief; marked limitation of activity	6
At rest; patient incapacitated	7
<b>Knee motion</b>	
80 degrees or more	0
60 to 80 degrees	1
30 to 60 degrees	3
Less than 30 degrees	6
<b>Flexion contracture</b>	
None to 5 degrees	0
5 to 15 degrees	1
15 to 30 degrees	2
30 to 45 degrees	4
More than 45 degrees	6
<b>Varus or valgus deformity</b>	
Less than 10 degrees	0
10 to 20 degrees	2
20 to 30 degrees	3
More than 30 degrees	4
<b>Medial-lateral instability</b>	
Less than 10 degrees	0
10 to 20 degrees	2
More than 20 degrees	4
<b>Quadriceps power</b>	
Normal to good	0
Good minus to fair plus	1
Fair	2
Poor	4
No motion	6
<b>Support</b>	
None	0
Occasionally uses cane	1
Uses cane all the time	2
Uses crutches	4
<b>Final rating</b>	
Excellent	0 to 2
Good	3 to 6
Fair	7 to 10
Poor	11+

\* Reproduced from Potter, T. A.; Weinfeld, M. S.; and Thomas, W. H.: Arthroplasty of the Knee in Rheumatoid Arthritis and Osteoarthritis. A Follow-up Study after Implantation of the McKeever and MacIntosh Prostheses. *J. Bone and Joint Surg.*, 54-A: 12, Jan. 1972.

cessive tightness will cause the prosthesis to lift up anteriorly as the femoral condyle rolls posteriorly on the prosthesis during flexion. If this does occur, it can usually be prevented by resecting a little more of the posterior femoral condyle or by contouring the bone of the tibial plateau so that it slopes downward posteriorly 10 or 15 degrees rather than sloping upward.

*Postoperative Regimen*

Postoperatively, the knee is immobilized in full extension with a knee-immobilizer. Quadriceps-setting exercises are initiated on the first postoperative day and active flexion in the side-lying position is begun on the second day. Active knee flexion over the side of the bed is begun after the patient has achieved 45 degrees of active side-lying flexion. Walking is begun on the third or fourth postoperative day using the knee-immobilizer and two crutches. Thirty to 50 per cent weight-bearing is allowed. The splint is discontinued after the patient is able to actively raise the leg with the knee fully extended. When sufficient active flexion has been gained, a stationary bicycle is used for fifteen minutes twice a day. If the patient fails to regain the flexion that was achieved at the end of the operative procedure within two weeks after surgery, manipulation under general anesthesia is performed. Seven (16 per cent) of the forty-four knees in this series required manipulation.

Two crutches are used for a minimum of six weeks. At that time, external support is decreased, as tolerated, to the use of one cane outdoors and no support indoors. By twelve weeks postoperatively, the continued use of any support depends on the patient's progress. Recovery after a McKeever arthroplasty can be expected to be longer than that after a cemented total knee arthroplasty. Some soreness in the resurfaced compartment usually persists for six to nine months, but gradually improves with time. This is often accompanied by an effusion. Support with a cane or crutch is continued as long as either pain or swelling is present.

**Results**

We examined all but three of the patients (four knees) who had retained the McKeever prosthesis at the time of the latest follow-up. For these three patients the last examination had been done within eighteen months by the operating surgeon, but they had moved away, and data on pain and functional status were obtained from these patients by telephone. Preoperative data and intermediate results were obtained from their records and confirmed by the patient.

The over-all results were classified as excellent, good, fair, or poor according to the demerit system used by Potter et al. (Table I). In essence, an excellent knee had no pain and normal function. A good knee had mild, trivial pain related to activities and little or no functional limitation. A fair knee had satisfactory pain relief but moderate functional limitation, and a poor knee had an unsatisfactory level of function.

The results at one year, three years, five years, and the

latest follow-up (five to thirteen years) are shown in Table II. At one year, thirty-eight (86 per cent) of the forty-four knees were in the good or excellent category, but this had gradually diminished to thirty-one (70 per cent) at the final follow-up evaluation. Three knees (7 per cent) had a poor result at the one-year evaluation, and this number gradually increased to seven knees (16 per cent) at the time of the final follow-up.

TABLE II  
 EVOLUTION OF RESULTS (IN PER CENT) AFTER  
 MCKEEVER ARTHROPLASTY IN FORTY-FOUR KNEES

Result	At 1 Yr.	At 3 Yrs.	At 5 Yrs.	At >5 to 13 Yrs.*
Excellent	7	7	7	7
Good	79	72	68	63
Fair	7	14	14	14
Poor	7	7	11	16
Revised	5	5	7	14

\* Average, eight years.

Six knees (14 per cent) required revision because of inadequate relief of pain. Three knees were revised to a unicompartmental total knee replacement and three, to a bicompartmental total knee replacement. All of them were graded as good or excellent when last seen. The revision was accomplished without difficulty, as the McKeever prosthesis did not compromise the bone stock of the tibial plateau. Two revisions were done within the first postoperative year and one each was done at four and a half, five, seven, and ten years.

*Pain relief:* All of the patients had had significant pain on weight-bearing before surgery. In patients who had had preoperative pain at night, this was relieved by the end of the first postoperative year and did not recur except in the patients who required revision. The three knees that had been rated as excellent and had had no pain at the one-year follow-up continued to be pain-free at the final follow-up. Eight of the thirty-five knees that were rated as good at one year had no pain regardless of activity. The remaining twenty-seven knees had some mild discomfort after strenuous activity, but no limitation of function.

*Range of motion:* Preoperative flexion of the knee averaged 110 degrees (range, 70 to 135 degrees). The flexion at final follow-up also averaged 110 degrees (range, 85 to 135 degrees). The average preoperative flexion contracture was 10 degrees (range, zero to 40 degrees), while the average flexion contracture at final follow-up was reduced to 5 degrees (range, zero to 20 degrees).

*Results in younger patients:* As we thought that the McKeever arthroplasty might have particular advantages in younger patients, we singled out, for special study, thirteen patients (fourteen knees) who were less than sixty-five years old at the time of surgery. The average age of these patients was fifty-four years (range, thirty-two to sixty-four years). Five years after surgery, thirteen of the fourteen knees were rated good or excellent. At five to twelve years of follow-

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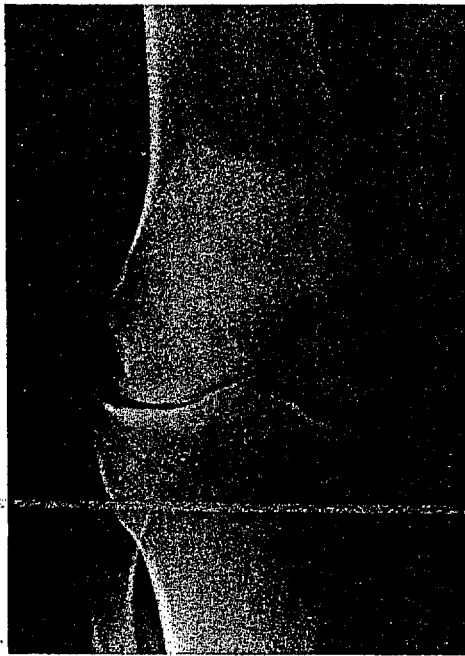


FIG. 2-A

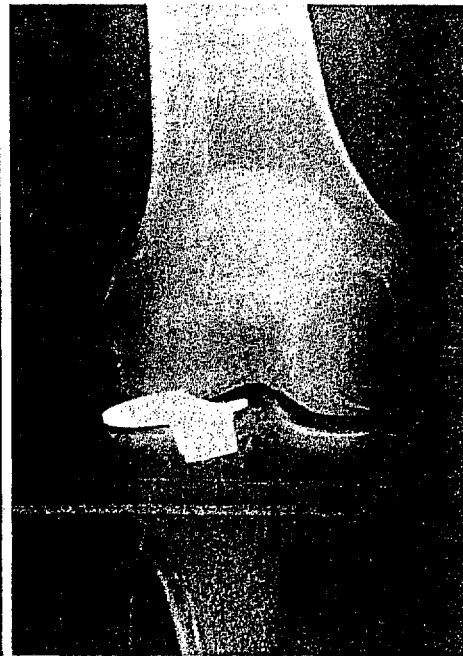


FIG. 2-B

Fig. 2-A: Preoperative radiograph of a knee with osteoarthritis involving the lateral compartment. The patient was fifty-eight years old and worked daily in the winter as a downhill-skiing instructor.

Fig. 2-B: Radiograph made three years after arthroplasty. Eburnated bone on the lateral condyle of the femur was drilled at the time of surgery. Minimum bone stock was sacrificed. The knee had a full range of motion, good stability, no effusion, and no pain. The patient returned to downhill skiing with no difficulty.

up (average, eight years) eleven knees (79 per cent) were still in the good or excellent category, one knee was rated fair, and two knees had been revised.

**Complications:** There were few perioperative complications and no infections. In one patient the surgical drain was retained, and repeat surgery was necessary to remove it. One patient had a large intra-articular hematoma that gradually resolved and did not compromise the result, and one patient had a superficial wound hematoma that drained spontaneously, with no effect on wound-healing. There were no clinically manifested cases of thrombophlebitis.

### Discussion

We are strong advocates of proximal tibial osteotomy as the procedure of choice in the younger, heavy, or active patient with medial unicompartmental degenerative arthritis. The McKeever interpositional arthroplasty, however, can provide an attractive surgical alternative in a knee with unicompartmental degenerative arthritis when proximal tibial osteotomy is contraindicated or has failed and the patient is too young, too heavy, or too active to consider total knee replacement.

In our opinion, the relative contraindications to osteotomy include active flexion of the knee of less than 90 degrees, a flexion contracture of more than 15 degrees, intercondylar osteophyte impingement as shown on a tunnel radiograph, the presence of pain at rest, a history of phlebothrombosis or venous stasis disease in that extremity, or signs of internal derangement (especially episodes of locking). Early degenerative changes in the contralateral joint compartment shown on a standing plain radiograph (per-

ipheral osteophytes, subchondral sclerosis, mild joint-space narrowing, or chondrocalcinosis) or a bone scan showing increased uptake in the opposite compartment are also contraindications.

It is more difficult to define what we mean by "too young, too heavy, or too active to consider total knee replacement", as so many factors must be considered for each individual patient. For example, we would not consider a twelve-year-old bedridden patient with juvenile rheumatoid arthritis who weighs forty kilograms to be too young for total knee replacement<sup>9</sup>, but we might think that a fifty-five-year-old laborer weighing 120 kilograms is too heavy and too active for the procedure.

The McKeever arthroplasty has some distinct advantages over tibial osteotomy, as a torn meniscal fragment and bone impingement can be removed at the time of surgery. After such débridement and the release of intra-articular adhesions, it is possible to gain both flexion and extension in patients who have significant preoperative limitation of motion. As we have not found postoperative immobilization to be necessary after a McKeever arthroplasty, the chance of venous thrombosis is diminished. Also, both knees can be operated on during the same hospitalization, significantly diminishing recovery time in a patient with bilateral involvement. The potential problem of delayed union or non-union of an osteotomy is avoided, and the incidence of peroneal palsy is less<sup>2,4,11</sup>.

In patients who already have early degenerative changes in the contralateral joint compartment of the same knee, the McKeever arthroplasty has an additional advantage over osteotomy. Slight overcorrection of the preoper-

active varus or valgus deformity, which is the goal of osteotomy, transfers extra weight-bearing forces to the contralateral compartment with early involvement. In the knee with preoperative varus alignment that has advanced medial-compartment disease but only early lateral-compartment disease, the correctly chosen width of McKeever prosthesis can adjust the postoperative alignment to neutral or only a few degrees of valgus angulation. This permits the resurfaced medial compartment to share substantial weight-bearing forces while protecting the opposite compartment from overload. It is permissible to allow the patient to engage in vigorous physical activity as tolerated. Finally, at an average of eight years of follow-up, the results in our patients were equal to or better than those that have been reported for osteotomy<sup>1,4,11</sup>.

A McKeever arthroplasty cannot be expected to produce an initial result that is comparable with that after cemented unicompartmental or bicompartamental total knee replacement. All of the patients in this series who had a cemented total knee replacement in the opposite knee or who eventually had a conversion to a total knee replacement preferred the total knee arthroplasty. However, the McKeever arthroplasty has several advantages over unicompartmental or bicompartamental total knee replacement in selected patients. As bone cement is not required, the po-

tential adverse effects on bone of late cement failure are eliminated. The minimum resection of bone stock results in little or no compromise of any later salvage procedure. The patients can resume vigorous physical activity as tolerated, allowing their potential return to a strenuous occupation or avocation (Figs. 2-A and 2-B).

Two categories of patients benefit from these advantages: the obese and the young. The obese patient is at greater risk of component loosening — the heavier the patient, the higher are the stresses that are generated across the bone-cement interface. However, obesity did not appear to adversely affect the outcome of the McKeever arthroplasty in our series and is, perhaps, a relative indication for the procedure. We have obtained good results with three years of follow-up in patients who were as heavy as 170 kilograms.

Youth is a relative contraindication to any prosthetic joint replacement. The McKeever arthroplasty, however, can be used to maintain a good functional knee during the years prior to a probably inevitable total knee replacement. Bone stock is preserved, and the delay will enable the patient to have the advantage of the latest joint-replacement technology.

NOTE: The authors would like to thank Dr. C. B. Sledge, Dr. M. S. Weinfeld, and Dr. R. Poss for their contribution to this study.

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# EXHIBIT 14

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# The Use of the McKeever Metallic Hemiarthroplasty for Unicompartamental Arthritis\*

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**ABSTRACT:** We reviewed the results of sixty-one McKeever unicompartamental arthroplasties performed by the senior one of us (T. P.) for osteoarthritis of the knee. The average follow-up was five years (range, two to thirteen years). Forty-four (72 per cent) of the arthroplasties were rated as good to excellent. The average postoperative range of motion in these knees was 110 degrees. Six knees were rated as fair and eleven knees, as poor. The poor results appeared to be caused by degenerative arthritis involving ipsilateral compartments that had not been resurfaced with an implant.

Osteoarthritis of the knee joint is not infrequently confined to one compartment, usually the medial one, with the lateral compartment being relatively free of disease<sup>7,10,13</sup>. The best treatment for this problem is controversial, and various methods have been proposed, including both tibial and femoral osteotomy<sup>1-3,7,8,10,15</sup>, unicompartamental cemented prosthetic replacement<sup>4,12</sup>, and total joint replacement<sup>9,15</sup>.

osteoarthritis with varus deformity have appeared to be generally satisfactory to date<sup>1-3,7,8,10</sup>. The reported results of tibial osteotomy for lateral compartment disease and valgus deformity have not been as satisfactory, however, and Shoji and Insall have stated that high tibial osteotomy is contraindicated in this situation. The alternatives that they have suggested are a supracondylar femoral osteotomy in the younger patient and a total knee replacement in the older patient. However, it has been reported that motion of the knee is frequently restricted following femoral osteotomy for arthritis<sup>6</sup>. Articular replacement of both joint compartments for unicompartamental arthritis seems excessive, and the results with cemented unicompartamental total joint replacements have been inconsistent<sup>4,5,9,12</sup>.

A series of exclusively unicompartamental uncemented tibial-plateau arthroplasties for osteoarthritis has not been previously reported. Prior reports have combined unicompartamental and bicompartamental implants in both rheumatoid and osteoarthritic patients<sup>11,14</sup>. The senior one of us (T. P.), however, has used the McKeever prosthesis as a

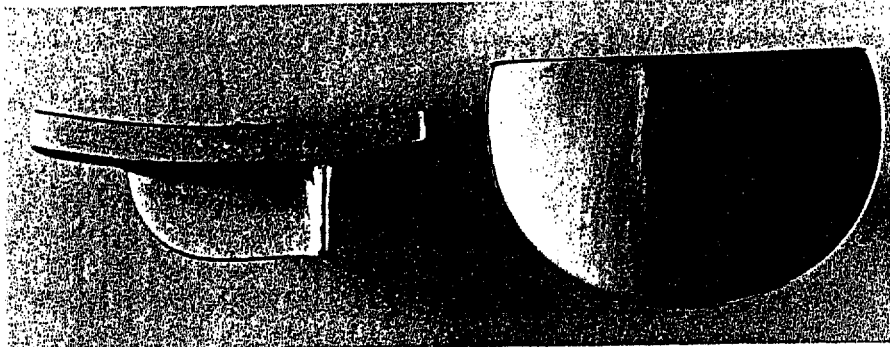


FIG. 1

Two views of the McKeever implant.

With time, it has become clear that the cemented total joint prosthesis, particularly in the young or active patient, has an appreciable risk of failure, primarily because of loosening at the bone-cement interface<sup>5,9</sup>. Salvage of a failed cemented implant is a major surgical challenge<sup>10</sup>. The reported results of tibial osteotomy for medial compartment

hemiarthroplasty in knees with unicompartamental osteoarthritis since 1971 (Figs. 1, 2, and 3).

The purpose of this paper was to retrospectively study this experience in an attempt to determine the role of the McKeever prosthesis in the treatment of unicompartamental osteoarthritis.

## Clinical Material

Seventy-two consecutive McKeever hemiarthroplasties for unicompartamental osteoarthritis were performed by the senior one of us in sixty-nine patients between 1971 and

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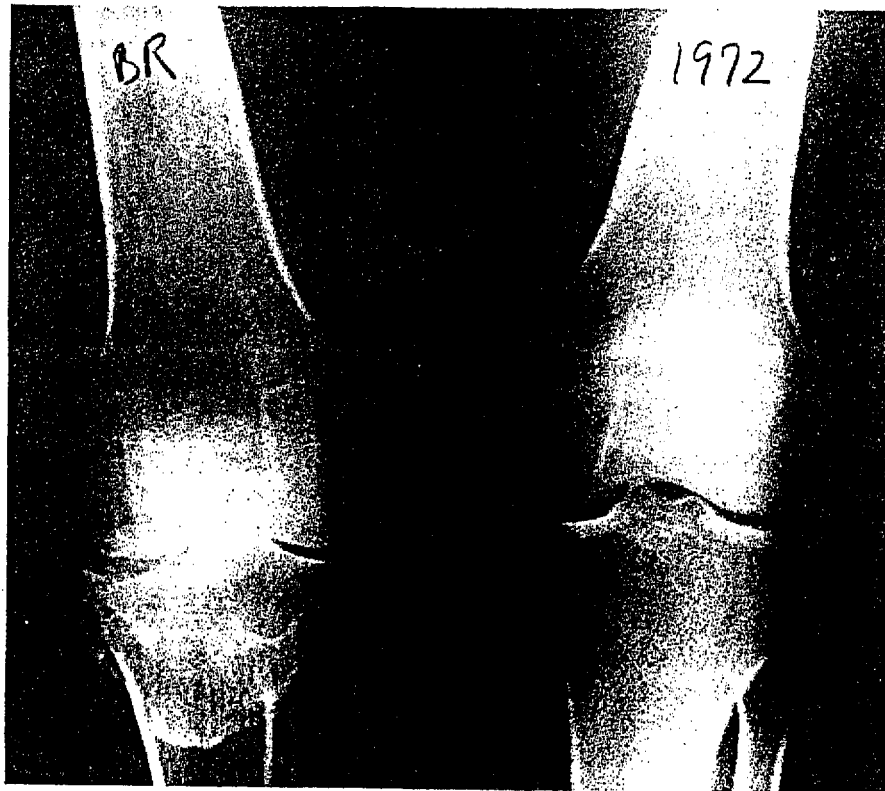


FIG. 2

Preoperative radiograph showing post-traumatic osteoarthritis of the lateral compartment.



FIG. 3

Postoperative radiograph of the knees shown in Fig. 2, three years after insertion of a McKeever implant in the lateral compartment.

1978. These patients' hospital charts, radiographs, and post-operative office records were reviewed. The patients were interviewed by telephone when necessary to complete the follow-up. All of the patients were personally followed by the senior one of us. Of the seventy-two arthroplasties, sixty-one knees in sixty-one patients were available for follow-

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up at two to thirteen years (average, five years) postoperatively.

The method of knee evaluation used in this study was reported previously by Potter et al. A grade of zero to 2 points is excellent; 3 to 6, good; 7 to 10, fair; and more than 11, poor.

The series consisted of thirty-three women and twenty-eight men, with thirty-five right and twenty-six left knee arthroplasties. The average age of the patients was sixty-one years (range, twenty-eight to eighty-one years).

Forty-eight implants were placed in the medial and thirteen, in the lateral tibial compartment. In the knees with replacement of the medial compartment, the preoperative varus deformity at the knee averaged 7 degrees (range, zero to 15 degrees). In the knees with replacement of the lateral compartment, the preoperative valgus deformity averaged 10 degrees (range, 2 to 20 degrees).

Twenty-four (39 per cent) of the knees had had previous surgery, of which a meniscectomy of the ipsilateral compartment was the most common. A total of forty previous operations had been done, with eight knees having had more than one procedure (Table I). The preoperative arc of motion for all knees averaged 84 degrees. Active flexion averaged 91 degrees (range, 60 to 120 degrees). There was an average flexion contracture of 7 degrees (range, zero to 25 degrees). Osteoarthritic involvement of the contralateral compartment

TABLE I  
PREVIOUS SURGERY  
(TWENTY-FOUR KNEES)

Procedure	No.
Meniscectomy	20
Débridement	3
MacIntosh implant	5
Intra-articular fracture	4
Synovectomy	2
Excision of a Baker's cyst	2
High tibial osteotomy	1
Ligament reconstruction	1

and of the patellofemoral articulation was frequent, fourteen knees (23 per cent) having significant involvement of the contralateral compartment and seventeen (28 per cent) having patellofemoral involvement. Thirteen of the former knees were rated as having mild and one, as having moderate involvement, and four of the latter were rated as having mild; ten, moderate; and three, severe involvement.

The McKeever implants (Howmedica) are available in two, three, four, and six-millimeter thicknesses. Larger sizes are available on special order. The most frequently used size in this study was four millimeters.

#### Surgical Technique

Proper surgical technique and careful attention to the postoperative program is necessary for a good result with this prosthesis. The surgical technique and postoperative regimen have been previously reported on by Potter et al.,

but some details of the technique used for unicompartmental prostheses must be emphasized.

The purpose of the unicompartmental prosthesis is primarily to resurface the arthritic tibial plateau and only secondarily to correct deformity. The least possible amount of bone should be removed, although the meniscus must be excised to accommodate the prosthesis. All osteophytes beneath the joint capsule should be removed to permit realignment of the leg. These osteophytes tent the capsule and produce a fixed deformity. Their removal permits the ligaments to return to their normal relationship with the joint surface. When this has been accomplished, the smallest implant that is stable should be used. The tendency to put in the largest implant to obtain better alignment of the leg should be resisted.

Postoperatively, in the operating room, a long cast is applied in one section from groin to toes to produce a stronger bivalved cast. As the patient must be observed carefully during the postoperative period for development of a flexion contracture, we prefer a bivalved long cast in extension rather than the usual prefabricated knee-immobilizer, which may produce a small flexion contracture. The cast is used in the hospital and, except during physical therapy sessions, is used at home at night for six to eight weeks.

The cast is bivalved in the recovery room about two hours after application to allow for swelling. Quadriceps-setting and gluteal-setting exercises are started on the first postoperative day. The bivalved cast is removed on the second or third day to allow the start of active, assisted range-of-motion exercises. The cast is lined and straps are applied for use as a night splint for the next eight to twelve weeks. Partial weight-bearing with crutches is allowed after 70 degrees of flexion has been attained, usually at about the third postoperative week.

If the patient does not attain 60 degrees of flexion by two weeks postoperatively, the knee is gently manipulated to 90 degrees under general anesthesia. The patient is instructed in a touch-down partial weight-bearing gait, which is used for a minimum of three months. If a residual knee-flexion contracture or excessive quadriceps weakness persists, the bivalved cast, holding the knee in maximum extension, is worn intermittently during the day. Several cast changes may be required to stretch out a residual flexion contracture. The importance of the postoperative regimen for the success of this procedure cannot be overemphasized.

#### Results

The average preoperative score of the sixty-one knees in this series was 9.5 points (range, 3 to 20 points) and the average postoperative score was 4.6 points (range, zero to 22 points). This was an average improvement of 4.9 points over the average preoperative score of 9.5 points (Table II). The results in knees with a medial compartment implant ranged from zero to 16 points (average, 3.7 points) and in knees with a lateral compartment implant they ranged from zero to 22 points (average, 6.8 points). Over-all, forty-four

TABLE II  
Records processed under FOIA Request #2016-622; Released by CDRH on 08-29-2016  
CHANGE IN RATING AS RESULT OF ARTHROPLASTY

Ratings	No. of Knees
Poor to poor	7
Poor to fair	0
Poor to good	6
Poor to excellent	10
Fair to poor	3
Fair to fair	2
Fair to good	7
Fair to excellent	10
Good to poor	1
Good to fair	2
Good to good	3
Good to excellent	10

(72 per cent) of the knees were graded as good to excellent. Thirty-seven (77 per cent) of the knees with a medial compartment implant were rated as good to excellent and seven (54 per cent) of those with a lateral implant attained this rating. The twenty patients who were less than fifty-six years old had an average postoperative score of 4.0 points, which was better than the rating for the over-all series. It should be particularly noted that this was an active group of patients, most of whom worked regularly and engaged frequently in non-strenuous athletics. While some of the younger patients admitted to some aching in the knees that had been operated on, after an extremely active day, none had limitation of their normal activities.

The forty-eight knees with a varus deformity that received a medial implant were corrected to an average of 2 degrees of valgus angulation, and the thirteen knees with a valgus deformity that received a lateral implant were corrected to an average of 6 degrees of valgus angulation.

The average postoperative active flexion in the knees with excellent and good results was 110 degrees (range, 60 to 135 degrees). Only three knees had less than 90 degrees of flexion, and nine had more than 120 degrees. Fifteen patients required manipulation of the knee at two weeks postoperatively, including two who had to have manipulation twice. Three knees had a 5-degree flexion contracture; two, a 10-degree contracture; and one, a 30-degree contracture.

Six knees (9 per cent), all with a medial implant, were rated as having a fair result. None required revision surgery. Eleven knees (18 per cent) were rated as having a poor result at follow-up. Six had had a medial and five had had a lateral implant. Seven of these knees have since had revision to a total knee replacement. One first had revision to a unicompartmental cemented prosthesis, which in turn was revised to a total knee replacement and ultimately to a knee fusion. The average time from unicompartmental surgery to total joint replacement was 2.8 years (range, 1.5 to four years). The knees with a poor result were especially characterized by pain and the need to continue the use of crutches. The average arc of motion in this group was 98 degrees (range, 60 to 130 degrees). All lacked 5 degrees to full extension except for one knee with a 30-degree flexion

contracture and only 60 degrees of flexion. The knees that subsequently required revision were those that had had the most severe arthritic involvement of the contralateral compartment and the patellofemoral joint.

### Complications

Complications related to the implant were rare. One medial implant dislocated several years postoperatively while the patient was engaged in vigorous dancing. This was treated by revision to a larger prosthesis and the patient had continued good function. The other complications were few in number and were typical of any major joint operation. There were five deep-vein thromboses, five hemarthroses requiring aspiration, one superficial infection with *Staphylococcus epidermidis*, one reflex sympathetic dystrophy, and one postoperative cardiac arrhythmia.

### Discussion

The alternative surgical procedures that are available today for the treatment of unicompartmental osteoarthritis include proximal tibial osteotomy, distal femoral osteotomy, and unicompartmental total joint replacement. The reported good to excellent results of high tibial osteotomy have ranged from 59 to 82 per cent<sup>1-3,7,8,10</sup>. The majority of these patients had varus deformity. The results of proximal tibial osteotomy for valgus deformity and lateral compartment osteoarthritis have generally been less satisfactory<sup>15</sup>, although Jackson and Waugh<sup>6</sup> reported that eleven of their patients with valgus deformity experienced considerable relief of pain.

The results of unicompartmental total joint replacement have also been variable. Insall and Walker<sup>4</sup> reported 45 per cent good to excellent results and Laskin, 65 per cent relief at two years of follow-up. Marmor reported 75 per cent good to excellent results at two to four years of follow-up.

The results of unicompartmental tibial-plateau arthroplasty with a McKeever implant have not been previously reported. Only two small groups of patients who received a McKeever implant for bicompartamental osteoarthritis have been reported on. The first such report was published following McKeever's death, from material of his that was assembled by Robert Elliott<sup>11</sup>. Seventy-six implants in forty knees were described and there was only one failure due to infection. Potter et al. reported on nineteen patients with bicompartamental osteoarthritis. Seventeen (89 per cent) of them had good to excellent results with the same knee-evaluation scoring that we used in this series.

The results in our series were similar to the best results reported for the other techniques that have been used to address the problem of unicompartmental osteoarthritis<sup>1-3,7,8,10</sup>. There are, however, several advantages to the McKeever implant. Few complications are directly related to the prosthesis. The loosening problems that are inherent in cemented prostheses do not exist. The McKeever implant does have the capacity to correct some varus or valgus deformity by means of varying implant widths, but it is our opinion that overcorrection must be avoided. It can also be

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used as an interpositional implant without changing the varus or valgus alignment of the joint in an arthritic knee without malalignment or in a knee with a depressed tibial-plateau fracture. A failed tibial osteotomy in a younger patient, in whom a cemented prosthesis could be a liability, can be easily converted to a McKeever hemiarthroplasty. There were two such patients in this series. One patient had an excellent result at the time of his death three years post-operatively, and the other, who has been followed for seven years to date, was working as an athletic coach with no significant pain or limitation of activity. Another significant advantage of the McKeever prosthesis is that its insertion does not require the removal of a significant amount of bone, thus making subsequent total joint-replacement surgery easier, and allowing the use of conventional total joint prostheses. The McKeever prosthesis has the capacity to function as a bicompartamental implant, although indications for this use are fewer in this era of total knee replacement. In special circumstances, however, such as in the younger patient, this use should be investigated.

The chief disadvantage of the McKeever implant is the prolonged rehabilitation that is required for a good result. Many older patients are not able to adhere to the regimen of strict partial weight-bearing. These patients, however, are probably better suited for a cemented joint arthroplasty than for the McKeever implant.

It is our opinion that the McKeever implant acts in a fashion similar to the cup arthroplasty of the hip. Observation of the established implant at surgery reveals a smooth glistening surface on both the tibial and femoral osseous surfaces, and while there is obviously motion on the femoral side, it is our opinion that there is micromotion on the tibial side which is important to the success of the implant. There is, therefore, a biological response of the tissues to the

implant. The exacting and prolonged rehabilitation program is required to obtain this local tissue response. In addition, it is our clinical observation that this biological adaptation appears to be inhibited by too tight a fit between the implant and the joint surfaces.

The chief reason for failure in this series appeared to have been multicompartamental arthritis. As this was more common in the older patients, it may partially explain why the younger patients tended to do better. Also, the younger patients were better able to participate in the rehabilitation program, which is more demanding than that required for a cemented prosthesis. The patients in this series were operated on before the era of reliable total knee arthroplasty, and today many of the older patients would be treated with a total joint replacement. Bicompartamental arthritis or severe patellofemoral arthritis would now be considered a contraindication to the use of the McKeever prosthesis.

There continues to be, however, the occasional patient with limited osteoarthritis of the knee who is not a candidate for total joint replacement, due either to age or to the desire to engage in vigorous activities. Osteotomy continues to be the procedure of choice for this type of patient, in our opinion, since no artificial implant is required. In the patient with unicompartamental arthritis without significant deformity, however, in whom realignment of the limb has no rationale, the McKeever prosthesis offers a feasible alternative to the cemented prosthesis. Another indication for use of the McKeever prosthesis is a failed osteotomy, when avoidance of a cemented prosthesis is desirable. While one may not see a great number of patients who will require the McKeever prosthesis, in our opinion it is the best alternative for a small subset of patients, and if it is properly applied it can provide a reliable solution for the complaints of some patients.

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# EXHIBIT 15

## The Classic

# Tibial Plateau Prosthesis

DUNCAN C. MCKEEVER, M.D., F.A.C.S.

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Duncan Clark McKeever (Fig. 1) was born on September 13, 1905, in Valley Falls, Kansas. After attending local schools, he graduated from the University of Kansas Medical School in 1929. As a naval reservist, he spent the next four years in naval training centers, followed by a residency in pathology at St. Luke's Hospital in Kansas City. While there, he fell under the influence of Drs. Frank Dickson and Rex Divley and became interested in orthopedics. After three years of association with them, he moved to Houston in 1939 to open a private practice. From 1941 to 1945, during World War II, he was back in the navy as chief of several hospitals. After the war, he returned to his private practice.

McKeever's knowledge of engineering principles led to his research interest in stress analysis as it applied to operative procedures on bones. His advanced ideas in orthopedic surgery led him to develop original procedures, and his exacting attention to details helped make them successful. His success led to additional innovative procedures, which included prostheses of the hip, patella, and tibial plateau.

His continuing studies kept him in demand as a teacher. Frequent visits from his many friends included those from Latin American countries. Dr. McKeever enjoyed hunting and fishing, and he was always delighted to be at his ranch.

McKeever was one of the founders of the Association of Bone and Joint Surgeons and became its third president. He was also a member and active participant in many orthopedic organizations and on local hospital boards and staffs.

On a rainy evening, October 13, 1959, when driving someone else's car, he ran out of gas; while filling the tank, he was struck by another car and killed. His untimely death was a great loss to orthopedics as well as a personal loss to his many friends.

JUSTUS C. PICKETT, M.D.

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In the past, when a badly damaged knee joint lost any of its articular surfaces, we destroyed it. If the patella is rough, some surgeons take it out. Usually this is not necessary. If the condyles and the plateaus lose their articular surfaces, we arthrodesis

the knee. This is not an answer; it is an escape. A constructive solution must be found to replace this destructive one. Arthrodesis is an easy way out for surgeons and for patients who have trouble in only one knee, but what of those who have two bad knees? Arthrodesis is an admission of defeat. It is an answer that will be accepted less readily as knowledge of endoprostheses accumulates.

The tibial plateaus present a special problem in endoprosthetic restoration. Mechanically, each plateau forms part of a separate joint. They must function synchronously, but the degree of damage of the two may not be identical. Within the same joint space

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The material in this chapter was assembled by Dr. Robert B. Elliott, of Houston, Texas, after Dr. McKeever's death. Part was at Dr. McKeever's home, part was found in his wrecked automobile. Dr. Elliott also read the contents of this chapter at the meeting of the American Fracture Association held in New Orleans, October, 1959.

Reproduced with permission from McKeever, D. C.: Tibial plateau prosthesis. Clin. Orthop. 18:86, 1960.



FIG. 1. Duncan Clark McKeever (1905-1959).

the patellofemoral articulation must function. The knee joint has little structural stability.

### BIOMECHANICS

There are several fundamental considerations applicable to all prostheses intended for functional restoration of joint surfaces. These factors should determine the design and the use of endoprostheses, and must always be given due consideration. The important fundamentals lie within the field of biomechanics. Prosthetic design need not continue to be developed solely by trial and error.

A. There must be an optimal relation between surface area and the range of functional stress to be borne by the prosthesis and transmitted from it to bone. We can obtain a rough idea of the range of these stresses in normal joints by the application of simple mathematical formulas. From this application we can assume that the stresses

must at times exceed 2,000 lbs. per square inch.

In relation to the tibial plateau, the knee is a lever of the 2nd class. The point of action is between the applied force and the fulcrum. If the weight is 150 lbs., the femur is 18 inches long and the fulcrum is 1 inch from the center of application of the force on the tibial plateau, the force exerted is  $17 \times 150$ , or 2,550 lbs. If the area to which it is applied is 1 square inch, the load is 2,550 pounds per square inch.

The object of an endoprosthesis is to achieve functional restoration. If we wish to restore normal function, we must make as close an approach as possible to the surface areas and contours existing in the normal joint, since in nature there is a correlation between these areas and the functional stresses imposed on them when in use. Their contour, design and density are determined by the effect of function during growth.

B. An endoprosthesis must be self-retaining. It must be so designed and inserted that the normal forces existing in the joint in action hold it in place. Any screw, pin, flange or other retention device that functions as anything more than a guide to alignment or to retention of the prosthesis when the joint is at rest must eventually give way as a result of cyclic stress.

C. The direction of stress transfer between the endoprosthesis and the bone on which it rests must be constant. The importance of this factor is very seldom appreciated. Bone will withstand repeated applications of stress, and even increase in sectional density to offer increased resistance to the stress, provided that the stress is constant in direction. If there is an angular variation in direction of stress, absorption certainly will take place. The prosthesis cannot have just anatomic continuity with the bone; it must have functional continuity.

D. The stress transfer from prosthesis to bone must take place at a single level. Any part of a prosthesis that passes this level will

be nothing more than an alignment device to maintain a constant direction of stress. If a significant portion of the stress to be transferred from the endoprosthesis to the bone bypasses one part to reach another level of bone, absorption will occur and will continue until a balance is reached. This absorption will be in proportion to the amount of stress that bypasses the contact point. If all of it bypasses this point, total absorption will occur. Bone that is not functional as a stress-transmitting unit will disappear. We must not lose sight of the fact that endoprostheses transfer stress on two surfaces. The stress is transferred from one articular surface to the prosthesis, is transmitted through it and again is transferred to the bone.

E. Complete functional restoration of the joint by a thorough surgical procedure must be the goal. A prosthesis may play a small, though vital, part in the result. Such problems as range of motion, stability, muscle balance and restoration of periarticular gliding surfaces must be given due attention individually and in relation to each other.

### CLINICAL CHOICE

Case selection is an important consideration in the use of endoprostheses. It is a common error in surgical judgment to use a new procedure, or device, such as a prosthesis, in the most hopeless and difficult case that we can find. This attitude has been responsible for many discouraging failures of good surgical procedures; for instance, in the hip. I have done it, others have done it, and it is so natural that we probably shall continue to do it. But it is not logical. The proper case to select for the first use of an endoprosthesis is one in which the only functional deficit in the joint can be replaced by insertion of the prosthesis. This would suggest that the joint still is functional, or at least that it only recently has lost its function.

The mental attitude of the patient, his tolerance to pain, his economic and psycho-

logical incentives to cooperate may be decisive. Some patients, through sheer will power, continue to get about on a joint that functionally is so deranged that others of weaker moral fiber and lower pain tolerance would long since have ceased to use it. Such people are good patients on whom to try a new surgical procedure.

The physiology of the patient frequently is ignored. To do this is to invite failure. Prostheses are *biomechanical* problems. A functional unit that is satisfactory in a machine may fail in a living body. A machine cannot alter its structure to compensate for variations in stress; its margins of safety are constant. In a healthy body, bone can increase in density and in size to meet the additional strain if the stress is not applied too rapidly or in too great an amount. The direction of application should not change, but its margins of safety may be variable. In an unhealthy body, where the stress is applied too fast and in too great an amount or in a variable direction, bone will melt away. We must ensure a positive reaction to the prosthesis. Bone responds according to certain laws. We must know what they are and apply this knowledge.

### PHYSIOLOGICAL CONSIDERATIONS

We cannot afford to assume that a patient's physiology is normal; we must use every test at our command to detect any possible abnormality. Vital functions for which we have no laboratory or clinical test must be assumed to be subnormal. We should take steps to ensure their function at physiologic levels. Many reconstruction procedures have failed because the doctor did not realize the importance of the general health of the patient and did not take steps to improve it. All aging individuals, and many who have sustained an injury or have had other surgery, are in some degree of catabolism. The essence of degenerative change, the cardinal characteristic of aging, is that catabolism exceeds



anabolism in rate. The body must be made to react positively to the prosthesis. This implies normal physiology, as expressed by rapid healing. Normal osteogenesis will ensure proper arrangement of stress lines for the transfer of strain from the prosthesis to bone and enable the bone to attain optimal cross-sectional density in a minimal time. Unless the patient is in a positive metabolic state, these positive reactions to the prosthesis cannot occur; ultimate failure then is certain.

The metabolic phase of this problem must be considered in the light of the patient's life expectancy. Optimal physiology must be maintained for the remainder of the patient's life. Part of the surgeon's job is to emphasize to the patient and his responsible relatives the importance of this factor, so that they will see to it that the regimen is continued after the patient has been discharged from direct medical supervision.

Muscle function and balance must be restored with proper exercises. In the knee joint the function of the flexors is very important. The extensor mechanism cannot function normally unless it is balanced by hamstrings of good strength and resiliency. The hamstrings must be given adequate progressive exercises, for, paradoxically, the knee will not extend fully if the flexors are weak. Full extension must be restored. Full flexion is not essential, but good functional flexors are.

Occasionally, arthroplasty of an ankylosed knee is indicated and justified, but there are many more knees in which restoration of one or both tibial plateaus for weight-bearing surfaces is indicated. Such restoration will avoid an arthrodesis and restore a functional range of pain-free motion not possible without it. In centrally or totally depressed tibial plateau fractures, restoration of position may not restore a smooth surface. In traumatic and degenerative arthritides, particularly in elderly individuals in whom a gradually developing flexion contracture precludes weight-bearing, a smooth plateau may restore function. Such conditions may follow trauma that occurred many years before. They may

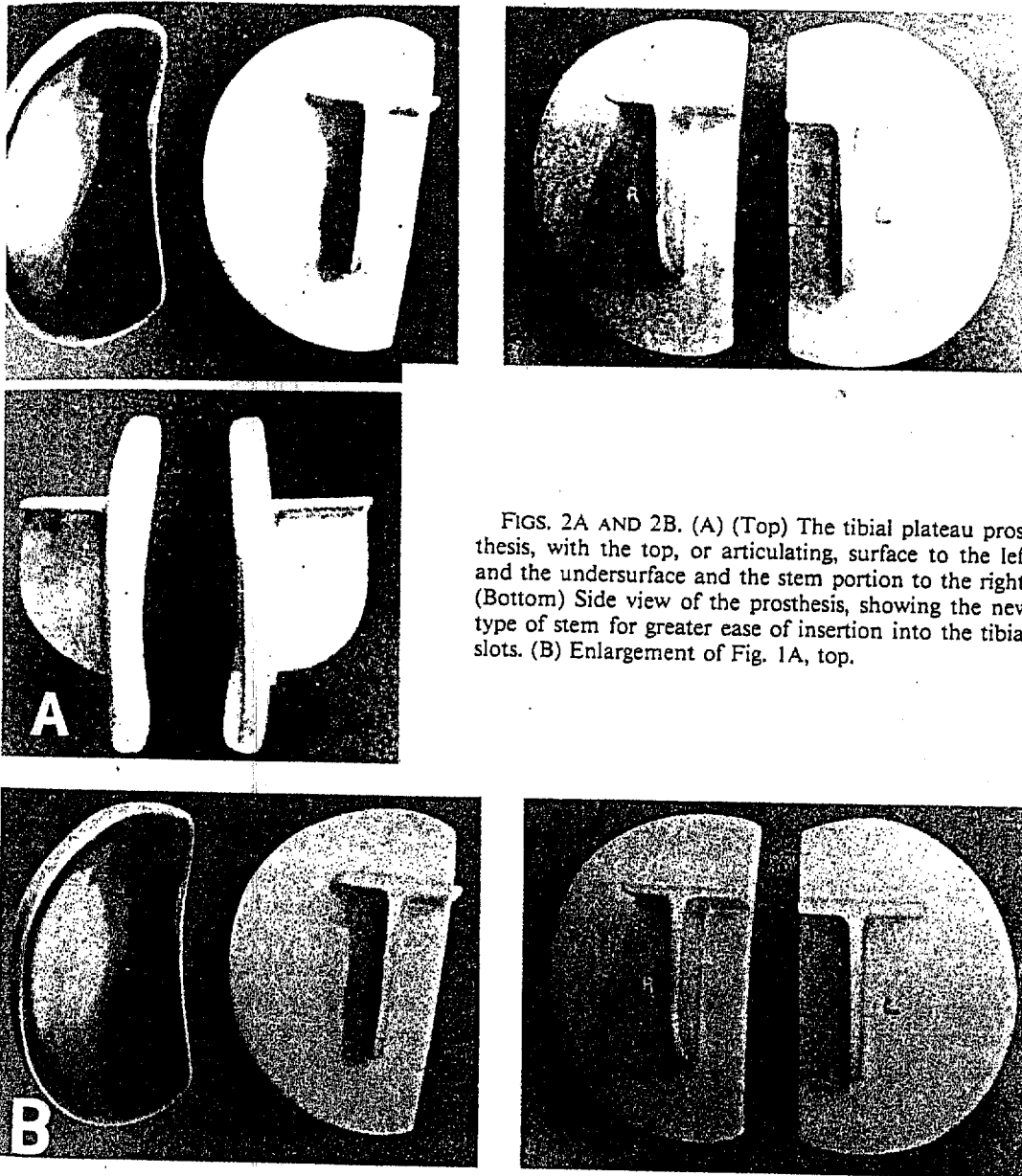
be the end result of osteochondritis dissecans, old untreated cartilage injuries, or the abnormal weight-bearing stresses occurring with a knock-knee or a bowleg. They may occur incidentally in rheumatoid arthritis. Many such cases are subjected needlessly to arthrodesis.

## DESIGN OF PROSTHESIS

For some years I tried to design a prosthesis for application to the lower end of the femur. During this time I made several different drawings with a number of minor variations in each. Instinctively I felt that there was something wrong with them. After several years of study of the mechanical principles, during which time I made more and more application of these principles to the problems of endoprostheses in other locations, the basic fault of this approach to the problem finally occurred to me: Such a prosthesis violates one of the given principles. "There must be a constant direction of stress transfer from the prosthesis to the bone." How does this apply to the knee joint? In the lower end of the femur, stress applied may vary through an arc up to 145° between the limits of flexion and extension. This precludes stress transfer from prosthesis to bone in a constant direction. In such a case extension produces a direct thrust. In flexion, the lower femur becomes the site of application of forces exerted through a lever. Bone will not withstand angular variations of stress at the point of contact with a prosthesis.

The functional stress applied to the surface of the tibial plateau has a constant direction. It is in line with the axis of the tibial shaft no matter what position the knee is in. Any prosthesis applied to the knee and functionally similar joints—for example, the interphalangeal and the metacarpophalangeal joints—should be on the distal side of the joint.

The restoration of the tibial plateau must be accomplished by two separate pieces, one for each tibial plateau. In many knees it is



FIGS. 2A AND 2B. (A) (Top) The tibial plateau prosthesis, with the top, or articulating, surface to the left and the undersurface and the stem portion to the right. (Bottom) Side view of the prosthesis, showing the new type of stem for greater ease of insertion into the tibial slots. (B) Enlargement of Fig. 1A, top.

necessary to restore only a single plateau, in which case it is important to have a single-plateau type of prosthesis. Of importance also is the observation that there is a change in axis at the knee joint as flexion occurs. In many cases, this would cause either rocking or binding of a one-piece prosthesis made to cover both plateaus. The only way to avoid

this with a one-piece prosthesis would be to have the lateral ligament sufficiently loose to prevent binding. Such a joint would be unstable in extension (Fig. 2).

The first prosthesis designed had exactly the same contact articular surface as the present prosthesis. This surface design was achieved by measuring 40 tibias of different

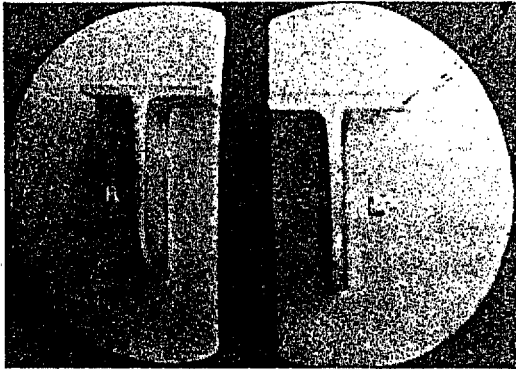


FIG. 3. The undersurface of a pair of tibial plateau prostheses, labeled L and R. This does not refer to the right knee and the left knee but to the right side and the left side of *either* knee as one faces the knee during surgery.

sizes. These measurements disclosed that, while considerable variation existed in the overall diameters of the upper surfaces, there was little variation in the central weight-

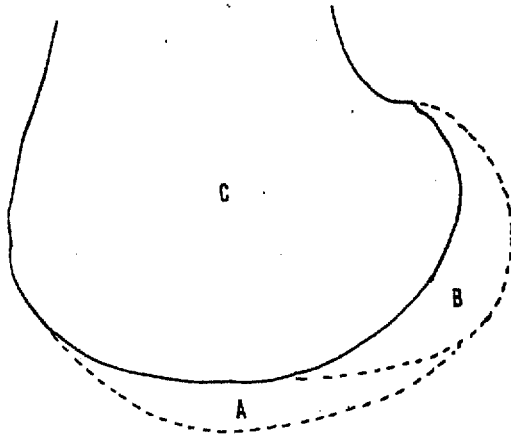


FIG. 4. Diagrammatic lateral view of the distal end of the femur in certain cases. If the femoral condyle has been badly worn away and flattened, then it is necessary to remove some of the posterior condyle to restore the normal elliptical contour of the articular surface to permit normal smooth flexion. "A" represents the portion of the femur worn away and flattened, and in this case "B" represents the portion of the posterior condyle to be removed to restore the normal elliptical contour. "C."

bearing areas. The largest tibia did not exceed the articular surface of the present prosthesis, and its dimensions were within the anatomic limits of the smallest adult tibia of those tested. The articular surface of the larger specimens was found to be an extension of the elliptical contour of the weight-bearing area of the smaller tibias. The central areas were almost identical. Furthermore, in practice, this contour has proven to be satisfactory. The original stem has been altered for greater ease of insertion. The prostheses are made in pairs. A pair will do both sides of either knee. For example, the prosthesis for the right medial plateau fits the left lateral plateau. They are labeled right and left. This is not an anatomic designation but refers to the right or the left side of the knee being operated upon as one faces it. (Fig. 3).

#### OPERATIVE TECHNIQUE

Through a median parapatellar incision the semilunar cartilage, or its remnant on the involved side, is removed. The femoral condyle may be flattened if the weight-bearing surface is worn away badly. This necessitates the removal of a portion of the posterior part of the condyles to restore the elliptical contour of the articular surface and permit smooth flexion (Fig. 4).

With a reciprocating saw, a triangular piece of bone is removed from the tibial plateau and the tibial spines. An anteroposterior cut is made  $\frac{1}{4}$  inch from and parallel to the vertical edge, where the triangular piece of bone was removed. A transverse cut then is made at right angles to the anteroposterior cut and approximately  $\frac{1}{2}$  inch from the anterior edge of the plateau (Fig. 5). It extends medial to the anteroposterior cut and then lateral to it. These cuts need not be deep, but they must penetrate the subchondral bone (Fig. 6). The prosthesis then is inserted so that the anteroposterior flange on the prosthesis rests in the anteroposterior saw cut. It is pushed or driven back into the knee until the transverse flange on the prosthesis

lies directly over the transverse saw cut. It may be necessary to distract the joint in order to do this (Fig. 7). Distraction may be obtained by manipulation of the leg or by placing a lamina spreader in the intercondylar groove. With the flanges on the prosthesis in position over the grooves, the knee is extended. The prosthesis will seat itself as the joint tightens in extension. Flexion of the joint then can be tested. If it is smooth and the joint is stable in extension, the insertion is satisfactory.

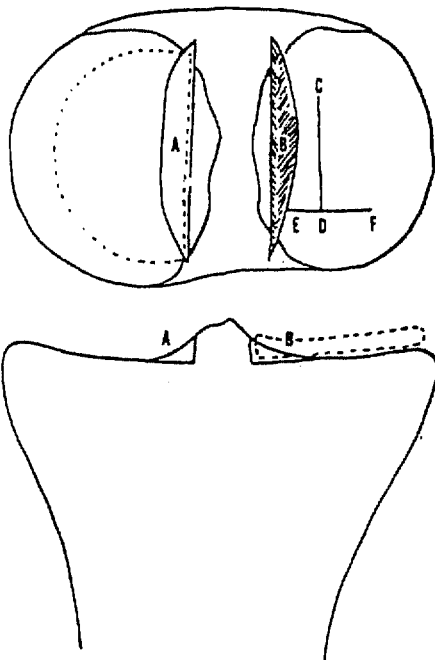


FIG. 5. (Top) View of the superior articulating surface of the tibia showing (A and B) the portions of the tibial plateaus and the tibial spines removed for insertion of the tibial plateau prosthesis. C to D is the anteroposterior slot and E to F is the transverse slot, which are cut into the tibia, by measurement, to allow insertion of the stem of the prosthesis. This is done on both sides of the tibia, of course, for insertion of a pair of prostheses in each knee, although here it has been done on one side only. (Bottom) An anterior view of the same portion of the tibia showing the triangle of bone removed from the tibial plateau and the tibial spine areas to allow insertion of the prosthesis, as represented by the broken line on the right.

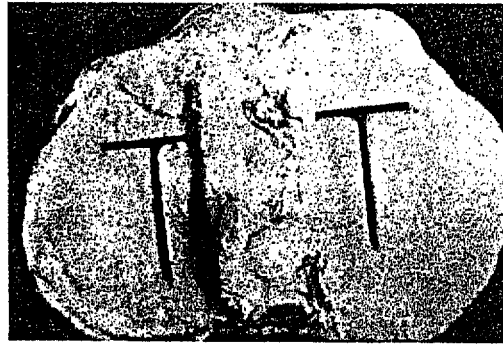


FIG. 6. Gross tibial specimen of the preparation of the tibial plateau prosthesis bed and the slots to receive the stem of the prosthesis.

The patella may show chondromalacia or proliferative changes. If it is badly damaged, it should be restored with a patellar prosthesis.

The other tibial plateau may be restored in exactly the same manner. Any necessary smoothing of the edges of the condyles or debridement of the remainder of the joint should be carried out. I am of the opinion that these overhanging edges should be gently hammered flat rather than cut off. The surface will be much smoother if this is done. The articular margins of the condyles should be treated in this way.

If it is necessary to elevate the tibial plateau to correct valgus or varus deformity, the prosthesis should be inserted first. The collateral ligament and periosteum are elevated, maintaining continuity with the periosteum on the tibial shaft. A transverse saw cut should be made beneath the prosthesis. I prefer to cut it with an osteotome. The entire plateau, in which the prosthesis is embedded, is elevated, and the cut-out piece of bone may be removed and used to fill the defect. The plateau should be held in this elevated position by a carefully fitted autogenous bone graft, preferably formed from a full thickness of ilium with the crest at the tibial cortex (Fig. 8).

#### COMMENTS

Most of the cases in which this prosthesis has been used would otherwise have been

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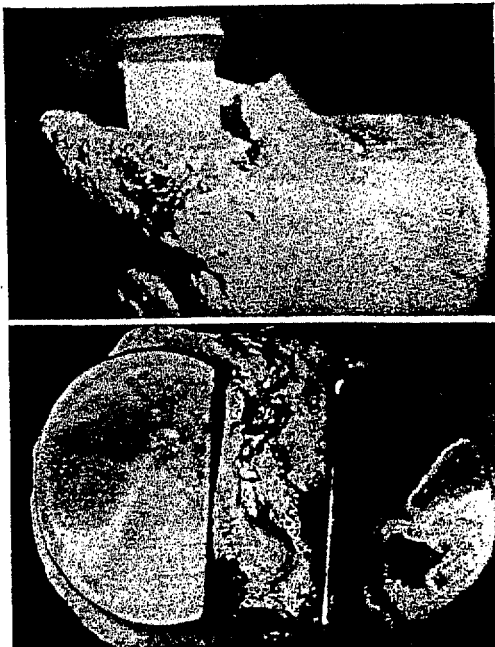


FIG. 7. (Top) Anterior view of gross specimen as would be presented at operation, showing the technique of inserting the prosthesis with the anteroposterior stem in the slot, pushing it backward (posteriorly) until the transverse stem fits into the transverse slot, and then seating the prosthesis by pushing or tapping on it. Extension of the knee joint will also tighten the joint, and the pressure of the femoral condyles will aid in seating the prosthesis. Insertion of the prostheses initially may be aided by distraction of the joint by manipulation or by use of a lamina spreader in the intercondylar notch region. (Bottom) Superior view of articular end of the tibia (knee joint) showing the prostheses seated in correct position and alignment.

subjected to an arthrodesis. At least one of them could not have been ambulatory except in so far as one is able to be ambulatory with both knees arthrodesed. Both knees of the woman were involved in a very advanced rheumatoid arthritic process, the degenerative changes of which had been accentuated by decalcification incident to long-continued administration of large doses of cortisone.

The first case was operated on in April, 1952. This was an almost hopeless joint, due to an advanced villonodular synovitis. This

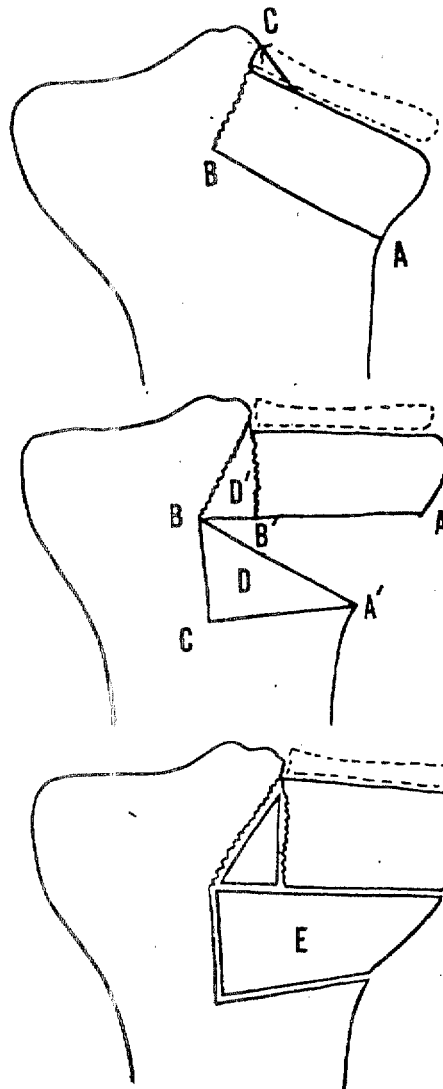


FIG. 8. (Top) Technique of using the prosthesis and elevating the tibial plateau when markedly depressed from old fracturing, bone disease, or erosion. (A) Prosthesis is inserted first, and the tibial plateau is elevated by making an anteroposterior saw cut from A to B and then breaking or cutting the attachment between B and C as the plateau is elevated with the prosthesis in place. (Center) Next, a triangle of bone (D) is removed by cutting from A' to C and from B to C; then this piece (D) is placed at D' to fill the gap and to add stability. (Bottom) Finally, a piece of autogenous iliac bone, shown as E, is cut and fitted carefully into place, as illustrated, to complete the elevation and the support of the tibial plateau and prosthesis.

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woman was such a case as I have said should not be chosen for trial of a new device or procedure; she had been in flexion contracture, partially disabled for 11 years, and on crutches for 5 years. She had a restoration of both tibial plateaus by a prosthesis, a patellar prosthesis and an extensive joint debridement. Cellophane was interposed to restore the periarticular gliding surfaces and the suprapatellar pouch. Eight days after operation she had a smooth range of passive motion from 30° of flexion to complete extension. Three weeks later she had almost 90° of flexion and lacked a very few degrees of complete active extension against gravity. This patient had taken her medication in a rather haphazard fashion. In spite of this, she continued to be quite active. When seen 1 year later, she had a range of motion, voluntary and against gravity, from 80° to 180°. She walked with a cane outside the house and without a cane in the house. Two years after the operation she had lost some motion. She had stopped all medication and had had an acute exacerbation of her general arthritic process. Six years postoperatively, after resuming her medical regimen, she was walking without a crutch or cane, has 70° of flexion and complete extension against gravity. She did not have any pain unless she was on her feet all day.

When it is considered that this patient, aged 57, had a villonodular synovitis of 11 years' duration and a generalized rheumatoid and degenerative arthritis with almost complete destruction of all joint surfaces of the knee, that she had been on crutches for several years, and that she had a 30° flexion contracture when first seen, this result seems quite satisfactory. She is still quite active, walks without a crutch or a cane and drives her own car.

Another case was a woman of 34. She had had rheumatoid arthritis for 8½ years. She had taken 150 mg. of cortisone daily for 5½ years. She could walk a few steps with crutches. She had advanced chondromalacia of the patella and extensive destruction of

the joint surfaces. There was flexion contracture in both knees, also valgus deformity of 40° on the left knee and about 20° on the right knee.

On February 14, 1955, a partial synovectomy and excision of the semilunar cartilages were carried out on the left knee. A lateral tibial plateau prosthesis was inserted, and the plateau was elevated to correct the valgus deformity as much as possible. A patellar prosthesis was inserted.

Extensive alterations in her medical regimen were instituted, and all activity of her arthritic process ceased. About 6 weeks after the first operation the right knee was operated on in a similar manner, a lateral tibial plateau prosthesis and a patellar prosthesis being used. Extensive debridement and synovectomy were done. It was not considered necessary to elevate the tibial plateau on this side because the prosthesis itself produces some correction, and it seemed sufficient in this knee. The result might have been better if it had been raised enough to correct the valgus completely. The patient gets about without crutches or a cane. She goes up and down stairs with some difficulty. She is working full time as a secretary. She has had no acute exacerbation of her rheumatoid arthritis in spite of very unusual stress due to the prolonged serious illness of her husband. She has continued to carry most of the load of family activity.

Similar operations have been carried out on other patients. To date, I have inserted 76 plateaus in 40 patients. In most of these, patellar prostheses have been used in conjunction with the plateau prostheses. All of them were badly damaged knee joints, and varying degrees of debridement and contouring of the edges of the condyles were carried out. Excision of one or both semilunar cartilages was necessary in every case.

There has been one failure due to recurrence of an old infection. This necessitated the removal of both plateau prostheses and the patellar prosthesis, and the patient now has an ankylosis.

All the other cases are ambulatory without cane or crutches, though some of the older patients are encouraged to carry a cane for safety. All have a satisfactory functional range of motion, from complete extension to 90° or more of flexion. In one patient recurrent pain has persisted. Because it is relieved completely by a small injection of 1 percent procaine, administered every 2 or 4 months, this pain is believed to be of functional stress origin. Several other cases are in varying

stages of convalescence but are not considered to have reached an end-result status.

#### CONCLUSION

With this prosthesis it is possible to restore satisfactory function to most of the badly damaged knee joints that ordinarily would be subjected to an arthrodesis. If this prosthesis will function satisfactorily in these severely damaged knee joints, it will function in any case other than that with an infection.

# EXHIBIT 16

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## THE USE OF THE HEMIARTHROPLASTY PROSTHESIS FOR ADVANCED OSTEOARTHRITIS AND RHEUMATOID ARTHRITIS OF THE KNEE

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The surgery of advanced arthritis of the knee joint is attracting considerable attention, and the value of osteotomy (Jackson and Waugh 1961, Gariépy 1964, Coventry 1965, Benjamin 1969) and of arthroplasty (Walldius 1957, McKeever 1960, Shiers 1960, Young 1963, Platt and Pepler 1969, Turner and Aufranc 1969) has been discussed in the recent orthopaedic literature.

MacIntosh gave a preliminary report on the value of hemiarthroplasty in 1958 and in 1966 reported a review of fifty-eight rheumatoid knees. This further review was undertaken to make an independent assessment of the results of the operation and to determine its place in the surgical treatment of advanced osteoarthritis and rheumatoid arthritis of the knee.

### AIMS OF HEMIARTHROPLASTY

The aims of hemiarthroplasty are to correct the varus or valgus deformity by inserting a tibial plateau prosthesis of appropriate diameter and thickness to build up the worn side of the joint, and thus to restore normal stability of the knee, to relieve pain and to improve function and gait.

The collateral ligaments usually maintain their own length in spite of long-standing varus and valgus deformity, and stability is maintained by a prosthesis that is thick enough to correct the deformity and take up the slack in the collateral ligaments.

The operation should be considered only when more conservative methods such as meniscectomy, synovectomy, joint debridement and tibial osteotomy would be of no value, and when the disease has progressed to a stage at which all the articular cartilage on the weight-bearing surfaces of the knee has been destroyed and bone is articulating with bone.

### HISTORY OF HEMIARTHROPLASTY

In 1954 a seventy-three-year-old woman was admitted to the Toronto General Hospital for proposed fusion of an arthritic knee with severe valgus deformity. At operation it was noticed that the valgus deformity could be passively corrected; the lateral ligament then became taut, restoring stability. In the operation theatre at that time there happened to be an acrylic prosthesis for replacement of the whole upper end of the tibia, as used by Dr Sven Kiaer and Dr Knud Jansen of Copenhagen. The prosthesis was cut in two, and one half was inserted in the lateral space to correct the deformity. This produced a stable straight knee which flexed to 90 degrees, and the patient lived free from pain for a further twelve years.

Acrylic was later abandoned, mainly because of widespread dissatisfaction with the use of this material in the hip. In the knee it showed only slight wear, and four of six patients who are still alive, but not included in this series, have a good result more than ten years after the operation.

A trial was then made with Teflon, but this wore badly and promoted an acute foreign body reaction. Only five knees out of sixteen reviewed showed a good result, and fusion or total knee replacement was soon necessary in over half of this group.

Titanium implants were then used, but discontinued because the polished surface of the prosthesis appeared to score and metallic dust discoloured the entire synovium.

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Since 1964 Vitallium has been used exclusively and no further change in the design of the prosthesis has been found necessary. The prosthesis is available in three diameters and in serial thicknesses from six to twenty-one millimetres. It can be used in the medial or lateral compartment of either knee. The prosthesis is held in position by the anatomy of the knee joint, and stability depends upon the taut collateral ligaments. No additional fixation is necessary. The top of the prosthesis has a contoured surface with rounded edges to provide the condyle with a permanent low friction area. The undersurface is flat with multiple serrations to ensure a snug fit and stability (Fig. 1).

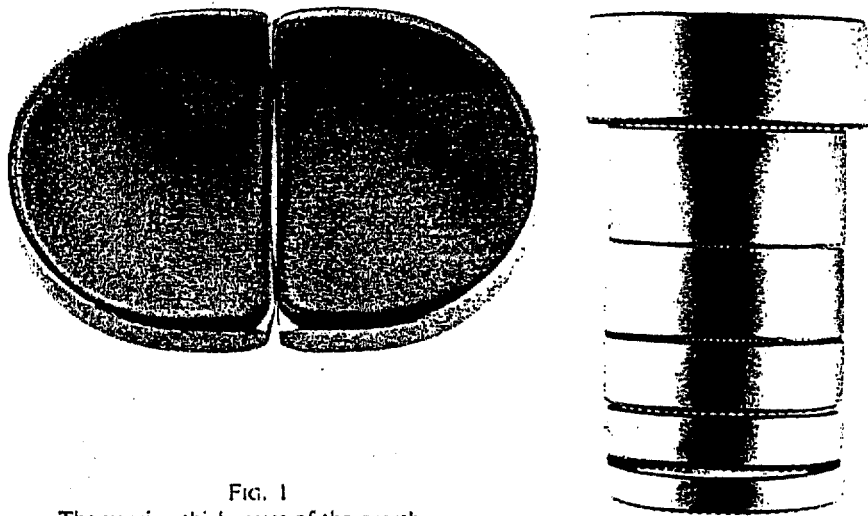


FIG. 1  
The varying thicknesses of the prostheses.

#### ASSESSMENT BEFORE OPERATION

The principal complaints were pain, deformity, instability and limitation of function.

Clinical examination revealed painful bone-on-bone crepitus in one or both compartments of the knee. Most knees in the osteoarthritic group showed varus deformity and most of those in the rheumatoid group had a valgus deformity, but this was not invariable.

Radiographs taken with stress applied to the affected knee were found to be of more value than standing films in assessing the cartilage space of each tibio-femoral compartment (Figs. 2 and 3).

A final decision on whether one prosthesis or two should be inserted often could not be made until both joint surfaces had been examined at operation. Preliminary arthroscopy or arthrography had not been found helpful.

#### TECHNIQUE OF OPERATION

The operation is done on the exsanguinated limb usually through a medial parapatellar incision with complete lateral displacement of the patella. If there is flexion deformity of over 30 degrees the patellar tendon is detached with a small rectangular block of bone before transfer downwards and medially to be dovetailed into the medial border of the tibia. If this transfer is done it is combined with release of the lateral expansion, and in these patients a lateral parapatellar incision may be preferred.

A thorough examination is done to determine the extent of synovial proliferation and cartilage destruction. In rheumatoid arthritis the synovium is often thin and atrophic at this advanced stage and is preserved. If, however, it is hypertrophic, synovectomy is done. A

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flare-up in a rheumatoid knee after prosthetic hemiarthroplasty with or without synovectomy, is rare.

The meniscus, when present, is excised. In rheumatoid arthritis both cruciate ligaments are usually absent or attenuated. If a taut anterior cruciate ligament prevents extension it is divided (Somerville 1960). Loss of either cruciate ligament has not interfered with stability.

After a long-standing knee flexion deformity, an unworn ridge of bone along the anterior aspect of the medial femoral condyle may have to be cut away to improve knee extension (Fig. 4); at the same time marginal osteophytes, if present, are excised from each femoral condyle. Flexion deformity of up to 30 degrees can be corrected at arthroplasty in the cutting of the bed for the prosthesis and by freeing the capsule at the back of the joint. More severe flexion deformities may need posterior release, but this is best done some months later.



FIG. 2

FIG. 3

The value of stress radiography in the assessment of the cartilage space in each tibio-femoral compartment before operation is shown by comparing Figures 2 and 3.

A level bed is cut for the prosthesis on one or both tibial plateaux. The first osteotomy cuts are vertical, protecting the intercondylar area, and the plateau shaped accurately to a level bed, using an air-powered drill with reciprocating saw, as little bone as possible being removed (Figs. 5 to 7). The bed should be at right angles to the coronal and sagittal planes. No lateral or posterior ridge need be left to stabilise the prosthesis; stability is ensured by the rough undersurface of the prosthesis and a perfectly flat bed.

Varus or valgus angulation is corrected by the insertion of a prosthesis of appropriate thickness and diameter in each compartment (Figs. 8 to 15). If there has been a long-standing varus or valgus deformity the femoral condyles may have acquired a medial or lateral slope, and the prominent margins will have to be cut back.

If on flexing the knee to a right angle tilting of the prosthesis occurs, it is essential to ensure that the beds are level in both planes. Rarely it is necessary to reshape the femoral condyles posteriorly to prevent their impinging on the prosthesis when the knee is flexed.

No attempt is made to correct the lateral rotation deformity so commonly associated with a valgus knee in rheumatoid arthritis. This rotation deformity is caused by a combination of flexion deformity and a tight ilio-tibial band. It is thought that the knee establishes its own plane of motion in lateral rotation, and that no correction need be attempted.

Trimming of marginal osteophytes from the patella is often needed, but excision of the patella should be avoided at the time of hemiarthroplasty whenever possible because it delays rehabilitation.

The tourniquet is released before closure. The wound is irrigated with Bacitracin solution and closed in layers with catgut and subcuticular wire. Blood transfusion is seldom needed. Prophylactic antibiotics have not been routinely used in this series.

#### MANAGEMENT AFTER OPERATION

The knee is kept in extension for five days after operation in a massive compressive bandage or very occasionally in a Thomas splint. Static quadriceps exercises are started on the first day after operation, even if the patellar tendon has been transferred. The patient is

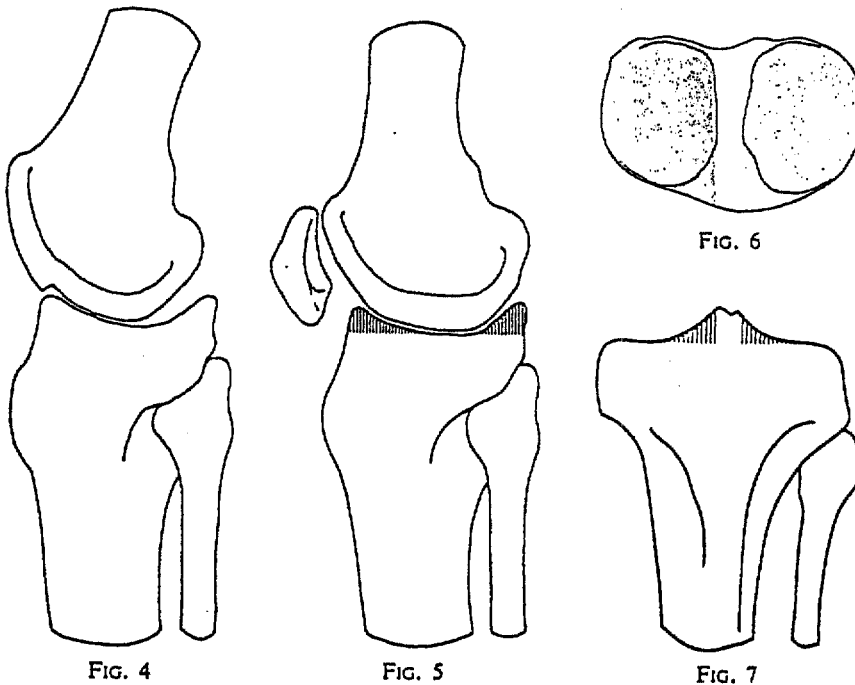


FIG. 4  
FIG. 5  
FIG. 6  
FIG. 7  
Figure 4—The unworn ridge of bone on the medial femoral condyle is often present after a long standing flexion deformity. Figures 5 to 7—The direction of osteotomy of the upper surface of the tibia.

allowed up fully weight-bearing in a walking frame or with crutches after two days and active flexion is encouraged after five days if wound healing is adequate, initially in the ward and later in a hydrotherapy pool.

If movement is slow to return a gentle manipulation under anaesthesia to 90 degrees of flexion, with an intra-articular injection of a corticosteroid, is given in the second week after the operation; the manipulation is repeated after a further week if progress continues to be slow.

Crutches are replaced by walking sticks as soon as the patient can safely manage with them, and may be necessary for two or three months after the operation.

#### ANALYSIS OF CLINICAL MATERIAL

In the ten years from 1959 to 1969, 122 patients were operated upon by the senior author. Eleven patients were not available for review, ten had died from intercurrent disease and two had revision procedures too recent for review.

Records processed under FOIA Request #2016-622; Released by CDRH on 08-29-2016.

Of the ninety-nine patients available for review, sixty-eight had had arthroplasty of one knee and thirty-one had had arthroplasties of both knees, making a total of 130 knees to be assessed.

Sixty patients fulfilled the accepted criteria for the diagnosis of rheumatoid arthritis, and the remaining thirty-nine had pathological and radiological findings consistent with osteoarthritis.

There were thirty medial, fourteen lateral and eighty-six double hemiarthroplasties.

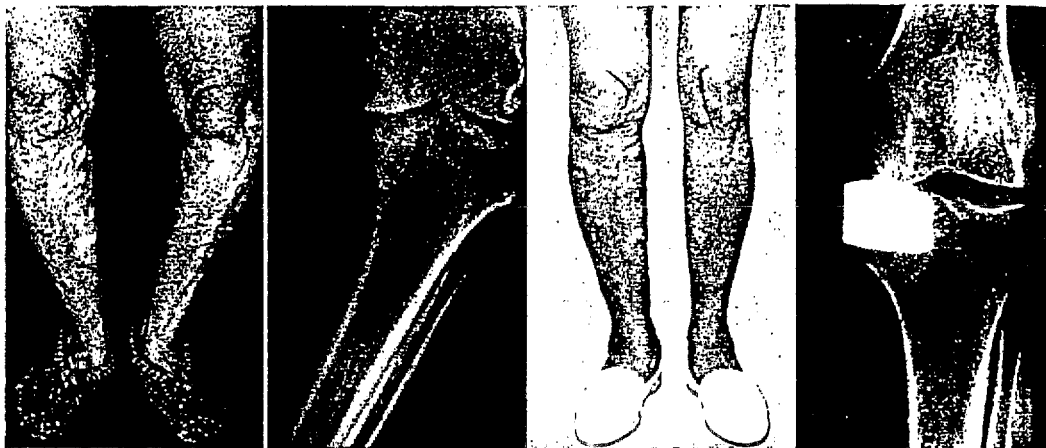


FIG. 8

FIG. 9

FIG. 10

FIG. 11

The correction of a varus deformity by a single plateau in the medial compartment of an osteoarthritic knee.



FIG. 12

FIG. 13

FIG. 14

FIG. 15

The correction of a valgus deformity by a single plateau in the lateral compartment of an osteoarthritic knee.

*Sex*—There were twenty men and seventy-nine women.

*Age*—The age at the time of operation was between twenty-one and seventy-eight years, with an average age of fifty-six years. The age distribution is shown in Figure 16. The patients with rheumatoid arthritis were much younger than those with osteoarthritis.

*Side*—The operation was performed on the right knee on seventy-two occasions and the left knee on fifty-eight occasions.

*Type of prosthesis*—A titanium prosthesis was in use until 1964, but since that time only Vitallium has been used (Table I). Five patients who previously had a hemiarthroplasty performed by other surgeons but who required revision are included in this series.

*Duration of symptoms*—The duration of symptoms before operation ranged between three and forty years, with an average of fifteen years.

HEMIARTHROPLASTY FOR ADVANCED ARTHRITIS OF THE KNEE

*Length of follow-up*—The follow-up period was from one to ten years, with an average of three and a half years (Fig. 17).

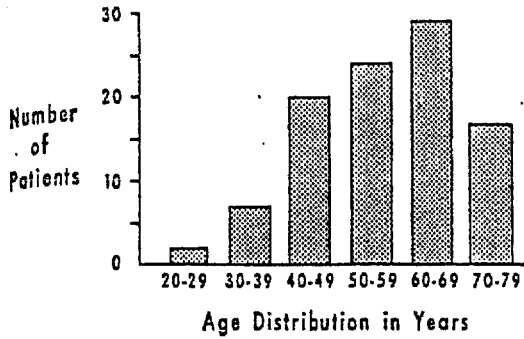


FIG. 16

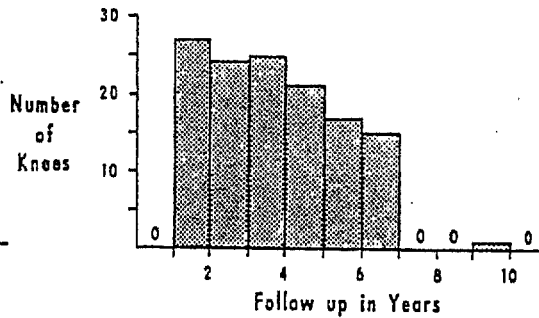


FIG. 17

Figure 16—Age distribution (ninety-nine patients). Figure 17—Duration of follow-up (130 knees).

METHOD OF ASSESSMENT

All patients were assessed personally by one of the authors (G. A. H.). It was necessary to travel more than 5,000 miles in Ontario to ensure adequate follow-up; the patients were interviewed, their knees examined, their gait studied, and radiographs were made available locally where appropriate.

TABLE I  
TYPES OF PROSTHESIS (130 KNEES)

Metal	Number
Titanium .	17
Vitallium .	107
Mixed .	6

TABLE II  
RANGE OF MOVEMENT (130 KNEES)

Range (degrees)	Number of knees	Result
More than 90.	70	53 Good 17 Poor
60 to 89	49	41 Good 8 Poor
Less than 60	5	Poor
Later fusion or total replacement	6	

TABLE III  
FLEXION DEFORMITY (130 KNEES)

Flexion deformity (degrees)	Number of knees	Result
0 to 10	104	87 Good 17 Poor
11 to 20	12	7 Good 5 Poor
More than 20.	8	Poor
Later fusion or total replacement	6	

The assessment of results after operation is difficult. In both groups the disease is subject to periods of remission and recurrent activity. "The enthusiasm of the surgeon for the procedure and the loyalty of the patient towards his surgeon must be minimised if accurate reproducible results are to be obtained" (Potter 1969). For this reason we felt that the surgeon's or the patient's assessment would be inaccurate.

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The aims of arthroplasty are fivefold. 1) To relieve pain so that no analgesics are required for the knee joint itself. 2) To increase range of movement. All the patients with good results were found to have at least 60 degrees of flexion from the extended position (Table II). In seven patients there was a good result in spite of fixed flexion deformity of 15 to 20 degrees (Table III). The range of movement was recorded by the zero neutral method. 3) To provide stability. This was assessed subjectively by the patient, who complained of giving way at the knee, and objectively by assessment of the stability of the cruciate and collateral ligaments, and the power of the quadriceps muscle. 4) To improve function and gait. Enquiry into the activities of daily living after the operation and to that before operation as estimated by the patient and from the records. Most patients found it impossible to kneel and had difficulty in descending stairs normally both before and after the operation. No patient was considered to have a good result if two crutches were still used. Many patients used one stick outside the house. 5) To correct the lateral deformity to within 5 degrees of varus or 10 degrees of valgus. The actual degree of valgus in a normal knee, when measured from the mid-inguinal point is only 3 degrees (Hall 1965). The degree of lateral deformity was measured clinically from the mid-inguinal point and allowance made for 7 to 8 degrees in either direction.

Radiographic measurements before operation, often in the presence of a flexion and external rotation deformity, were thought to be too unreliable to make any valuable comparison with those after operation.

For the operation to have achieved a good result, all five of the above criteria had to be fulfilled. If one or more of these aims had not been achieved the result was poor. The operation was recorded as a failure when subsequent fusion or total knee replacement was necessary.

A knee that needed revision was assessed at least one year after the revision.

The results were assessed for each knee rather than for each patient. It must be emphasised that this report is a continuing review of experience with hemiarthroplasty. The overall results are shown in Table IV.

Most of the poor results needing revision or other operation were apparent within two years. If a patient continued to have pain after the operation the cause was determined and a revision advised when possible, rather than proceeding directly to total replacement or arthrodesis.

The percentage of good results was almost constant over each two-year period after operation, suggesting that the good results are maintained (Table V).

If the principle of hemiarthroplasty is sound, then the analysis of the poor results and failures should give more information than an analysis of the good results.

#### CAUSES OF POOR RESULTS

The causes of the poor results, often multiple, are shown in Table VI. This analysis includes an assessment of a further fifty-two knees operated on by other surgeons at the Toronto General Hospital using the metallic prosthesis.

*Lateral subluxation* of the knee cannot be corrected by hemiarthroplasty and is a contra-indication to the operation (Fig. 18). It may be that in this group hemiarthroplasty should be combined with tibial osteotomy.

*Patello-femoral disease* probably causes a poor result because of continuing pain and limitation of flexion.

*Deep infection after operation* occurred in four knees to give two poor results and two arthrodeses.

*Failure to correct deformity* to within 5 degrees of varus or to within 10 degrees of valgus occurred in eight patients. If the angular deformity is greater than 20 degrees, replacement by a tibial prosthesis may have to be combined with a tibial osteotomy (Figs. 19 and 20).

HEMIARTHROPLASTY FOR ADVANCED ARTHRITIS OF THE KNEE

*Previous ankylosis or fusion*—If the knee has previously been arthrodesed or is ankylosed from previous disease, the results have been poor. The pericapsular structures are too tight and the quadriceps muscle too weak to produce efficient knee function.

TABLE IV  
OVERALL RESULTS IN 130 KNEES

Result	Number	Per cent
Good .	94	72.3
Poor .	30	23
Failure .	6	4.6

Rheumatoid Arthritis			Osteoarthritis		
Result	Number	Per cent	Result	Number	Per cent
<i>Details of 89 knees</i>			<i>Details of 41 knees</i>		
Good . . .	61	68.5	Good . . .	33	80.5
Poor . . .	24	27	Poor . . .	6	14.6
Failure . . .	4	4.5	Failure . . .	2	4.9
<i>Details of single plateau</i>			<i>Details of single plateau</i>		
Good . . .	7		Good . . .	27	
Poor . . .	3		Poor . . .	6	
Failure . . .	0		Failure . . .	1	
<i>Details of double plateaux</i>			<i>Details of double plateaux</i>		
Good . . .	54		Good . . .	6	
Poor . . .	21		Poor . . .	0	
Failure . . .	4		Failure . . .	1	

TABLE V  
FOLLOW-UP PERIOD RELATED TO RESULTS

Time (years)	Good results		Poor results	
	Number	Per cent	Number	Per cent
1 to 3 .	42	78	12	22
3 to 5 .	32	76	10	24
5 to 7 .	20	74	7	26
7 plus .	0	—	1	—
Total .	94		30	

TABLE VI  
CAUSES OF POOR RESULTS

Lateral subluxation of the knee
Patello-femoral disease
Infection after operation
Failure to correct varus or valgus deformity
Ankylosis before operation
Excessive joint destruction
Failure of operative technique
Poor motivation

*Excessive joint destruction* of both femoral and tibial condyles, often with subluxation of the joint, is a contra-indication to hemiarthroplasty, and such a knee would be better managed by arthrodesis or total replacement. Recently, in such severe cases the plateau has been built

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up with methyl methacrylate. Stability is restored by use of the cement as a "filler", but the results are too early for assessment. Normally no such additional fixation is necessary.

*Failure of operative technique*—Failure to cut level beds on the tibia, failure to place the prosthesis well back in the knee joint and failure to reshape the femoral condyle when necessary will lead to tilting of the prosthesis with subsequent movement within the knee joint. The prosthesis does not normally move from its bed, and we have confirmed this by cineradiography

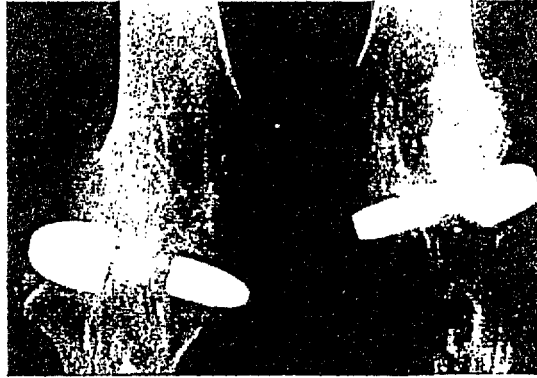


FIG. 18

The prostheses are seen to be unstable because of lateral subluxation of the knee.

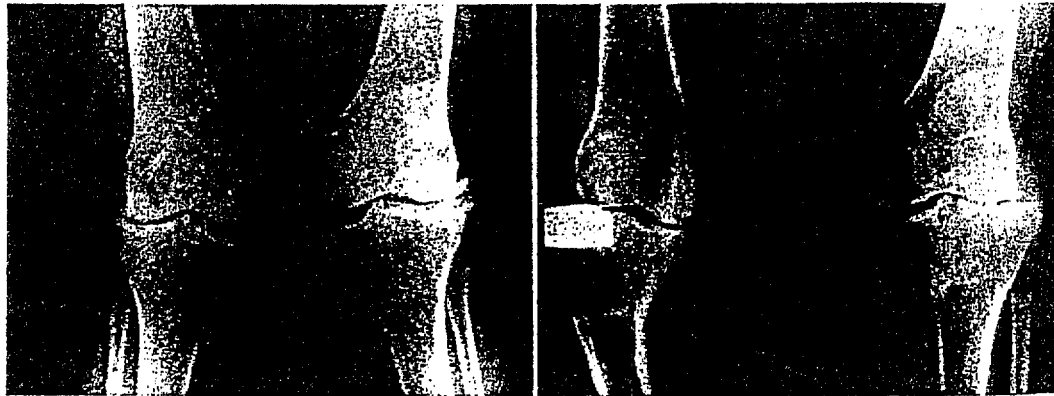


FIG. 19

FIG. 20

Hemiarthroplasty has been combined with tibial osteotomy. The tibial osteotomy alone has not corrected the deformity of the lateral part of the left knee.

and by the fact that at revision the upper tibial surface is cross-hatched to coincide with the serrations on the under-surface of the prosthesis.

*Poor motivation* is a contra-indication to most elective orthopaedic procedures, and particularly to arthroplasty of a knee, for which the full cooperation of the patient is needed.

#### COMPLICATIONS

Complications are shown in Table VII. The late sequelae are shown in Table VIII.

*Detachment of the patellar tendon* occurred twice. On each occasion it was reattached with a successful outcome.

*Lateral popliteal nerve palsy* was noted on five occasions: all recovered within a few months of the operation.

HEMIARTHROPLASTY FOR ADVANCED ARTHRITIS OF THE KNEE

ASSOCIATED OPERATIONS

**Tibial osteotomy**—If the valgus or varus deformity exceeds 20 degrees, hemiarthroplasty should be combined with preliminary tibial osteotomy. This was performed in four patients with good results.

**Excision of the patella**—This should be avoided if possible at the time of hemiarthroplasty, because it interferes with the recovery of knee movement in the period after operation. However, good results were obtained in seven of twelve knees in which it was necessary.

TABLE VII  
COMPLICATIONS

Haemarthrosis . . . . .	2
Superficial wound infection . . . . .	1
Deep wound infection . . . . .	4
Wound dehiscence (sterile) . . . . .	1
Detachment of patellar tendon . . . . .	2
Foot drop . . . . .	5
Thrombo-embolism (non-fatal) . . . . .	3

TABLE VIII  
LATE SEQUELAE

Revision procedure . . . . .	16
Hinge arthroplasty . . . . .	3
Fusion . . . . .	3
Death (intercurrent disease) . . . . .	10

TABLE IX  
REASON FOR REVISION IN SIXTEEN KNEES

Movement of prosthesis . . . . .	8
Failure to correct varus or valgus deformity . . . . .	5
No obvious cause . . . . .	3

**Posterior capsulotomy**—This was done at the same time or soon after the arthroplasty in nine knees, with good results in all but one.

**Quadricepsplasty** was necessary in three knees after operation. It achieved good results in two knees, and flexion of 50, 65 and 80 degrees respectively was obtained.

REVISION

A revision was done in sixteen knees. The reasons are shown in Table IX.

*Movement of the prosthesis* is abnormal and occurs with failure of technique—such as failure to correct lateral deformity—or with a pre-existing subluxation of the tibia on the femur.

*Failure to correct varus or valgus deformity* occurs in osteoarthritis because of undercorrection of the more common varus deformity and in rheumatoid arthritis because of overcorrection of the more common valgus deformity by a single plateau.

*No obvious cause* was found in three knees needing revision for continuing pain. The patients had poor results over one year after the revision.

Nine of the fourteen knees had a good result after revision. Two patients who have had a recent revision are excluded from this series.

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## CONTRA-INDICATIONS

These are summarised in Table X.

Initially hemiarthroplasty was used to replace the fractured lateral tibial plateau. Although a Teflon prosthesis was used in these early cases, eight out of fifteen subsequently had an arthrodesis or total replacement. It is probable that the younger patient expects too much of the operation and that the hemiarthroplasty cannot stand up to the demands of heavy work in young manual labourers. No fractures of the tibial plateau have been included in this series.

## CONCLUSIONS

In osteoarthritis involving a single compartment of the knee, tibial osteotomy is nowadays the procedure of choice. It can be used in young patients at an early stage of the disease and it avoids the introduction of a foreign body into the knee joint. Hemiarthroplasty should only be used in the elderly patient (over seventy years of age) because the rehabilitation after operation is more rapid, and for the rare type of osteoarthritis in which there is loss of articular cartilage in both compartments of the knee joint.

TABLE X  
CONTRA-INDICATIONS TO HEMIARTHROPLASTY

Fractures of the tibial plateau (early or late)
Single compartment osteoarthritis
Previous sepsis or ankylosis
Lateral subluxation of the tibia on the femur
Extensive joint destruction
Neuropathic arthritis
Poor motivation

In rheumatoid arthritis hemiarthroplasty is the procedure of choice because tibial osteotomy does not offer a reasonable alternative. Both tibio-femoral compartments are usually involved and two prostheses are required. It is still thought that, in the rheumatoid knee with the usual valgus deformity, if the cartilage of the medial compartment is still present it should be preserved, but that revision to double hemiarthroplasty may be necessary at a later date.

Occasionally correction of severe deformities in both osteoarthritis and rheumatoid arthritis is best accomplished by a combination of hemiarthroplasty and tibial osteotomy.

## SUMMARY

1. Hemiarthroplasty is a method of dealing with painful deformities of advanced osteoarthritis and rheumatoid arthritis of the knee.
2. The indications and contra-indications for this procedure are discussed. Careful selection of patients is essential.
3. The technique of operation and management after operation are described.
4. The results of such a procedure, as done by one surgeon, are given. Good results have been obtained in 80 per cent of the osteoarthritic knees and in 69 per cent of the rheumatoid knees.
5. The complications, place of associated operations and value of revision procedures are discussed.

We are indebted to Miss Maureen Barnes for secretarial assistance, to the Department of Medical Art of the University of Toronto and to the Department of Photography of the Toronto General Hospital for the figures. This work was done by one of us (G. A. H.) during the tenure of a Bilton Pollard Fellowship, awarded in 1969 by University College Hospital, London, England.

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# EXHIBIT 17

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# The Journal of Bone and Joint Surgery

The Official Publication of  
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The British Orthopaedic Association  
The American Academy of Orthopaedic Surgeons  
The Australian Orthopaedic Association  
The Canadian Orthopaedic Association  
American Society for Surgery of the Hand  
New Zealand Orthopaedic Association  
South African Orthopaedic Association  
Western Orthopedic Association

SEPTEMBER 1971

American Volume

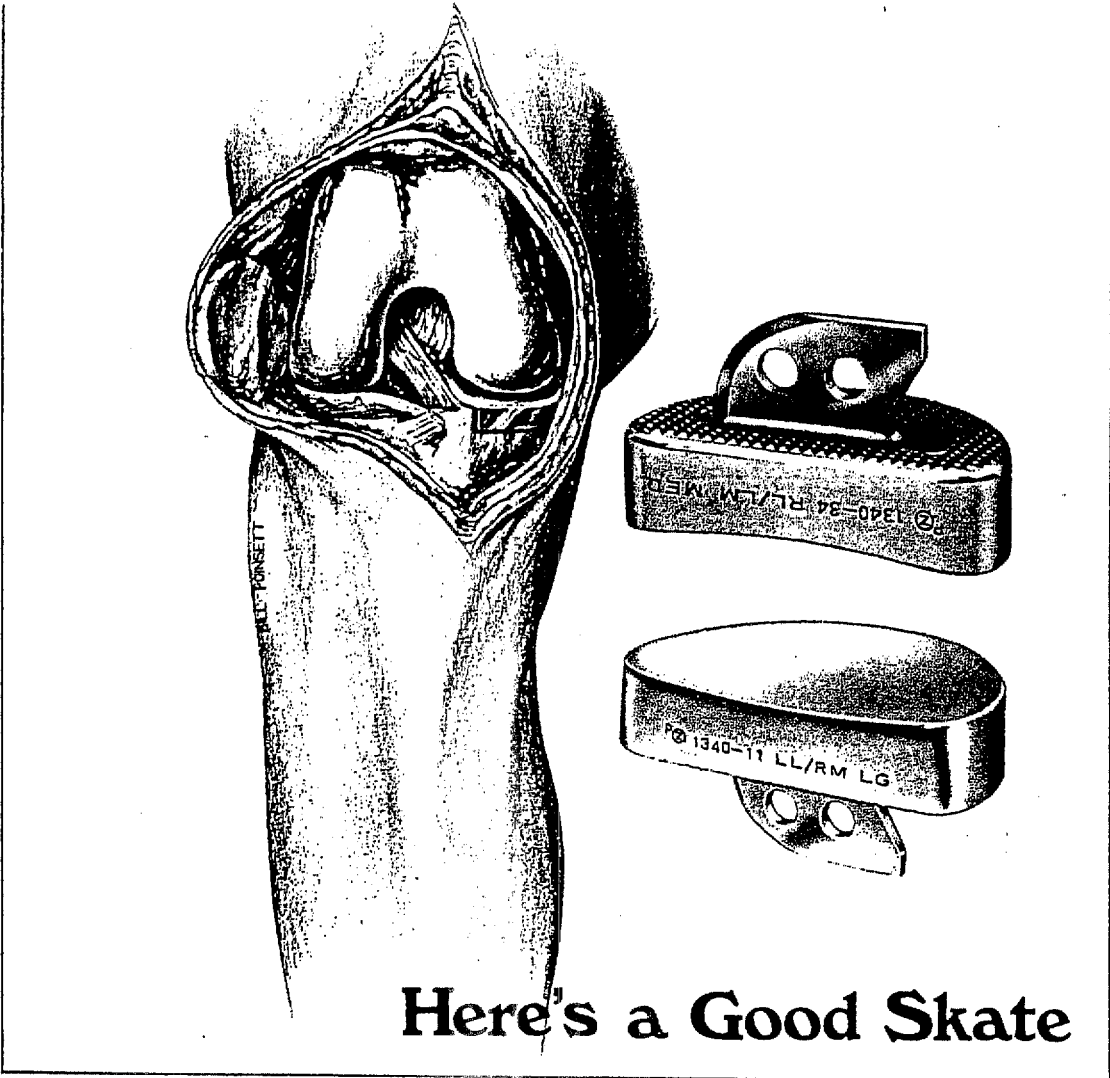
Vol. 53-A, No. 6

10 SHATTUCK STREET, BOSTON, MASSACHUSETTS 02115, U.S.A.

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## Here's a Good Skate

It's a blade-shaped skate on the inferior aspect of the Sbarbaro Tibia Plateau Prosthesis. Easily seated with a simple driver, it has two fenestrations for vascularization and retention. The tibial surface of the Plateau itself is cross-hatched and rough to inhibit slipping after final impaction. The femoral surface of the Plateau presents nothing new; it just articulates smoothly with the condyles, as all good Zimaloy® prostheses should.

Lasting results have been obtained with the Sbarbaro Tibia Plateau in 85% of over 350 cases with an average follow-up of five years. Your man from Zimmer has all of the facts (and he's a good skate, too).

let of Percodan con-  
: HCl (Warning: May  
g. oxycodone tereph-  
: habit forming), 0.38  
nalate, 224 mg. aspi-  
and 32 mg. caffeine.  
be used in patients with  
sitive to its ingredients  
e and homatropine).  
alities of Percodan are  
: and somewhat greater  
tions should be observed  
dan should be used with  
sias. It is generally well  
, emesis, or constipation

hours, preferably after

ty, N.Y. 11530. **Endo**

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tibia plateau prostheses

**SBARBARO TIBIA PROSTHESES IN ZIMALOY**

Designed by John L. Sbarbaro, M.D., this Zimaloy prosthesis is indicated in degenerative arthritis and other instances where replacement of the tibia shelf is required. Anatomically contoured to replace the tibia shelf and to mount solidly with its unique barb and serrations. Dr. Sbarbaro's technique is available.

1340-11



Cat. No.	Description	Size	Width		Depth		Thickness	
			Inch	mm	Inch	mm	Inch	mm
1340-01	Left Lateral/Right Medial	Small	1 1/4	27	1 3/8	41	3/8	9.5
1340-02	Right Lateral/Left Medial	Small	1 1/4	27	1 3/8	41	3/8	9.5
1340-03	Left Lateral/Right Medial	Medium	1 1/2	29	1 3/8	44	3/8	9.5
1340-04	Right Lateral/Left Medial	Medium	1 1/2	29	1 3/8	44	3/8	9.5
1340-05	Left Lateral/Right Medial	Large	1 5/8	33	2	51	3/8	9.5
1340-06	Right Lateral/Left Medial	Large	1 5/8	33	2	51	3/8	9.5
1340-11	Left Lateral/Right Medial	Small	1 1/4	27	1 3/8	41	3/8	9.5
1340-12	Right Lateral/Left Medial	Small	1 1/4	27	1 3/8	41	3/8	9.5
1340-13	Left Lateral/Right Medial	Medium	1 1/2	29	1 3/8	44	3/8	9.5
1340-14	Right Lateral/Left Medial	Medium	1 1/2	29	1 3/8	44	3/8	9.5
1340-15	Left Lateral/Right Medial	Large	1 5/8	33	2	51	3/8	9.5
1340-16	Right Lateral/Left Medial	Large	1 5/8	33	2	51	3/8	9.5
1340-31	Left Lateral/Right Medial	Small	1 1/4	27	1 3/8	41	3/8	9.5
1340-32	Right Lateral/Left Medial	Small	1 1/4	27	1 3/8	41	3/8	9.5
1340-33	Left Lateral/Right Medial	Medium	1 1/2	29	1 3/8	44	3/8	9.5
1340-34	Right Lateral/Left Medial	Medium	1 1/2	29	1 3/8	44	3/8	9.5
1340-35	Left Lateral/Right Medial	Large	1 5/8	33	2	51	3/8	9.5
1340-36	Right Lateral/Left Medial	Large	1 5/8	33	2	51	3/8	9.5
1340-41	Left Lateral/Right Medial	Small	1 1/4	27	1 3/8	41	1/2	13
1340-42	Right Lateral/Left Medial	Small	1 1/4	27	1 3/8	41	1/2	13
1340-43	Left Lateral/Right Medial	Medium	1 1/2	29	1 3/8	44	1/2	13
1340-44	Right Lateral/Left Medial	Medium	1 1/2	29	1 3/8	44	1/2	13
1340-45	Left Lateral/Right Medial	Large	1 5/8	33	2	51	1/2	13
1340-46	Right Lateral/Left Medial	Large	1 5/8	33	2	51	1/2	13
1340-101	Left Lateral/Right Medial	Small	1 1/4	27	1 3/8	41	1 1/2	15
1340-102	Right Lateral/Left Medial	Small	1 1/4	27	1 3/8	41	1 1/2	15
1340-103	Left Lateral/Right Medial	Medium	1 1/2	29	1 3/8	44	1 1/2	15
1340-104	Right Lateral/Left Medial	Medium	1 1/2	29	1 3/8	44	1 1/2	15
1340-105	Left Lateral/Right Medial	Large	1 5/8	33	2	51	1 1/2	15
1340-106	Right Lateral/Left Medial	Large	1 5/8	33	2	51	1 1/2	15

**SBARBARO TIBIA PROSTHESIS DRIVER**

Made of satin finished stainless steel for driving the 1340 Sbarbaro Tibia Prosthesis. Knurled handle provides directional control.

Cat. No.	Diameter		Overall Length		Handle Length	
	Inch	mm	Inch	mm	Inch	mm
1341-06	1/2	13	7 1/2	191	2 1/4	57

**IMPACTOR**

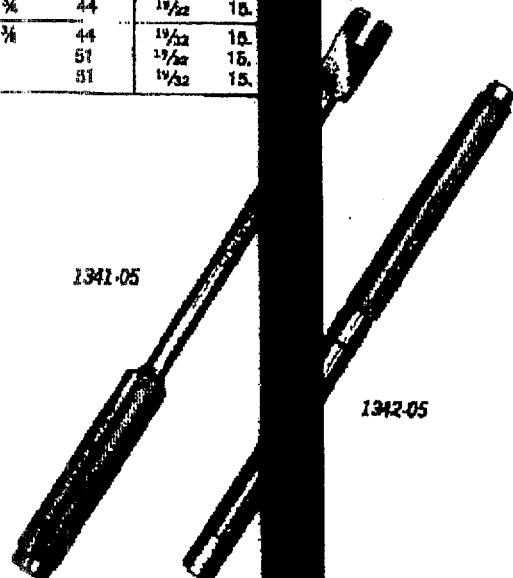
This satin finished stainless steel impactor is provided with a replaceable Teflon cap. For use with 1340 and 1345 Tibia Prostheses.

Cat. No.	Diameter		Length	
	Inch	mm	Inch	mm
1342-06	1/2	13	6 1/2	165

**CAP**

Replaceable Teflon cap for Impactor 1342-06.

Cat. No.	Diameter		Length	
	Inch	mm	Inch	mm
1342-10	3/8	9.5	1	25



1342-05



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## SURGICAL RECONSTRUCTION OF THE KNEE JOINT UTILIZING A TIBIAL PLATEAU PROSTHESIS.

John L. Sbarbero, Jr., M.D.  
Hospital of the University of Pennsylvania

The hemitibial plateau prosthesis has been designed for the restoration of the tibial plateau that has been destroyed by disease or trauma.

Experience at the Hospital of the University of Pennsylvania with 100 osteoarthritic knees and 150 rheumatoid knees indicates that this procedure can give improved function and lasting results. This has been confirmed in 85 per cent of cases with an average followup of five years.

The major indication for surgery is uncontrollable pain and effusion. Varus and valgus stability of the knee is evaluated with the knee to 10 degrees. Instability of less than 10 degrees (Class I) (fig. 1) is treated by synovectomy and debridement. Instability of 10 degrees to 20 degrees (Class II) (fig. 2) is treated by synovectomy, debridement, and insertion of a tibial plateau prosthesis on whichever plateau is destroyed. Instability in excess of 20 degrees (Class III) (fig. 3) is treated by hinge arthroplasty.

### SURGICAL TECHNIQUES

Following a routine skin preparation, a tourniquet is inflated high on the thigh and a medial parapatellar incision is placed on the skin and deepened through the subcutaneous tissues, quadriceps expansion and capsule. The incision extends from 5 centimeters above the superior pole of the patella to the tibial tubercle. The capsular incision is parallel to the patellar tendon (fig. 4). A complete anterior synovectomy is carried out and care is employed to remove the suprapatellar pouch as well as the infrapatellar fat pad. A pituitary rongeur is employed to remove synovium from under the collateral ligaments as well as the posterior recesses of the joint. The menisci are destroyed and the remnants are removed. Frequently the cruciate ligaments are destroyed and these may be removed in toto if necessary. The collateral ligaments are intact and are preserved. Hypertrophic bone about the femoral condyles and tibial plateau is removed with a curved osteotome (fig. 5). The patella is revised as needed but preserved.

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The sloping tibial plateau is revised so as to present a flat surface for the prosthesis (fig. 8). Frequently the slope is so contoured that a flat surface can be obtained without removing excessive bone. If such is the case, then enough bone is removed so as to give a 75 per cent seating of the prosthesis. A 0.25 inch straight osteotome is then used to cut a trough into the plateau. A proper sized plateau is then selected and fitted into the trough (fig. 7). A driver is then set against the skate and the plateau is seated in the trough with the knee in 45 degrees of flexion. Final seating is accomplished with a mallet. Stability of the joint is verified and the wound thoroughly irrigated with saline. The capsule is closed with 00 chromic and the subcutaneous tissue with 000 chromic catgut suture. The skin is closed with no. 35 wire and an elastic compression corset applied.

Ankle motion and straight leg raising exercises are started on the day following surgery. Range of motion exercises are started five days after surgery. A waterproof wound dressing is applied and whirlpool therapy is instituted on the seventh postoperative day. Seventy degrees of flexion is usually accomplished by the third postoperative week and partial weight bearing may be instituted at this time. If motion is slow in returning, then a manipulative procedure may be carried out under general anesthesia but this has to be done no later than the third postoperative week.

Transient peroneal palsy can be a frequent postoperative complication. If the patient is not closely observed during the first twelve hours. This palsy is related to postoperative swelling and the patient with a preoperative genu valgum deformity is particularly vulnerable. Splitting of the cotton dressing and release of the knee corset will alleviate the condition.

Another problem to be guarded against is the development of a postoperative knee flexion contracture. The patient should be encouraged to rest the knee in extension with either a sling or a pillow behind the heel.

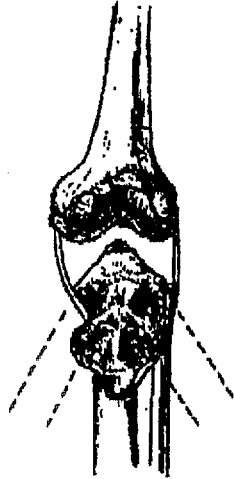
Patients are usually ready for discharge about four weeks following surgery. At that time they should have full extension and 90 degrees of flexion. Partial weight bearing is continued for three months. The knee will exhibit slight swelling, effusion, and warmth for three to six months. An enthusiastic quadriceps exercise program should be continued throughout the convalescent period.



Class I  
Fig. 1



Class II  
Fig. 2



Class III  
Fig. 3

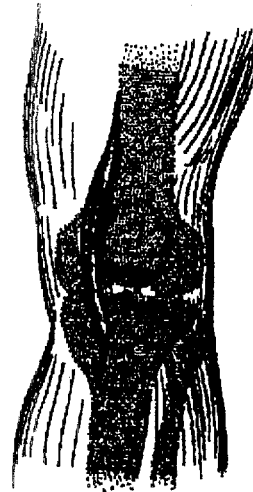


Fig. 4

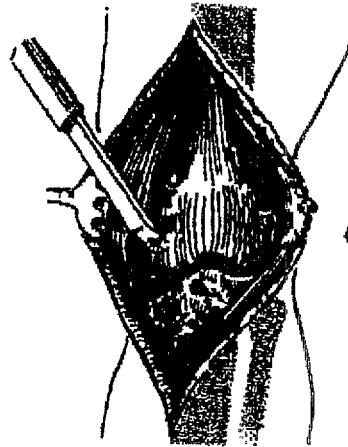


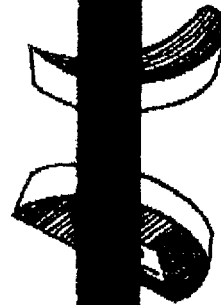
Fig. 5



Fig. 6



Fig. 7



Feb. 1971  
TR 4D

# EXHIBIT 18

**UNICOMPARTMENTAL INTERPOSITIONAL SPACER  
COMPARISON TO COMPETITIVE PREDICATE DEVICES**

FEATURE	SUBJECT DEVICE	PREDICATE DEVICES		
		McKeever Prosthesis	McIntosh Prosthesis	Sbarbaro Prosthesis
Manufacturer	Sulzer Orthopedics	Howmedica	Howmedica	Zimmer
Material	CoCr	Vitallium (CoCr)	Vitallium (CoCr)	Zimaloy (CoCr)
Sizes	7 (34-54mm)	1	3 (S, M, L)	3 (S, M, L)
Thicknesses	5 (1-5mm)	5 (3-15mm)	6 (3-21mm)	5 (3-15mm)
General Shape	Kidney	Semicircular	Semicircular	Semicircular
Femoral Surface	Smooth/concave	Smooth/concave	Smooth/concave	Smooth/concave
Tibial Surface	Smooth/convex <sup>1</sup>	Smooth/convex	Serrated/flat <sup>2</sup>	Serrated/flat
Other Features	N/A	T-shaped stabilization fin	N/A	Blade shaped stabilization fin
Bone resection?	No <sup>1</sup>	Yes, sagittal slots required	Yes, flat tibial surface required <sup>2</sup>	Yes, flat tibial surface required

<sup>1</sup> The largely conforming tibial surface "mates" to the existing tibial plateau without the need for bone resection. This technique has the advantage of requiring a lower level of surgical skill and should minimize the occurrence of technical mistakes.

<sup>2</sup> MacIntosh preferred to prepare the tibial plateau through bone resection in order to accept his flat-bottomed device. He further stated "Failure to cut level beds in the tibia, failure to place the prosthesis well back in the knee joint and failure to reshape the femoral condyle when necessary will lead to tilting of the prosthesis with subsequent movement within the knee joint..."

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# EXHIBIT 19

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SUMMARY OF PUBLISHED LITERATURE ON PREDICATE DEVICES

UNICONDYLAR INTERPOSITIONAL SPACER

Article/Author	Potter (Exhibit 11)	Swanson (Exhibit 12)	Scott (Exhibit 13)	Emerson (Exhibit 14)	Macintosh (Exhibit 16)
No. Patients	99	32	40	61	99
No. Implants	118	30	44	61	130
Diagnosis	99 RA, 19 OA	24 RA, 6 OA	44 Degen. Arthritis	61 OA	60 RA, 39 OA
Follow-up Range (Avg.)	1-9 yrs (3 yrs)	2-14 yrs (5 yrs)	5-13 yrs (8 yrs)	2-13 yrs (5 yrs)	1-10 yrs (3.5 yrs)
Age Range (Avg.)	RA: 22-76 (53); OA: 29-81 (64)	32-72 (55)	32-82 (67)	28-81 (61)	21-78 (56)
Clinical Rating, Postop	RA: 56.5% exc/good OA: 89.4% exc/good	94% good	75% good/exc @ 5 yrs 70% good/exc @ >5yrs	75% good/excellent	RA: 68.5% good OA: 80.5% good
ROM, Postop	RA: 71.7% w/≥80 deg OA: 84.2% w/>80 deg	95 deg (avg.)	110 deg (avg.)	110 deg (avg. in the 46 pts. w/good-exc result)	54% w/>90 deg
Flexion Contracture, Postop	RA: 61.6% w/<5 deg OA: 73.7% w/<5 deg	Not reported	5 deg (avg.)	3 pts. w/5 deg 2 pts. w/10 deg 1 pt. W/20 deg	80% w/0-10 deg.
Revisions	6 (2 for infection, 4 to correct varus/valgus deformity)	1 (RA patient had rapid progression of arthritis to opp. Compartment)	6 (inadequate pain relief - 2 @ < 1yr, 1 ea. @ 4.5, 5, 7 and 10 years)	7 (poor results due to inadequate pain relief and need for support)	16 (8 for failure of technique, 5 for failure to correct varus/valg deformity, 3 for pain)
Complications	4 infections 3 adhesions requiring open exploration 1 plateau fracture (fall) 1 peroneal nerve palsy 1 death (adrenal insuff.)	1 intraop. tib. plat. fracture 1 postop. tib. plat. fracture	1 drain removal 1 intraart. Hematoma 1 superfic. Hematoma	5 Deep venous thromb. 5 hemarthroses 1 dislocation 1 Superficial infection 1 Dystrophy 1 cardiac arrhythmia	5 foot drop 4 deep infections 3 Thromboembolism 2 Detached pat. Tendon 2 Hemarthroses 1 superficial infection 1 wound dehiscence



# EXHIBIT 20

## 510(k) SUMMARY

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807, this is to serve as a Summary of Safety and Effectiveness for the Sulzer Orthopedics Unicondylar Interpositional Spacer.

**Submitter:** Sulzer Orthopedics Inc.  
9900 Spectrum Drive  
Austin, Texas 78717  
(512) 432-9900

**Date:** October 16, 2000

**Contact Person:** Mitchell A. Dhority  
Manager, Regulatory & Clinical Affairs

**Classification Name:** 21 CFR 888.3590 - Knee joint tibial (hemi-knee) metallic resurfacing uncemented prosthesis

**Common/Usual Name:** Hemi-knee prosthesis

**Trade/Proprietary Name:** Unicondylar Interpositional Spacer (UIS)

### PRODUCT DESCRIPTION

Currently, arthroscopic debridements are performed regularly to address the pain and synovitis associated with early stage osteoarthritis; as many as half of those patients treated are estimated to have Grade III-IV chondromalacia. It is also estimated that failure occurs within 2 years in half of those treated. While the effectiveness of arthroscopic debridement is quite variable, it is clear that it does not address the mechanical alignment and laxity problems associated with the joint. Use of other options, such as knee arthroplasty and high tibial osteotomy (HTO), are more invasive, technically challenging and may compromise the joint to future treatment options. Anti-inflammatory medications have also been used to manage pain, but have limited effect on moderate arthritis and offer no solution in terms of repair to the joint.

The Unicondylar Interpositional Spacer was developed as an alternative to arthroscopy, HTO and knee arthroplasty treatments for those situations where limited degeneration/joint destruction exists. Instead of simply debriding soft tissues as in arthroscopy or resecting valuable unaffected bone and cartilage as in total knee replacement, this treatment allows for placement of a metallic "spacer" device into the joint space above the affected medial tibial plateau. The femur then articulates against the polished, curved surface of device. The device is intended to be used without cement and is held in place by its geometry and the surrounding soft tissue structures.

The device will be manufactured from either wrought cobalt chromium alloy (ASTM F1537) or forged cobalt chrome alloy (ASTM F799). The design is kidney shaped to mimic that of the medial tibial condyle; the shallow "dished" geometry allows for articulation with the femur. It is asymmetric (left and right components) and is available in seven sizes (30-54mm) and five thicknesses (1-5mm) to better restore joint alignment, tension and stability.

The surgical procedure to place the device is carried out in two stages. First, the posterior horn of the meniscus is debrided and resected arthroscopically. The device may then be inserted into the joint space above the affected medial tibial plateau via open surgical implantation.

Use of this device raises no new issues relative to safety or effectiveness and provides several potential advantages over other surgical options, including:

- Technically easier to implant than a unicompartmental total knee, high tibial osteotomy or meniscal transplant.
- Facilitates future conversion to total knee arthroplasty by eliminating the need for bone resections.
- Is surgically less invasive (e.g. unicompartmental treatment, smaller incision, fewer implant components required, no bone resection required).

### SPECIFIC DIAGNOSTIC INDICATIONS

The Unicondylar Interpositional Spacer is intended for uncemented use in treatment of the following:

- Moderate degeneration of the medial compartment of the knee (grade III-IV chondromalacia) with no more than minimal degeneration (grade I-II chondromalacia, no loss of joint space) in the lateral condyle and patellofemoral compartments.

### SUBSTANTIAL EQUIVALENCE

Substantial equivalence is based on comparison to the following preamendment devices:

- McKeever Hemiarthroplasty Prosthesis
- MacIntosh Hemiarthroplasty Prosthesis
- Sbarbaro Tibia Plateau Prosthesis

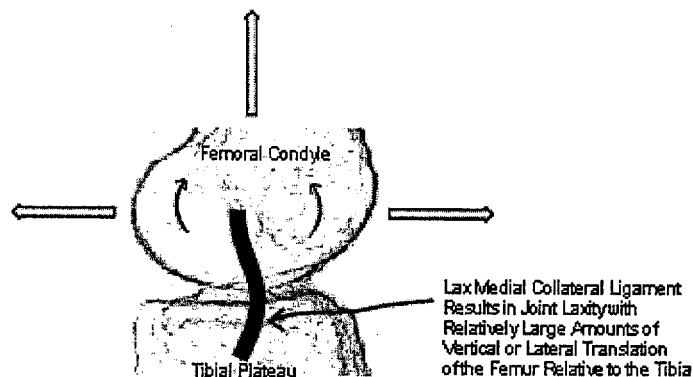
### Design Features

The subject and predicate devices are similar in terms of design features. All of these designs are unicondylar in nature and generally incorporate a metallic tibial resurfacing component of various sizes/thicknesses. The femoral condyle articulates against the curved upper surface of the implant.

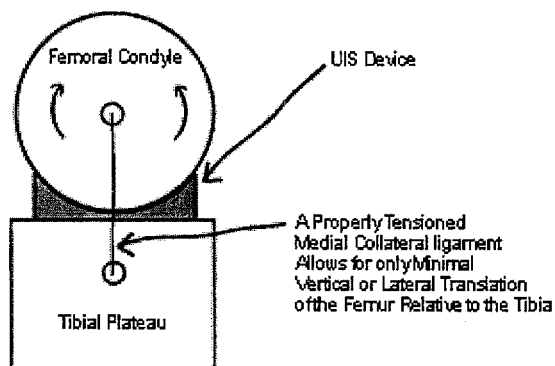
### Stability

Like the MacIntosh tibial prosthesis, the Unicondylar Interpositional Spacer has no obvious means of attachment.

In the osteoarthritic knee, substantial amounts of articular cartilage have been lost as a result of the disease. The knee compartment suffers a subsequent closing of the joint spacing as seen on X-ray. This joint closing allows the collateral ligament to become lax and the joint to become unstable and off-axis (varus deformity). Whereas normal motion of the femoral condyle is largely rotational, if ligament laxity is present, there will be increased translational motion of the femur relative to the tibia



Filling the joint space that was once occupied by the now missing articular cartilage can restore the correct tension of the collateral ligament. When the proper thickness of the Unicondylar Interpositional Spacer is chosen, the tightening of the collateral ligament prevents any excessive translational motion of the femoral condyle. Thus, almost all of the forces against the Unicondylar Interpositional Spacer now become rotational and the Unicondylar Interpositional Spacer will have no forces acting on it that would cause it to "spit" from the joint space. The stability of the joint is restored.



The surface geometry of the Unicondylar Interpositional Spacer also plays a significant role in its inherent stability.

MacIntosh states "The collateral ligaments usually maintain their own length...and that the stability is maintained by a prosthesis that is thick enough to correct the deformity and take up the slack in the collateral ligaments". He further states that "The prosthesis is held in position by the anatomy of the knee joint, and stability depends on taut collateral ligaments. The top of the prosthesis has a contoured surface with rounded edges to provide the condyle with a permanent low friction area."

The Unicondylar Interpositional Spacer has a femoral surface geometry that imitates that of the tibial plateau including an intact meniscus. On the other side, the tibial surface of the Unicondylar Interpositional Spacer imitates the surface of the tibial plateau without the meniscus.

When the Unicondylar Interpositional Spacer is properly placed into the knee compartment, it rests inside the boundaries of the resected meniscus. It has substantially intimate contact with the tibial plateau throughout the entire range of motion. The femoral side of the Unicondylar Interpositional Spacer also has substantially full contact with the femoral condyle when the knee is in full extension.

Thus, when the knee is in full extension, the Unicondylar Interpositional Spacer can only be located in one position in the joint space as determined by the relative position of the femoral condyle to the tibial plateau.

As the knee is flexed and the femoral condyle begins to rotate, since the collateral ligaments remain under tension, the posterior aspect of the femoral condyle remains in contact with the central weight-bearing surface of the UIS

Materials

The subject and predicate devices are similar in terms of materials used. All of these designs use cobalt chrome alloy.

Intended Use

Additionally, the subject and predicate devices share similar indications for use. The subject device, like the predicate devices, are used generically in the treatment of unicompartmental tibial arthritis where total knee replacement is not warranted.

Clinical Safety & Effectiveness

Based on review of the published clinical literature on this type of device, the known potential risks associated with these devices are essentially of the same type and frequency as unicompartmental or total knee replacement, arthroscopy and others. As shown in the publications associated with the predicate devices, these risks include hematoma, infection, nerve palsy, embolus, dislocation, fracture and need for revision. The less invasive nature of the device also lends itself to ease of conversion to the more conventional surgical treatments.

The history with the predicate devices also indicates that the effectiveness of this treatment is at least equal to that obtained with tibial osteotomy in terms of pain relief, correction of deformity and restoration of stability. Furthermore, it provides some added benefits which cannot be recognized with current treatments (e.g., ease of implantation, ease of conversion to other treatments, less invasive).

Testing did not raise any new issues of safety or effectiveness and indicated that this device should provide performance equivalent to commercially marketed products.



JAN - 4 2001

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Mitchell Dhority  
Manager, Regulatory & Clinical Affairs  
Sulzer Orthopedics, Inc.  
9900 Spectrum Drive  
Austin, Texas 78717

Re: K003269  
Trade Name: Unicondylar Interpositional Spacer (UIS)  
Regulatory Class: II  
Product Code: HSH  
Dated: October 17, 2000  
Received: October 18, 2000

Dear Mr. Dhority:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

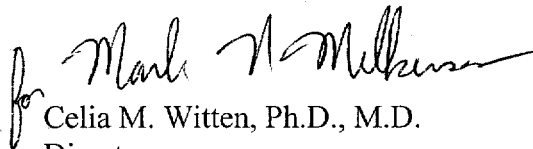
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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

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

Page 2 - Mr. Mitchell Dhority

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

Sincerely yours,



Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative and  
Neurological Devices

Office of Device Evaluation

Center for Devices and  
Radiological Health

Enclosure



510(k) Number (if known): 003269

Device Name: Unicondylar Interpositional Spacer

### Indications for Use:

The Unicondylar Interpositional Spacer is intended for uncemented use in treatment of the following:

- Moderate degeneration of the medial compartment of the knee (grade III-IV chondromalacia) with no more than minimal degeneration (grade I-II chondromalacia, no loss of joint space) in the lateral condyle and patellofemoral compartments.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

*for Mark A. Melkerson*

(Division Sign-Off)

Division of General Restorative Device

510(k) Number K003269 1/9/01

Prescription Use \_\_\_\_\_

OR

Over-The-Counter Use \_\_\_\_\_

(Optional Format 1-2-96)



Memorandum

From: Reviewer(s) - Name(s) Peter Allen

Subject: 510(k) Number 1C 00 3269

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

- Refused to accept.
- Requires additional information (other than refuse to accept).
- Is substantially equivalent to marketed devices.
- NOT substantially equivalent to marketed devices.

De Novo Classification Candidate?  YES  NO

Other (e.g., exempt by regulation, not a device, duplicate, etc.)

- Is this device subject to Postmarket Surveillance?  YES  NO
- Is this device subject to the Tracking Regulation?  YES  NO
- Was clinical data necessary to support the review of this 510(k)?  YES  NO
- Is this a prescription device?  YES  NO
- Was this 510(k) reviewed by a Third Party?  YES  NO
- Special 510(k)?  YES  NO
- Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers  YES  NO

This 510(k) contains:

- Truthful and Accurate Statement  Requested  Enclosed  
(required for originals received 3-14-95 and after)
- A 510(k) summary OR  A 510(k) statement
- The required certification and summary for class III devices
- The indication for use form (required for originals received 1-1-96 and after)
- Material of Biological Origin  YES  NO

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

- No Confidentiality
- Confidentiality for 90 days
- Continued Confidentiality exceeding 90 days

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

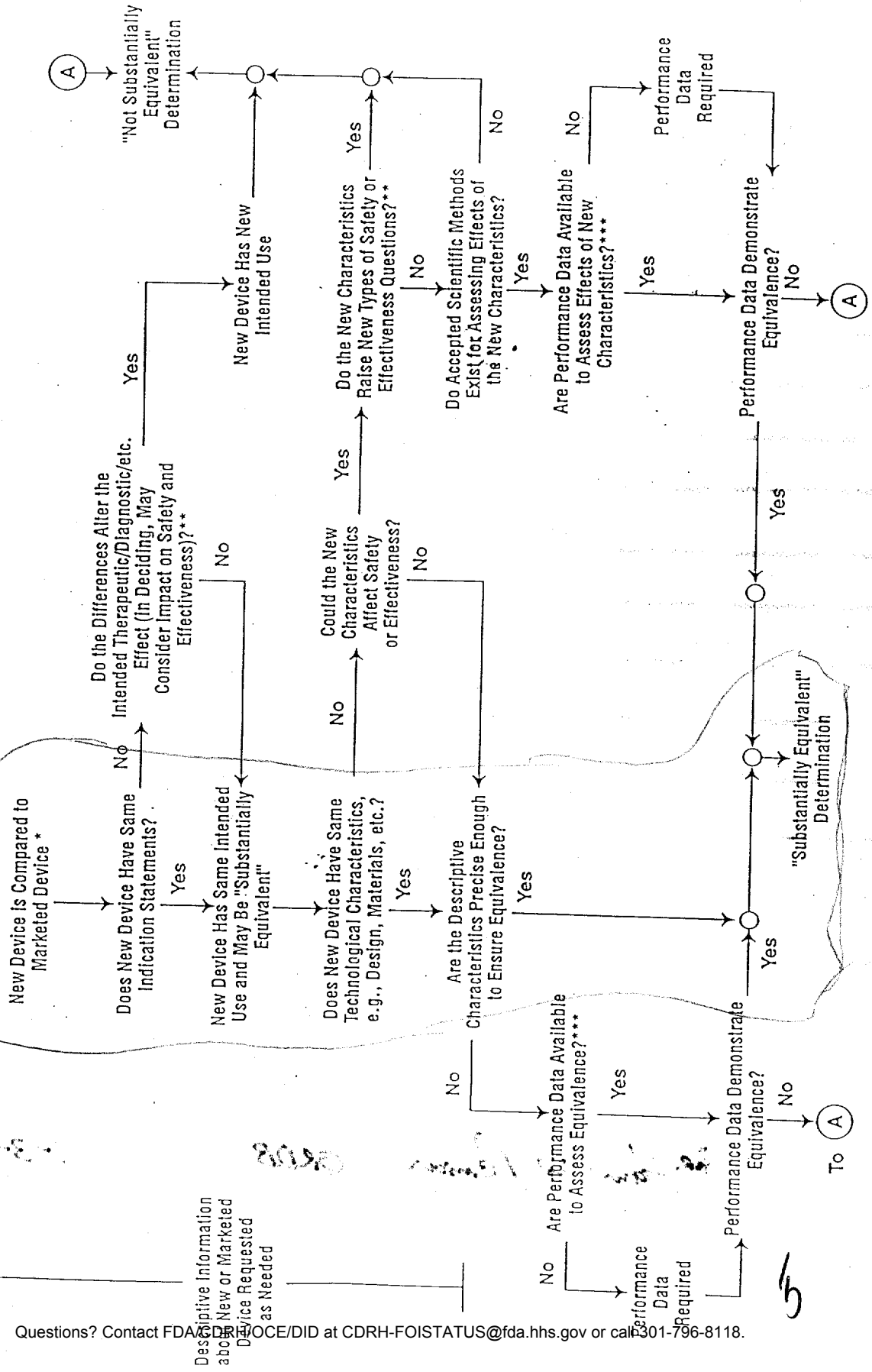
HSH, II

Review: for Harry W. Remiar GRDB 1-3-01  
(Branch Chief) (Branch Code) (Date)

Final Review: Mark N. Melkers 1/4/01  
(Division Director) (Date)

Revised: 8/17/99

# 510(k) "Substantial Equivalence" Decision-Making Process (Detailed)



Descriptive Information about New or Marketed Device Requested as Needed

\* 510(k) Submissions Compare New Devices to Marketed Devices. FDA Requests Additional Information on the Relationship Between Marketed and "Predicate" (Pre-Amendment or Reclassified Post-Amendments) Devices is Unclear.

\*\* This Decision is Normally Based on Descriptive Information Alone, But Limited Information is Sometimes Required.

\*\*\* Data May include the 510(k), Other 510(k)s, The Center's Classification Files, or the Literature.

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510(k) MEMORANDUM

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**TO:** K003269  
**FROM:** Peter G. Allen, Biomedical Engineer, M.S.  
FDA/CDRH/ODE/DGRND/Orthopedic Devices Branch  
**DATE:** December 8, 2000  
**SUBJ:** **Unicondylar Interpositional Spacer**  
Product Code: HSH, 87; 21 CFR 888.3590; Class II  
**Company: Sulzer Orthopedics, Inc.**  
Contact: Mitchell Dhority, Manager or Regulatory & Clinical Affairs  
Phone: (512) 432-9202 Fax: (512) 432-9291

---

**Recommendation:**

Based on similarities in design, materials, method of fixation, and intended use, I recommend that this device be found substantially equivalent (SE) to other legally marketed pre-amendments predicate devices.

**Review:**

1. **Administrative Requirements:**

Notification contains a 510(k) Summary, Indications for Use page, and a Truthful and Accuracy statement.

**EXPLANATIONS OF "YES" ANSWERS TO QUESTIONS 4, 6, 8, and 11 AND EVERY NO RESPONSE ON "SE" DECISION MAKING CHECKLIST AS NEEDED:**

Questions 4, 6, 8, and 11 are not applicable. See the SE Decision Making Checklist. There were no "No" responses.

2. **Device Description:**

The Unicondylar Interpositional Spacer (UIS) is intended to be placed in the medial joint space between the femoral and tibial condyles in patients with moderate chondromalacia. It was developed as an alternative to medication therapies, arthroscopy, high tibial osteotomy, and knee arthroplasty treatments for those situations where limited degeneration/joint destruction exists. The ability to provide 5, 10, or 15 years of non-total knee joint replacement that does not interfere with the subsequent conversion to a total knee implant is ideal. The UIS is designed to fill this interim therapeutic option. This device provides for a progressive approach to therapy. The UIS can be revised in its own right by using progressively thicker inserts and at any subsequent time can be converted to a primary total knee prosthesis when indicated. The UIS does not require any bone resection, even upon revision to a thicker version. This facilitates the eventual conversion to a primary total knee and enhances the potential for success of that treatment.

The surgical objective of the UIS is to:

- correct varus malalignment by filling the void created by lost articular cartilage
- redistribute load off of the damaged articular cartilage by recreating a conformal articular surface
- divorce the femoral and tibial surfaces and essentially eliminate motion against the tibial plateau
- eliminate the mechanical instability of the joint by reestablishing the proper tension in and the alignment of the medial collateral ligament (MCL)

The device will be manufactured from either wrought cobalt chrome alloy (ASTM F1537) or forged cobalt chrome alloy (ASTM F799). The design is kidney shaped to mimic that of the medial tibial condyle, which allows it to nest within the remaining meniscus. The shallow dish geometry allows for articulation with the femur. It is asymmetric (left and right components) and is available in seven sizes (30 -54mm) and five thicknesses (1 - 5mm) to better restore joint alignment, tension and stability.

The UIS is placed into the joint space above the affected medial tibial plateau. The femur then articulates against the polished, curved surface of the device. The device is intended to be used without cement and is held in place by its geometry, the compressive force between the femur and tibia, and the surrounding soft tissue structures.

3. **Intended Use:**

The Unicondylar Interpositional Spacer is intended for uncemented use in treatment of the following:

- Moderate degeneration of the medial compartment of the knee (grade III-IV chondromalacia) with no more than minimal degeneration (grade I-II chondromalacia, no loss of joint space) in the lateral condyle and patellofemoral compartments.

**4. Sterilization:**

All components are provided sterile.

Method: minimum of 25 kGy (range 25 – 35) of gamma radiation

Sterility Validation Method: AAMI/ISO TIR No. 13409-1996, "Sterilization of Health Care Products – Radiation Sterilization – Substantiation of 25 kGy as a Sterilization Dose for Small or Infrequent Production Batches".

Sterility Assurance Level:  $10^{-6}$

Description of packaging: The packaging consists of two nesting PETG plastic trays. Each tray is heat-sealed with a Tyvek lid. ARO burst tests are performed. The trays are inserted into a box and shrink wrapped.

Pyrogenicity: Products are not labeled as "pyrogen free" and orthopedic implants are not required to be nonpyrogenic.

Recommended re-sterilization method: not recommended (see package insert)

**5. Labeling:**

Appropriate representative package labels and a package insert were provided for the components in exhibits 9 and 8, respectively.

**6. Testing:**

Fatigue testing was conducted using worst-case conditions (e.g. combination of size and in-vivo load that results in earliest failure). (b)(4) Confidential and Proprietary Information - previously determined by FEA, was subjected to a condylar (b)(4) Confidential and Proprietary The spacers were mounted such that only perimeter support was provided. The spacers were then fatigue tested for ten million cycles similar to the method described in ASTM F1800-97. All six spacers survived the fatigue load without fracture of failure. Component fracture is not expected to be a problem. (b)(4) Confidential and Proprietary

(b)(4) Confidential and Proprietary Information - Testing information - Testing

**7. Sponsor's information in support of SE:**

McKeever Hemiarthroplasty Prosthesis, Pre-amendments, Howmedica  
MacIntosh Hemiarthroplasty Prosthesis, Pre-amendments, Howmedica  
Sbarbaro Tibial Plateau Prosthesis, Pre-amendments, Zimmer Inc.

**8. Review of 510(k)s for SE:**

None.

**9. Summary:**

The subject and predicate devices are similar in terms of design, materials, and indication for use. All designs are unicondylar and incorporate a semicircular metallic tibial resurfacing component in varying thicknesses and sizes. These devices are all intended for use without bone cement. Like the MacIntosh prosthesis the UIS is held in place mainly by its geometry and surrounding musculature. Filling the joint space restores joint alignment, stability, and the correct tension to the collateral ligament. Published clinical literature on the predicate devices is included in Exhibits 11 – 16 and 19. I recommend that the subject device be found substantially equivalent to the pre-amendments predicate devices.

**10. Contact History/Requests for More Information:**

None.

Peter G. Allen, Biomedical Engineer  
FDA/CDRH/DGRND/ORDB  
December 8, 2000

*Peter G. Allen*

## Screening Checklist

### For all Premarket Notification 510(k) Submissions

<b>Device Name:</b> <i>Unicondylar Interpositional Spacer</i>						K003269					
<b>Submitter (Company):</b> <i>Sulzer Orthopedics, Inc.</i>											
<b>Items which should be included</b> <i>(circle missing &amp; needed information)</i>						S P E C I A L	A B B R E V I A T E D		T R A D I T I O N A L	✓ IF ITEM IS NEEDED AND IS MISSING	
						YES	NO	YES	NO	YES	NO
<b>1. Cover Letter clearly identifies Submission as:</b>											
a) "Special 510(k): Device Modification"										X	
b) "Abbreviated 510(k)"											
c) Traditional 510(k)						GO TO # 2,3		GO TO # 2,4,5		GO TO #2, 5	
<b>2. GENERAL INFORMATION: REQUIRED IN ALL 510(K) SUBMISSIONS</b>											
✓ IF ITEM IS NEEDED											
<b>Financial Certification or Disclosure Statement for 510(k)s with a Clinical Study 807.87(i)</b>						NA		YES		NO	
						SPECIALS		ABBREVIATED		TRADITIONAL	
						YES	NO	YES	NO	YES	NO
						AND IS MISSING					
a) trade name, classification name, establishment registration number, device class											
b) OR a statement that the device is not yet classified						FDA-may be a classification request; see coordinator					
c) identification of legally marketed equivalent device						NA					
d) compliance with Section 514 - performance standards						NA					
e) address of manufacturer											
f) Truthful and Accurate Statement											
g) Indications for Use enclosure											
h) SMDA Summary or Statement (FOR ALL DEVICE CLASSES)											
i) Class III Certification & Summary (FOR ALL CLASS III DEVICES)											
j) Description of device (or modification) including diagrams, engineering drawings, photographs, service manuals											
k) Proposed Labeling:											
i) package labeling (user info)											
ii) statement of intended use											
iii) advertisements or promotional materials											
i) MRI compatibility (if claimed)											
l) Comparison Information (similarities and differences) to named legally marketed equivalent device (table preferred) should include:											
i) Labeling											
ii) intended use											
iii) physical characteristics											
iv) anatomical sites of use											
v) performance (bench, animal, clinical) testing						NA					
vi) safety characteristics						NA					
m) If kit, kit certification											
<b>3. "SPECIALS" - ONLY FOR MODIFICATIONS TO MANUFACTURER'S OWN CLASS II, III OR RESERVED CLASS I DEVICE</b>											
a) Name & 510(k) number of legally marketed (unmodified) predicate device											
b) STATEMENT - INTENDED USE AND INDICATIONS FOR											* If no - STOP not a special

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<b>USE OF MODIFIED DEVICE AS DESCRIBED IN ITS LABELING HAVE NOT CHANGED*</b>				
<b>c) STATEMENT - FUNDAMENTAL SCIENTIFIC TECHNOLOGY OF THE MODIFIED DEVICE HAS NOT CHANGED*</b>			* If no - STOP not a special	
<b>d) Design Control Activities Summary</b>				
i) Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis				
ii) Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria to be applied				
iii) A declaration of conformity with design controls. The declaration of conformity should include:				
1) A statement signed by the individual responsible, that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met				
2) A statement signed by the individual responsible, that manufacturing facility is in conformance with design control procedure Requirements as specified in 21 CFR 820.30 and the records are available for review.				

	SPECIALS		ABBREVIATED		TRADITIONAL		✓ IF ITEM IS NEEDED AND IS MISSING
	YES	NO	YES	NO	YES	NO	
<b>4. ABBREVIATED 510(K): SPECIAL CONTROLS/CONFORMANCE TO RECOGNIZED STANDARDS - PLEASE FILL OUT THE STANDARDS ABBREVIATED FORM ON THE H DRIVE</b>							
a) For a submission, which relies on a guidance document and/or special control(s), a summary report that describes how the guidance and/or special control(s) was used to address the risks associated with the particular device type							
b) If a manufacturer elects to use an alternate approach to address a particular risk, sufficient detail should be provided to justify that approach.							
c) For a submission, which relies on a recognized standard, a declaration of conformity to the standard. The declaration should include the following:							
i) An identification of the applicable recognized consensus standards that were met							
ii) A specification, for each consensus standard, that all requirements were met, except for							

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inapplicable requirements or deviations noted below			
iii) An identification, for each consensus standard, of any way(s) in which the standard may have been adapted for application to the device under review, e.g., an identification of an alternative series of tests that were performed			
iv) An identification, for each consensus standard, of any requirements that were not applicable to the device			
v) A specification of any deviations from each applicable standard that were applied			
vi) A specification of the differences that may exist, if any, between the tested device and the device to be marketed and a justification of the test results in these areas of difference			
vii) Name/address of test laboratory/certification body involved in determining the conformance of the device with applicable consensus standards and a reference to any accreditations for those organizations			
d) Data/information to address issues not covered by guidance documents, special controls, and/or recognized standards			

5. Additional Considerations: (may be covered by Design Controls)							
a) Biocompatibility data for all patient-contacting materials, OR certification of identical material/formulation:							
i) component & material							
ii) identify patient-contacting materials							
iii) biocompatibility of final sterilized product							
b) Sterilization and expiration dating information:							
i) sterilization method							
ii) SAL							
iii) packaging							
iv) specify pyrogen free							
v) ETO residues							
vi) radiation dose							
c) Software validation & verification:							
i) hazard analysis							
ii) level of concern							
iii) development documentation							
iv) certification							

Items shaded under "NO" are necessary for that type of submission. Circled items and items with checks in the "Needed & Missing" column must be submitted before acceptance of the document.

Passed Screening  Yes  No  
 Date: 12/7/00

Reviewer: Peter G. Allen  
 Concurrence by Review Branch: [Signature]

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REVISED:3/14/95

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

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

Reviewer: K003269  
Peter Allen  
 Division/Branch: DGRND/ORDB  
 Device Name: Unicondylar Interpositional Spacer  
 Product To Which Compared (510(K) Number If Known): Pre-amendments

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

Note: In addition to completing the form on the LAN, "yes" responses to questions 4, 6, 8, and 11, and every "no" response requires an explanation. Questions 4, 6, 8, and 11 are not applicable, see above. There were no "No" responses.

//



1. Intended Use:

*See Memo*

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

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

1. Explain why not a device:
2. Explain why not subject to 510(k):
3. How does the new indication differ from the predicate device's indication:
4. Explain why there is or is not a new effect or safety or effectiveness issue:
5. Describe the new technological characteristics:
6. Explain how new characteristics could or could not affect safety or effectiveness:
7. Explain how descriptive characteristics are not precise enough:
8. Explain new types of safety or effectiveness questions raised or why the questions are not new:
9. Explain why existing scientific methods can not be used:
10. Explain what performance data is needed:
11. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

**ATTACH ADDITIONAL SUPPORTING INFORMATION**

## Internal Administrative Form

	YES	NO
1. Did the firm request expedited review?		X
2. Did we grant expedited review?		X
3. Have you verified that the Document is labeled Class III for GMP purposes?	N/A	A
4. If, not, has POS been notified?		
5. Is the product a device?	X	
6. Is the device exempt from 510(k) by regulation or policy?		X
7. Is the device subject to review by CDRH?	X	
8. Are you aware that this device has been the subject of a previous NSE decision?		X
9. If yes, does this new 510(k) address the NSE issue(s), (e.g., performance data)?	N/A	A
10. Are you aware of the submitter being the subject of an integrity investigation?		X
11. If, yes, consult the ODE Integrity Officer.		
12. Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #I91-2 and Federal Register 90N0332, September 10, 1991.	N/A	A

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

October 18, 2000

SULZER ORTHOPEDICS, INC.  
9900 SPECTRUM DR.  
AUSTIN, TX 78717  
ATTN: MITCHELL A. DHORITY

510(k) Number: K003269  
Received: 18-OCT-2000  
Product: UNICONDYLAR  
INTERPOSITIONAL  
SPACER

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

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

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

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

Sincerely yours,

Marjorie Shulman  
Consumer Safety Officer  
Premarket Notification Staff  
Office of Device Evaluation

K003369

# SULZERMEDICA

Sulzer Orthopedics Inc.

9900 Spectrum Drive  
Austin, Texas 78717

Phone 512 432 9900  
Clinical Affairs Fax 512 432 9251  
Regulatory Affairs Fax 512 432 9291

October 17, 2000

Office of Device Evaluation  
510(k) Document Mail Center (HFZ-401)  
Center for Devices and Radiological Health  
Food and Drug Administration  
9200 Corporate Boulevard  
Rockville, MD 20850

Subject: 510(k) Notification  
Unicondylar Interpositional Spacer

SK-2-D  
RECEIVED  
18 Oct 00 11 00  
FDA/CDRH/OCE/DID

Dear Sir/Madam:

In accordance with Section 510(k) of the Federal Food, Drug and Cosmetic Act, and in conformance with Title 21 of the Code of Federal Regulations Part 807 (21 CFR 807), Subpart E, this premarket notification is submitted for substantial equivalence determination for the Unicondylar Interpositional Spacer.

The information provided in this 510(k) supports the substantial equivalence to similar previously marketed devices. In addition, the information provided in this 510(k) conforms to the requirements specified in the FDA's guidance document of March 28, 1995, entitled, "Draft Guidance Document for the Preparation of Premarket Notification [510(k)] Application for Orthopaedic Devices."

A Truthful and Accurate Statement, a 510(k) Summary and the Indications for Use form have also been provided in the enclosed information.

### Confidentiality Statement

- Sulzer Orthopedics regards its intent to market this device as confidential commercial information and requests that the FDA not disclose the existence of this device or any subsequent supplements or amendments to this application.
- Sulzer Orthopedics has not disclosed its intent to market the device to scientists, market analysts, exporters or other individuals who are not paid consultants to Sulzer Orthopedics Inc.
- Neither the undersigned nor, to the best of his knowledge, anyone else has disclosed the company's intent to market the device to anyone except employees of Sulzer Orthopedics Inc.

OK  
H

15

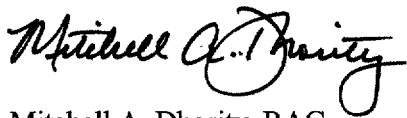
510(k) Notification  
Food and Drug Administration  
October 17, 2000  
Page L-2

- Sulzer Orthopedics has taken all reasonable and prudent precautions to protect the confidentiality of its intent to market the above-mentioned device.

We believe that this, along with the following information, fulfills your requirements for submission and would appreciate your earliest attention to this 510(k) notification.

Please do not hesitate to contact us if you have any questions regarding this matter.

Sincerely,



Mitchell A. Dhority, RAC  
Manager, Regulatory & Clinical Affairs

MD/ca

Enclosure

cc: Chris Peterson

# 510(k) NOTIFICATION

## UNICONDYLAR INTERPOSITIONAL SPACER

21 CFR Part 888.3590  
CLASS II

SUBMITTED BY:  
SULZER ORTHOPEDICS INC.

OCTOBER 17, 2000

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**I. Truthful and Accurate Statement**

The Truthful and Accurate Statement is provided as Exhibit 1.

**II. Administrative Information**

**A. Sponsor/Manufacturer Information**

Sulzer Orthopedics Inc.  
9900 Spectrum Drive  
Austin, TX 78717

**B. Establishment Registration No.**

2935620

**C. Official Contact Person**

Name: Mitchell A. Dhority  
Telephone number: 512-432-9202  
Fax Number: 512-432-9291

**D. Device Identification**

1. Trade/Proprietary Name

Unicondylar Interpositional Spacer

2. Common/Usual Name

Hemi-knee prosthesis

3. Classification Name

21 CFR 888.3590 - Knee joint tibial (hemi-knee) metallic resurfacing uncemented prosthesis

4. Device Classification

Class II

5. Device Product Code

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**III. Intended Use**

**A. *Specific Diagnostic Indications***

The Unicondylar Interpositional Spacer is intended for uncemented use in treatment of the following:

- Moderate degeneration of the medial compartment of the knee (grade III-IV chondromalacia) with no more than minimal degeneration (grade I-II chondromalacia, no loss of joint space) in the lateral condyle and patellofemoral compartments.

The Indications for Use form is provided in Exhibit 2.

**B. *Single Use/Reusable***

This device is intended for single use only.

**C. *Use with Other Cleared Devices***

This device is not intended to be used in combination with other cleared devices.

**IV. Device Description**

**A. *Background***

Clinically, there has always existed a need to address the special considerations of the arthritic knee. An erect bipedal posture imposes bio-mechanically complex motion and stress distribution on the knee joint. The high load condition and complex motion requirements of the normal knee place extraordinary stresses on this critical joint. Aging, disease and traumatic conditions dramatically alter the ability of the knee to withstand these otherwise normal physiologic requirements.

The knee is a complex compound joint capable of limited rotational movement and a constantly variable radius of rotation. The weight of the body is transmitted downward through the lower extremities to the ground. The knee passes the majority of this force through the medial condyle and medial portion of the tibial plateau. Thus, wear of the knee's articular surfaces is not uniform. Loss of hydration, disease, trauma and wear of the articular surfaces continually narrow the joint space of the knee. As the joint space narrows, laxity of the stabilizing ligaments supporting the knee occurs. Loss of stability leads to

additional wear and inflammation in a non-uniform fashion. A sequence is established that results in progressive successive cycles of degeneration and loss of function. Over time, significant deformity, severe pain and near complete loss of ambulatory ability result.

Historically, treatment for this progressive disability centered on rest, splinting, bracing, casting, anti-inflammatory agents, surgery and ultimately arthrodesis. This was the case until approximately 45 years ago.

The advent of modern high strength orthopedic implant materials altered the therapeutic approach to treating troublesome degenerative knee conditions. In the United States, three progressive surgeons (McKeever, MacIntosh and Sbarbaro) began implanting specially designed hemiarthroplasty knee prostheses. All three implant designs shared the common concepts of improved articular surfaces, restoration of proper joint spacing and attendant re-tensioning of the formerly lax knee ligaments. Two of the devices (McKeever & Sbarbaro) were stabilized by a keel or key inserted into a surgically created tibial plateau groove or notch. The remaining MacIntosh device was centered within a prepared tibial plateau bed. The geometry of the MacIntosh implant's articulating surface and dynamic re-tensioning of the knee ligaments stabilized the device in the joint.

All three devices predated the use of PMMA bone cement and effective total knee joint replacement devices.

The procedure to implant the keyed devices was exacting and relatively time consuming. If the keyway or notch was incorrect, even slightly, the articulating surfaces did not match optimally. Early device failure and re-operation resulted. The "keyless" MacIntosh device, though constrained, was capable of limited realignment of the articular surfaces during flexion and extension. Failure to establish ideal dynamic re-tensioning of the knee ligaments during implantation could lead to dislocation of the device and subsequent re-operation, including arthrodesis.

The patient population most in need of these devices was elderly with a significant degree of disability and deformity. Because the disease process was so advanced in many patients, maximum potential benefit was seldom realized. In fact, most of these patients were perhaps better suited to a total knee replacement, had one existed. Therapy was pointed primarily at the relief of pain and restoration of modest daily activities.

The advent of PMMA bone cement combined with modern implant materials changed this situation dramatically. For the first time, total joint replacement of the knee became a real alternative. Almost overnight, total joint replacement became the treatment of choice for this long-suffering patient population. The use of the hemiarthroplasty knee device essentially ceased in the early to mid 1970's.

The present patient population in need of knee restoration surgery has changed significantly. Today's knee patient is younger and more active with many patients suffering athletic related arthritic knee conditions. Even the finest total knee prostheses currently available are sometimes unable to withstand the demands of this patient population. Revision after 5-10 years of use is not uncommon. Many of these patients are under age 50, some much younger. With such highly active lifestyles, such patients face two or even three total knee replacement revision surgeries during the remainder of their lives. For most patients, repeated revision surgery on this scale is unlikely due to progressive bone loss at each additional surgery.

The need for the hemiarthroplasty knee implant has therefore come full circle. The ability to provide 5, 10, 15 or more years of non-total knee joint therapy that does not interfere with subsequent conversion to a total knee implant is ideal.

The Unicondylar Interpositional Spacer (UIS) is a device designed to fill this interim therapeutic option. Use of this device provides a progressive approach to therapy. The UIS implant can be revised in it's own right by using progressively thicker inserts. At any subsequent time, the UIS can be converted to a primary total knee prosthesis when and if indicated.

**B. *Subject Device Description***

Arthroscopic debridements have now become the routine treatment to address the pain and synovitis associated with early stage osteoarthritis with approximately half of the patients treated presenting with Grade III-IV chondromalacia. It is estimated that symptoms recur within 2 years in half of those patients who receive this form of treatment. While the effectiveness of arthroscopic debridement is quite variable, it is clear that it does not address the mechanical alignment and laxity problems associated with the joint.

Anti-inflammatory medication has also been used to manage joint pain, but has limited effectiveness on moderate arthritis and offers no solution in terms of repair to the joint structure.

As described previously, the use of other surgical options such as knee arthroplasty and high tibial osteotomy (HTO) are more invasive, technically challenging and may compromise the joint to future treatment options.

The Unicondylar Interpositional Spacer was developed as an alternative to medication therapies, arthroscopy, HTO and knee arthroplasty treatments for those situations where limited degeneration/joint destruction exists. Instead of simply debriding soft tissues as in arthroscopy or resecting valuable unaffected bone and cartilage as in total knee replacement, this treatment allows for placement of a metallic "spacer" device into the joint space above the affected medial tibial plateau. The femur then articulates against the polished, curved surface of device.

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The device is intended to be used without cement and is held in place by its geometry and the surrounding soft tissue structures. Further discussion lending to the inherent stability achieved with this design is provided in Exhibit 3.

The device will be manufactured from either wrought cobalt chromium alloy (ASTM F1537) or forged cobalt chrome alloy (ASTM F799). The design is kidney shaped to mimic that of the medial tibial condyle; the shallow "dished" geometry allows for articulation with the femur. It is asymmetric (left and right components) and is available in seven sizes (30-54mm) and five thicknesses (1-5mm) to better restore joint alignment, tension and stability.

The surgical procedure to place the device is carried out in two stages. First, the posterior horn of the meniscus is debrided and resected arthroscopically. The device may then be inserted into the joint space above the affected medial tibial plateau via open surgical implantation. A copy of the draft surgical technique is provided as Exhibit 4.

Use of this device provides several potential advantages over other surgical options, including:

- Technically easier to implant than a unicompartmental total knee, high tibial osteotomy or meniscal transplant.
- Facilitates future conversion to total knee arthroplasty by eliminating the need for bone resections.
- Is surgically less invasive (e.g. unicompartmental treatment, smaller incision, fewer implant components required, no bone resection required, no cement used).

**C. *Sizes***

The device is available in seven sizes (30-54mm) and five thicknesses (1-5mm) to better restore joint alignment, tension and stability. A list of sizes and catalog numbers is included as Exhibit 5.

**D. *References to Drawings***

Engineering drawings are included as Exhibit 6.

**E. *References to Photos***

Photos are provided as Exhibit 7.

**F. *Instrumentation***

Instrumentation to be included with this system includes an implant holder, trial prosthesis holder, depth/thickness gauges, and an extractor instrument.

**V. Materials**

**A. *Material Composition of Device***

The Unicondylar Interpositional Spacer will be manufactured from either wrought cobalt chromium alloy or forged cobalt chromium alloy.

**B. *Applicable Voluntary Standards***

- ASTM F799 Standard Specification for Cobalt-28 Chromium-6 Molybdenum Alloy Forgings for Surgical Implants
- ASTM F1537 Specification for Wrought Cobalt-28 Chromium-6 Molybdenum Alloy for Surgical Implants

**VI. Labeling/Promotional Materials**

**A. *Draft Physicians Insert***

A copy of the draft Physicians Inserts is included as Exhibit 8.

**B. *Draft Product Labeling***

A copy of the draft product labeling is included as Exhibit 9.

**VII. Additional Information**

**A. *Mechanical Testing - Fatigue Analysis***

Fatigue testing was conducted using worst-case conditions (e.g., combination of size and in-vivo load that results in earliest failure). The spacers were mounted such that only perimeter support was provided. The spacers were then fatigue tested for ten million cycles similar to the method described in ASTM F1800-97. All six spacers survived the fatigue load without fracture or failure. A copy of this report is provided as Exhibit 10.

**VIII. Sterility Information**

**A. *Sterilization Status***

This device will be provided sterile.

**B. Sterilization Method**

1. Sterilization Method

The component will be sterilized by a minimum of 25 kGy (range 25-35) of gamma radiation.

2. Sterilization Validation Method

Sterilization cycles are validated using AAMI/ISO TIR No. 13409-1996, "Sterilization of Health Care Products - Radiation Sterilization - Substantiation of 25 kGy as a Sterilization Dose for Small or Infrequent Production Batches".

3. SAL

Cycles are validated as stated above for a SAL of  $10^{-6}$ .

4. Pyrogenicity Statement

Product will not be labeled "pyrogen free".

**IX. Packaging Description**

Products are packaged using two nesting PETG plastic trays. Each tray is heat-sealed with Tyvek® inner lidding. A heat-sealed outer Tyvek lid follows the inner lidding process. Seal integrity is verified visually as well as by performing ARO burst tests. The packaged product is then placed inside a box and shrink-wrapped.

**X. Substantial Equivalence Determination**

**A. Predicate Comparison**

Substantial equivalence is based on comparison to the following devices relative to similarities in design, materials, intended use, and published clinical results pertaining to their safety and effectiveness:

- McKeever Hemiarthroplasty Prosthesis (Exhibit 11, 12, 13, 14, 15)
- MacIntosh Hemiarthroplasty Prosthesis (Exhibit 16)
- Sbarbaro Tibial Plateau Prosthesis (Exhibit 17)

A table comparing the design features of the subject and predicate devices is provided as Exhibit 18.

Design Features

The subject and predicate devices are similar in terms of design features. In general, all of these designs are unicondylar and incorporate a semicircular metallic

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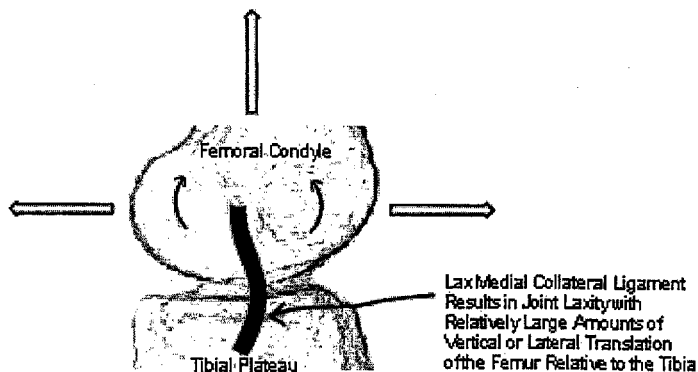


tibial resurfacing component in varying thicknesses and sizes. In each design, the femoral condyle articulates against the curved upper surface of the implant. These devices are intended for use without bone cement. The Unicompartamental Interpositional Spacer is similar to the MacIntosh prosthesis in that it does not rely on a fin for additional stabilization; the prosthesis is held in place mainly by its geometry and the surrounding musculature. The Unicompartamental Interpositional Spacer is similar to the McKeever prosthesis in that they both have a convex tibial surface.

### Stability

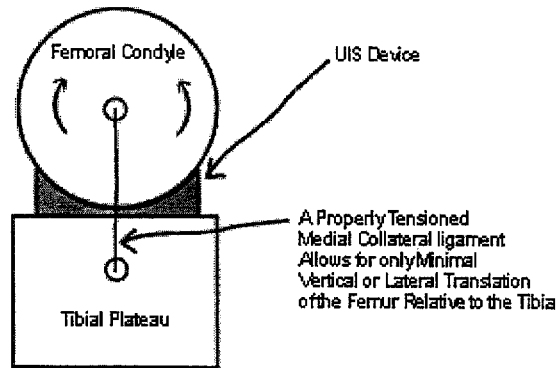
Like the MacIntosh tibial prosthesis, the Unicondylar Interpositional Spacer has no obvious means of attachment.

In the osteoarthritic knee, substantial amounts of articular cartilage have been lost as a result of the disease. The knee compartment suffers a subsequent closing of the joint spacing as seen on X-ray. This joint closing allows the collateral ligament to become lax and the joint to become unstable and off-axis (varus deformity). Whereas normal motion of the femoral condyle is largely rotational, if ligament laxity is present, there will be increased translational motion of the femur relative to the tibia



Filling the joint space that was once occupied by the now missing articular cartilage can restore the correct tension of the collateral ligament. When the proper thickness of the Unicondylar Interpositional Spacer is chosen, the tightening of the collateral ligament prevents any excessive translational motion of the femoral condyle. Thus, almost all of the forces against the Unicondylar Interpositional Spacer now become rotational and the Unicondylar Interpositional Spacer will have no forces acting on it that would cause it to "spit" from the joint space. The stability of the joint is restored.

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The surface geometry of the Unicondylar Interpositional Spacer also plays a significant role in its inherent stability.

MacIntosh (Exhibit 16) states "The collateral ligaments usually maintain their own length...and that the stability is maintained by a prosthesis that is thick enough to correct the deformity and take up the slack in the collateral ligaments". He further states that "The prosthesis is held in position by the anatomy of the knee joint, and stability depends on taut collateral ligaments. The top of the prosthesis has a contoured surface with rounded edges to provide the condyle with a permanent low friction area."

The Unicondylar Interpositional Spacer has a femoral surface geometry that imitates that of the tibial plateau including an intact meniscus. On the other side, the tibial surface of the Unicondylar Interpositional Spacer imitates the surface of the tibial plateau without the meniscus.

When the Unicondylar Interpositional Spacer is properly placed into the knee compartment, it rests inside the boundaries of the resected meniscus. It has substantially intimate contact with the tibial plateau throughout the entire range of motion. The femoral side of the Unicondylar Interpositional Spacer also has substantially full contact with the femoral condyle when the knee is in full extension.

Thus, when the knee is in full extension, the Unicondylar Interpositional Spacer can only be located in one position in the joint space as determined by the relative position of the femoral condyle to the tibial plateau.

As the knee is flexed and the femoral condyle begins to rotate, since the collateral ligaments remain under tension, the posterior aspect of the femoral condyle remains in contact with the central weight-bearing surface of the UIS

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Materials

The subject and predicate devices are similar in terms of materials used. All of these designs use cobalt chrome alloy.

Intended Use

Additionally, the subject and predicate devices share similar indications for use. The subject device, like the predicate devices, are used generically in the treatment of moderate/severe unicompartmental tibial arthritis to relieve pain, restore stability and correct deformity in cases where total knee replacement is not warranted.

Clinical Safety & Effectiveness

The published clinical literature on the predicate devices (Exhibits 11-16) was reviewed and tabulated (Exhibit 19).

As indicated in the proposed labeling/Physicians Insert, the known potential risks associated with these devices are essentially of the same type and frequency as unicompartmental or total knee replacement, arthroscopy and others. As shown in the publications associated with the predicate devices, these risks include hematoma, infection, nerve palsy, embolus, dislocation, fracture and need for revision. As with the other orthopedic options, these risks are mitigated through appropriate warnings in the labeling as well as through proper training for the surgeon.

The history with the predicate devices also indicates that the effectiveness of this treatment is at least equal to that obtained with osteotomy or arthroplasty in terms of pain relief, correction of deformity and restoration of stability. Furthermore, it provides some added benefits, which cannot be recognized with these current treatments (e.g., ease of implantation, ease of conversion to other treatments, less invasive).

**XI. 510(k) Summary**

The 510(k) summary is included as Exhibit 20.

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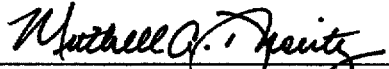
# EXHIBIT 1

**PREMARKET NOTIFICATION**

**TRUTHFUL AND ACCURATE STATEMENT**

**(As Required By 21 CFR 807.87(j))**

I certify that, in my capacity as Manager of Regulatory & Clinical Affairs at Sulzer Orthopedics Inc., to the best of my knowledge that reasonable efforts have been made to ensure that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

  
\_\_\_\_\_  
Mitchell A. Dhority, RAC

  
\_\_\_\_\_  
Dated

\_\_\_\_\_  
[Premarket Notification (510(k)) Number]

# EXHIBIT 2

510(k) Number (if known): 003269

Device Name: Unicondylar Interpositional Spacer

### Indications for Use:

The Unicondylar Interpositional Spacer is intended for uncemented use in treatment of the following:

- Moderate degeneration of the medial compartment of the knee (grade III-IV chondromalacia) with no more than minimal degeneration (grade I-II chondromalacia, no loss of joint space) in the lateral condyle and patellofemoral compartments.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use \_\_\_\_\_

OR

Over-The-Counter Use \_\_\_\_\_

(Optional Format 1-2-96)

# EXHIBIT 3







# EXHIBIT 4

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**DRAFT - DRAFT - DRAFT**

**OPERATIVE TECHNIQUE FOR THE UNICONDYLAR  
INTERPOSITIONAL SPACER**

Currently, there is a void in options used to treat relatively young patients with **moderate to severe chondromalacia** involving mainly the **medial compartment** of the knee.

Articular cartilage and meniscal cartilage provides the mobile weight bearing surfaces of the knee joint. Damage to these surfaces is generally due to

- Genetic predisposition,
- Trauma,
- And/or aging.

The result of such damage is usually the

- Development of chondromalacia,
- Thinning and softening of the articular cartilage, and
- Degenerative tearing of the meniscal cartilage.
- Secondary osteophyte formation along the femoral condyle and tibial plateau that functionally shortens the medial collateral ligament.
  - These combined changes in the medial compartment result in varus malalignment with alteration in joint loading. (Figures 1, 1A)

Various methods of treatment are available to treat these disease processes. Each option usually has specific indications and is accompanied by a list of benefits and deficiencies that may be compared to other options.

- Some patients cannot tolerate or do not want the risk or potential side effects of NSAIDs.
- Repeated cortisone injections actually weaken articular cartilage after a long period of time.
- Arthroscopic debridement alone frequently does not provide long-lasting relief of symptoms.
- High tibial osteotomy (HTO) corrects the varus malalignment between the tibia and femur but since it is performed below the joint line, it does not fill the cartilage void or re-tension the medial collateral ligament (MCL). Removing bone and changing the joint line does not complicate the conversion to TKA. However, a HTO does leave a hard sclerotic region of bone which is difficult to penetrate making conversion to a total knee replacement (TKR) technically challenging.
- Unicompartmental and bi-compartment total knee replacements resect significant amounts of bone and, if performed on younger patients, will likely require revision surgery as they age.
- Revision total knee replacement surgery is usually extensive and results in predictably diminished mechanical life expectancy.
  - Therefore, it is best to delay this type of bone resecting surgery as long as possible.

**The surgical objective** of UNICONDYLAR INTERPOSITIONAL SPACER (UIS) is to

- Correct the varus malalignment by filling the void created by lost articular cartilage,
- Redistribute load off of the damaged articular cartilage by recreating a conformal articular surface,
- Divorces the femoral and tibial surfaces and essentially eliminates motion against the tibial plateau and
- Eliminate the mechanical instability of the joint by reestablishing the proper tension in and the alignment of the medial collateral ligament (MCL)

It accomplishes this **without resecting bone or attaching the device** with screws, keels, or methyl-methacrylate adhesive.

**The procedure** outlined below will describe how the **major problems** associated with knee joint degeneration are **corrected with the UIS** without creating some of the concerns associated with previously described alternative medication and surgical solutions.

## **OPERATIVE PROCEDURE**

**The operative procedure** begins with an initial arthroscopic evaluation followed by insertion of the Unicondylar Interpositional Spacer (UIS) via a small median parapatellar arthrotomy.

- After routine preoperative preparation the patient is brought into the operating room and placed on a standard operating table in the supine position. A knee post may be used to aid in exerting a valgus stress during the procedure.
- Preoperative prophylactic antibiotic treatment should precede inflation of a tourniquet or, if a tourniquet is not used, initiation of the surgical procedure.
- The patient is prepped and draped in a routine fashion for a standard arthroscopy and arthrotomy.
- The planned arthroscopy portals, the planned arthrotomy incision, and the intra-articular space are all infiltrated with Marcaine with epinephrine.
- Initial arthroscopic evaluation and debridement is performed prior to insertion of the UIS.
  - Standard arthroscopic portals are used for introduction of the arthroscope into the knee.
  - An initial inspection of the whole joint is followed by the arthroscopic debridement.
  - Particular attention to the femoral condyles, menisci, and weight-bearing surface of the tibial plateau is necessary to assess the knee for appropriate indications for use of the UIS. The indications and contraindications are located in the Physicians Insert included with the component packaging; a copy is also provided at the end of this technique for reference (Figure 2)
  - Resection of the leading edge of the posterior and middle thirds of the meniscus is necessary to allow proper seating of the implant on the tibial plateau. (Figures 3, 4)

- Resection of degenerative tears of the meniscus, arthroscopic debridement of the femoral condyle and tibial plateau can also be performed to prepare the knee for insertion of the UIS.
- There is one instrument (that functions as two instruments) in the set that can now be used for assessment of implant size and thickness.
  - The **Thickness Gauge** (Figure 5) is made of a semi-rigid Delrin and comes in various thicknesses that correspond to the available thicknesses of the UIS. The device is inserted while the knee is in flexion, through the anterior arthroscopy portal between the weight bearing surfaces of the tibial and the femoral condyle. While the gauge remains in position, the knee is gently brought into extension. A snug fit without undo force on the gauge determines the best fit. This instrument allows the surgeon to select one of the offered thicknesses.
  - The **Sizing Gauge**, (Figure 6) etched onto the surface of the thickness gauge, is demarcated into divisions representative of the various length sizes of the UIS. It is also placed through the anterior portal and is gently pushed up against the posterior rim of the meniscus, while maintaining its course under the most distal portion of the femoral condyle. The gauge is then measured against the anterior, leading edge of the meniscus. This anterior-posterior measurement is used to select the correct implant size. These two measurements together are used to select the initial trial implant. See Figure.
- Our research has shown a definitive correlation of the radius of curvature of the femoral condyle to the length and width of the device. Thus, **only an intra-operative length and thickness measurement are required for proper sizing of the UIS.**
- **After the arthroscopic portion of the procedure is completed, a standard median parapatellar arthrotomy is necessary to insert the implant.** For any surgeon who trained or practiced before 1980, this portion of the procedure will be a walk down memory lane.
  - A longitudinal incision three to four centimeters long is placed parallel to the patellar tendon. If there is a previous open menisectomy scar from one of our older colleagues, this could be used for placement of the incision. The subcutaneous tissue is dissected down to the joint capsule, which is incised along the same axis as the incision.
  - A knee retractor can then be placed into the incision. This should provide stable visualization of the medial compartment of the knee.
  - Osteophytes should then be removed from the medial femoral condyle and from the medial tibial plateau.
    - This allows the medial collateral ligament to return to its original length. The combination of loss of articular cartilage thickness and restoration of MCL length will produce instability and allow shear stress on the articular surface of the joint. If there is contracture of the MCL, a recession of the collateral ligament can be performed to release the contracture and ease the insertion of the UIS.
- **Trial sizing**, once adequate exposure has been obtained, can be performed prior to insertion of the actual device. The best-fit selection can be confirmed by sizing up or down from the preoperatively preselected size. **The same instruments are used for insertion and removal of the trials and the final implant.** The insertion handle fits over the **non-removable peg** on

the anterior edge of the **trial**. The handle comes off the peg at a 60-degree angle and may be rotated 360 degrees on the axis of the peg. This feature allows the surgeon to insert or remove the trial from any angle, which is especially important when previously existing scars must be utilized, as is often the case.

- **Insertion of the trial UIS** is quite simple.
  - The knee is **flexed** to approximately **50 degrees** and opened medially with the application of a **slight valgus** stress.
  - The trial is then placed as far into the knee as possible, **up against the posterior rim of the meniscus, adjacent to the femoral condyle**.
  - **While holding the trial in position against the femoral condyle apply an increasing amount of valgus stress as the knee is brought into extension.**
    - With a palpable release the posterior edge of the trial seats behind the femoral condyle.
    - Remove the insertion tool by loosening the clamping knob.
- Fit and stability are confirmed by placing the knee in flexion and extension with varus, valgus, and rotational forces applied to the joint.
  - Properly fitted, the knee will be able to **easily achieve** full extension through 120 degrees of flexion with minimal movement of the UIS
    - Inability to easily achieve full extension could indicate that the trial is too thick or that there are still osteophytes present which need to be removed.
    - Significant translation (>1mm) of the UIS through the range of motion indicates too thin a UIS or too small a length
    - Overhang of the UIS over the anterior portion of the meniscus indicates too long a UIS selection, insufficient removal of the posterior meniscus or meniscal or articular cartilage fragments present in the joint space.
  - The **lateral stability** of the joint should now approximate that of a normal, healthy Knee (Figure 7)
  - The femur should now have a neutral to slightly valgus relationship to the tibia (Figure 8)
  - To insure the **proper length** of the UIS, a **C-arm** is used to radiographically inspect the size in relation to the bony landmarks. A **true lateral image with femoral condyles superimposed** is the best view to assess anterior-posterior length. See Figure. **It is very difficult to assess proper length of implant by visual inspection.**
    - Proper length sizing will ensure that the UIS sits inside the boundaries of the trimmed meniscus and does not overhang the medial boundary of the tibial plateau. (Figure 9, 10)

- To **remove the trial**,
  - Reattach the insertion handle to the peg of the trial,
  - Reapply the valgus stress with the knee in extension, and,
  - While maintaining the valgus stress, flex the knee to approximately 50 degrees and remove the trial with continuous, gentle pulling
- **Insertion of the actual UIS implant**
  - Once the correct size and thickness have been confirmed, the UIS is now inserted in a similar fashion.
    - The **peg** on the anterior aspect of the actual UIS implant is **removable** and it **MUST** be removed.
    - An additional instrument that is similar to the insertion tool is used to unscrew the peg from the device and remove it from the knee. The peg removal instrument, slips over the peg and removes it from the UIS implant in a ratcheting fashion. The tool captures the peg during this motion and minimizes the risk of dropping the removed peg into the operative area.
    - Properly fitted, the knee will be able to **easily achieve** full extension through 120 degrees of flexion with minimal movement of the UIS
      - Inability to easily achieve full extension could indicate that the trial is too thick or that there are still osteophytes present which need to be removed.
      - Significant translation (>1mm) of the UIS through the range of motion indicates too thin a UIS or too small a length
      - Overhang of the UIS over the anterior portion of the meniscus indicates too long a UIS selection, insufficient removal of the posterior meniscus or meniscal or articular cartilage fragments present in the joint space.
    - The **lateral stability** of the joint should now approximate that of a normal, healthy Knee (Figure 7)
    - The femur should be now have a neutral to slightly valgus relationship to the tibia (Figure 8)
    - To insure the **proper length** of the UIS, a **C-arm** is used to radiographically inspect the size in relation to the bony landmarks. A **true lateral image with femoral condyles superimposed** is the best view to assess anterior-posterior length. See Figure. **It is very difficult to assess proper length of implant by visual inspection.**
      - Proper length sizing will ensure that the UIS sits inside the boundaries of the trimmed meniscus and does not overhang the medial boundary of the tibial plateau. (Figure 9, 10)
  - **Closure** of the arthrotomy involves closing the capsule, subcutaneous tissue, and skin in layers using routine technique. A Hemovac drain may be placed into the knee prior to wound closure. The leg is then placed in a large cotton dressing and the tourniquet is deflated.



## **POSTOPERATIVE PROTOCOL**

The postoperative care for the UIS will be very similar to that for any arthrotomy of the Knee.

- Prophylactic antibiotics should be used for approximately 24 hours.
- The Hemovac drain can be removed at any point in the first 24 hours when drainage subsides.
- A leg immobilizer should be used until the bulky cotton dressing is removed
- Physical therapy can be initiated for crutch training with toe touch weight bearing.
- Quadriceps setting exercises and straight leg lifts should be started while the bulky cotton dressing is in place.
- The bulky cotton dressing can be removed after 24-48 hours.
- Once this is off, the patient may begin range of motion exercise.
- Cold therapy should also begin after the bulky cotton dressing is removed.
- Oral analgesic medication can be used for pain control.
- There is no contra indication to the use of nonsteroidal anti-inflammatory medication as well.

# EXHIBIT 5

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**UNICOMPARTMENTAL INTERPOSITIONAL SPACER  
SIZES/CATALOG NUMBERS**

Size	Thickness	Side	Catalog No.
30mm	1mm	L	6200-20-301
		R	6200-30-301
	2mm	L	6200-20-302
		R	6200-30-302
	3mm	L	6200-20-303
		R	6200-30-303
	4mm	L	6200-20-304
		R	6200-30-304
	5mm	L	6200-20-305
		R	6200-30-305
34mm	1mm	L	6200-20-341
		R	6200-30-341
	2mm	L	6200-20-342
		R	6200-30-342
	3mm	L	6200-20-343
		R	6200-30-343
	4mm	L	6200-20-344
		R	6200-30-344
	5mm	L	6200-20-345
		R	6200-30-345
38mm	1mm	L	6200-20-381
		R	6200-30-381
	2mm	L	6200-20-382
		R	6200-30-382
	3mm	L	6200-20-383
		R	6200-30-383
	4mm	L	6200-20-384
		R	6200-30-384
	5mm	L	6200-20-385
		R	6200-30-385
42mm	1mm	L	6200-20-421
		R	6200-30-421
	2mm	L	6200-20-422
		R	6200-30-422
	3mm	L	6200-20-423
		R	6200-30-423
	4mm	L	6200-20-424
		R	6200-30-424
	5mm	L	6200-20-425
		R	6200-30-425

CONTINUED ON NEXT PAGE

40

46mm	1mm	L	6200-20-461
		R	6200-30-461
	2mm	L	6200-20-462
		R	6200-30-462
	3mm	L	6200-20-463
		R	6200-30-463
	4mm	L	6200-20-464
		R	6200-30-464
	5mm	L	6200-20-465
		R	6200-30-465
50mm	1mm	L	6200-20-501
		R	6200-30-501
	2mm	L	6200-20-502
		R	6200-30-502
	3mm	L	6200-20-503
		R	6200-30-503
	4mm	L	6200-20-504
		R	6200-30-504
	5mm	L	6200-20-505
		R	6200-30-505
54mm	1mm	L	6200-20-541
		R	6200-30-541
	2mm	L	6200-20-542
		R	6200-30-542
	3mm	L	6200-20-543
		R	6200-30-543
	4mm	L	6200-20-544
		R	6200-30-544
	5mm	L	6200-20-545
		R	6200-30-545

# EXHIBIT 6

48





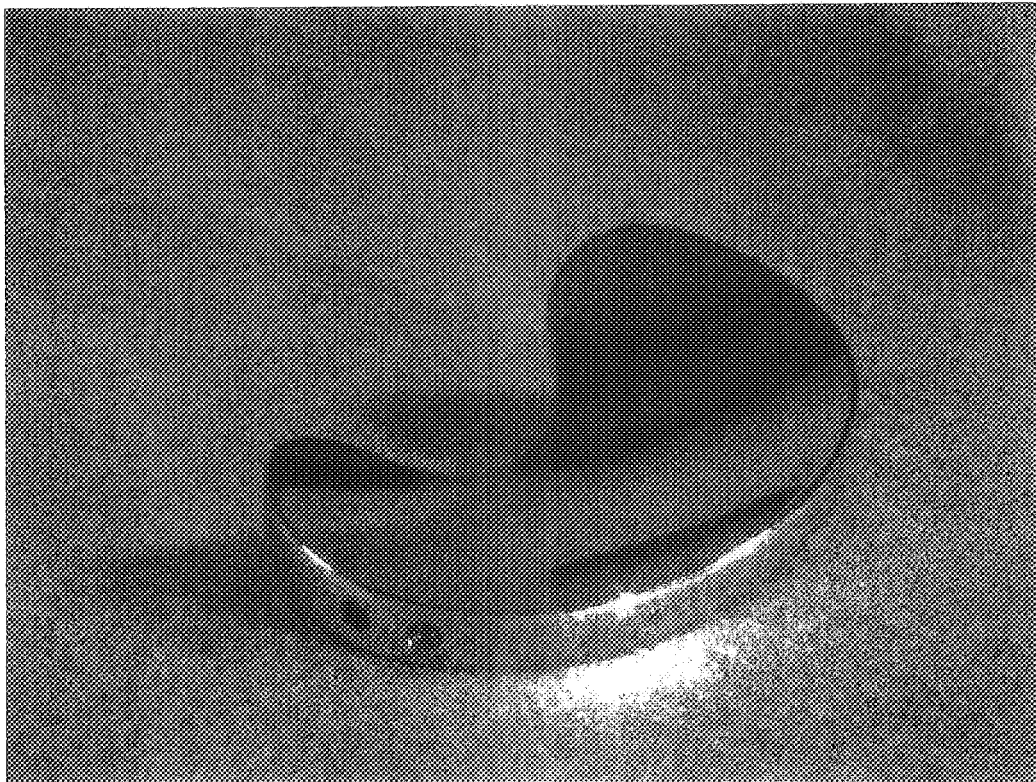






# EXHIBIT 7

**Sulzer Orthopedics  
Unicondylar Interpositional Spacer**



# EXHIBIT 8

2700??

**SULZER MEDICA**  
Sulzer Orthopedics Inc.

CE 0123

<b>Manufacturer:</b>	<b>Distributor:</b>	<b>Authorized EC Representative</b>
9900 Spectrum Drive	Sulzer Orthopedics Ltd.	Sulzer Orthopädie Ges.m.b.H.
Austin, Texas 78717	Grabenstrasse 25	Enzersdorferstrasse 12a
(512) 432-9900	CH-6341 Baar, Switzerland	A-2340 Mödling b. Wien, Austria
Toll Free 800-888-4676	+41(0)41-768-3232	

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

## UNICONDYLAR INTERPOSITIONAL SPACER

### Description of Prosthesis

The Interpositional Spacer is a unicondylar device intended to be placed in the medial joint space between the femoral and tibial condyles in patients with moderate chondromalacia. The component is kidney shaped to allow it to nest within the remaining meniscus. The device articulates directly with the existing tibiofemoral anatomy. Stability is achieved without mechanical fixation via the geometry of the device as well as the surrounding soft tissue structures. The component is available in a variety of sizes and thicknesses and is manufactured from forged cobalt-chrome alloy (CoCr, ASTM F799 or ISO 5832-12).

### Information for Use

The advancement of orthopedic surgery has provided the surgeon numerous means of restoring mobility and reducing pain for many patients. While these treatments are largely successful in attaining these goals, they should not be expected to replace or fully restore that seen with the normal joint.

In using this device, the surgeon should be aware that the following factors can be of extreme importance to the eventual success of the procedure:

- This device requires careful insertion, placement, and adequate surrounding structures (e.g., bone, muscle, ligaments, etc) for stability and should be restricted to limited functional stress.
- In selecting patients, the following factors can be of extreme importance to the eventual success of the procedure:
  - The patient's weight:** An overweight or obese patient can produce loads on the prosthesis that can lead to failure.
  - The patient's occupation or activity:** If the patient is involved in an occupation or activity, that involves significant levels of walking, running, lifting and/or muscle strain, the resultant forces can cause failure of the device.
  - 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.
  - 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.
  - Foreign body sensitivity:** Where material sensitivity is suspected, appropriate tests should be made prior to material selection or implantation.
  - Infection:** Local infection, recent or chronic, may be a contraindication for the use of this device. Extreme care should be used in patient selection in the event of recent or chronic infection.

### Indications and Contraindications

Indications and contraindications for the use may be relative or absolute and must be carefully weighed against the patient's entire evaluation and the prognosis for possible alternative procedures such as nonoperative treatment, arthroscopy, arthroplasty and others.

Patient selection will be largely dependent on patient's age, general health, conditions of available bone and tissue stock, prior surgery and anticipated further surgeries.

- Indications
  - Moderate degeneration of the medial compartment of the knee (grade III-IV chondromalacia) with no more than minimal degeneration (grade I-II chondromalacia, no loss of joint space) in the lateral condyle and patellofemoral compartments.
- Contraindications
  - Degeneration greater than Grade I-II chondromalacia, loss of joint space or moderate osteophyte formation in the lateral condyle or patellofemoral compartment.
  - Greater than 5 degrees of varus (as determined by AP erect radiograph of both knees).
  - Bone loss, large areas of avascular necrosis or large subchondral bone cysts of the femoral condyle or tibial plateau.
  - Flattening of the femoral condyle over a large radius (area).
  - Ipsilateral hip with poor/limited rotation, severe degenerative arthritis or contracture.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

- Conditions that will require use of bone cement or mechanical fixation.
- Patient physical conditions that would eliminate or tend to eliminate adequate support or prevent the use of an appropriately sized implant, e.g., insufficient quality or quantity of bone resulting from conditions such as cancer or congenital dislocation, osteoporosis, osteomyelitis, neuromuscular compromise or vascular deficiency in the affected limb in sufficient degree to render the procedure unjustifiable (e.g., absence of musculoligamentous supporting structures, joint neuropathy), or other conditions that may lead to inadequate stability.
- Active, old or remote infection. This may be an absolute or relative contraindication. Every effort should be undertaken to rule out preoperative infection in a patient with suspicious symptoms, such as a history of, or when there are signs of, local inflammation, abscesses, fever, increased blood sedimentation rate, evidence of rapid joint destruction or bone resorption.
- Severe instability secondary to advanced loss of muscle, ligament or soft tissue integrity.
- Other conditions that will place excessive demands on the joint:
  - Charcot's joints
  - muscle deficiencies
  - multiple joint disabilities
  - refusal to modify postoperative physical activities
  - obesity
- Conditions that tend to impose severe loading on the affected extremity include, but are not limited to, the following:
  - obesity
  - heavy labor
  - active sports
  - history of falls
  - general neurological abnormalities or neurological conditions including mental conditions (e.g., mental illness, senility, drug use, alcoholism) that tend to preempt the patient's ability or willingness to follow the surgeon's postoperative instructions.
- Physical conditions that tend to adversely affect the stability of the implant includes, but is not limited to, the following:
  - marked osteoporosis
  - systemic and metabolic disorders leading to progressive deterioration of bone, (e.g., cortisone therapies, immunosuppressive therapies)
  - tumors and/or cysts of the supporting bone structure
  - suspected allergic reactions to metals
  - other joint disabilities (i.e., hips or ankles)

### Warnings and Precautions

#### A. Preoperative

- The preoperative planning and surgical technique for implantation of the device represents principles that are basic to sound surgical management. 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. 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.
- When this device 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 surgery, limitations particular to the patient, the possible consequences resulting from these limitations and, therefore, the necessity of following preoperative instructions.
- Allergies and other reactions to implant materials, although rare, should be considered and ruled out preoperatively.
- X-ray templates should be used to estimate size and placement. An adequate inventory of 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).
- The correct handling of the implant is extremely important. The implant should be used without nicks, scratches, or other alterations; these can produce defects and stresses that may become the focal point for eventual failure of the implant.
- 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 that may lead to failure. Only new implants may be used.**
- The safety and effectiveness of the use of this device in bilateral applications have not been established.

#### B. 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.
- Proper preparation of the joint is important in enhancing prosthesis success. Soft tissue excision should be limited to the amount necessary to accommodate the

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implant. Excessive removal may result in subsequent failure of the procedure due to degenerative changes, increased pain, loss of stability or deformation of the implant. When preparing and positioning the components, proper placement, soft tissue tension and alignment must be ensured.

3. Prior to closure, the surgical site should be thoroughly cleansed. Presence of third body structures may lead to dislocation or painful and restricted motion. Range of motion should be thoroughly checked for soft tissue balance and instability.

#### C. 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.

1. Early postoperative care should be carefully structured to maintain range of motion, and to prevent dislocation.
2. 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 soft tissue quality may necessitate extending the period of limited weight bearing.
3. 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 instability and evidence of device failure (e.g. breakage, bending, etc.).
4. The patient should be encouraged to promptly report any unusual changes in the operative extremity to his physician.

#### D. Adverse Events

The potential adverse effects are similar to those occurring with any orthopedic procedure. These effects are often attributable to factors listed under "Warnings and Precautions" and commonly include:

1. Changing position of the prosthesis (dislocation, bending or fracture of component) with or without instability or clinical symptoms.
2. Subluxation, dislocation, decreased range of motion, and shortening or lengthening of the extremity.
3. Fractures of the bone.
4. Ectopic ossification.
5. Early or late infection.

6. Cardiovascular disorders, including damage to blood vessels, wound hematoma, venous thrombosis, pulmonary embolism, and myocardial infarction.

7. Temporary or permanent neuropathies.
8. Pulmonary disorders including pneumonia and atelectasis.
9. Aggravated conditions in other joints or back due to intraoperative trauma, leg length discrepancy, or muscular deficiencies.
10. Excessive wear of the component or surrounding anatomy from damage to mating wear surfaces or debris particles.
11. Tissue reactions and allergies to corrosion or wear products.
12. Urological complications, especially urinary retention and infection.
13. Other complications associated with general surgery, drugs, or ancillary devices used, blood, etc.

#### 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 Unicompartmental Interpositional Spacer may be obtained from Sulzer Orthopedics Inc.

**THE UNICONDYLAR INTERPOSITIONAL SPACER IS INTENDED FOR USE WITHOUT BONE CEMENT.**

# EXHIBIT 9

**SULZER MEDICA**  
Sulzer Orthopedics Inc.  
CAT NO. 6200-20-341  
LOT NO. XXXXXXXXXX QTY. (1)  
MATL: CoCr STERILE



<b>LEFT</b>	<b>34MM X 1MM</b>	<b>SPACER</b>
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**UNICOMPARTMENTAL INTERPOSITIONAL SPACER**



CAUTION: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.  
SULZER ORTHOPEDICS INC. 9900 SPECTRUM DRIVE, AUSTIN, TX 78717

**SULZER MEDICA**  
Sulzer Orthopedics Inc.  
**REF** 6200-20-341 **LOT** XXXXXXXXXX QTY. (1)  
MATL: CoCr



<b>UNICOMPARTMENTAL INTERPOSITIONAL</b>	<b>34MM X 1MM</b>
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**STERILE R**

**CE 0197**

SULZER ORTHOPEDICS INC. 9900 SPECTRUM DRIVE, AUSTIN, TX 78717

**SULZER MEDICA**  
Sulzer Orthopedics Inc.  
**STERILE CE 0197**  
UNICOMPARTMENTAL INTERPOSITIONAL SPACER  
CAT NO. 6200-20-341  
LOT NO. XXXXXXXXXX  
MATL: CoCr

**SULZER MEDICA**  
Sulzer Orthopedics Inc.  
CAT NO. 6200-20-341 LOT NO. XXXXXXXXXX  

<b>LEFT</b>	<b>34MM X 1MM</b>	<b>SPACER</b>
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UNICOMPARTMENTAL INTERPOSITIONAL SPACER

<b>LEFT</b>	<b>34MM X 1MM</b>	<b>SPACER</b>
-------------	-------------------	---------------

SULZER ORTHOPEDICS INC. 9900 SPECTRUM DRIVE, AUSTIN, TX 78717

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# EXHIBIT 10

















# EXHIBIT 11

3yr  
17-19 Oct  
73-118

# The Journal of Bone and Joint Surgery

*American Volume*

VOLUME 54-A, No. 1

JANUARY 1972

## Arthroplasty of the Knee in Rheumatoid Arthritis and Osteoarthritis

A FOLLOW-UP STUDY AFTER IMPLANTATION OF THE MCKEEVER  
AND MACINTOSH PROSTHESES \*

BY T. A. POTTER, M.D.†, M.S. WEINFELD, M.D.‡, AND W. H. THOMAS, M.D.‡,  
BOSTON, MASSACHUSETTS

*From the Department of Orthopaedic Surgery of the Robert Breck  
Brigham Hospital, Harvard Medical School, Boston*

Relief of pain and restoration of function in arthritic joints have challenged surgeons for over a century. Credit for one of the first operative procedures performed to accomplish these ends belongs to John Rhea Barton who, in 1826, did an osteotomy adjacent to an ankylosed temporomandibular joint in an attempt to produce a pseudarthrosis. Rodgers subsequently performed several similar procedures but re-ankylosis was a persistent problem. After the advent of aseptic technique, more extensive procedures were developed, and in 1860 Verneuil suggested interposition of soft tissue between the exposed bone ends after the joint was resected. After several successful procedures on the temporomandibular joint using this method, he attempted arthroplasty of the knee in 1863 and used the joint capsule as the interposing membrane. In 1886, Ollier proposed the use of muscle as a covering to prevent re-ankylosis, and in 1894 Helferich reported a successful arthroplasty of the knee using this tissue. Gluck later covered the new joint surfaces with skin but reported no consistently good results.

Knee arthroplasties were first performed in this country by Murphy who used fat and fascia to provide a lining for the joint and, in 1913, recorded five ankylosed knees which were treated successfully by this method. Baer tried covering the exposed bone surfaces with chromicized pig bladder and, in 1918, reported on twenty-three knee arthroplasties of which seven resulted in motion in excess of 40 degrees. In the same year, Henderson reviewed 117 knee arthroplasties collected from a number of centers, and added four of his own. He concluded that only eighteen of the 121 could be considered successful. Several years later Campbell<sup>5</sup> discussed his experience with twenty-four arthroplasties in which fascial flaps (ten cases), chromicized pig bladders (nine cases), and free fascia lata (two cases) were used. Of these twenty-four knees, only thirteen were followed long enough for evaluation, and of these only five obtained useful motion. Ryerson, in his discussion of this paper, added eleven cases in which there was one good result. In spite of the discouraging reports from previous surgeons, Putt, in 1921 strongly advocated knee arthro-

\* Read in part at the Annual Meeting of The American Academy of Orthopaedic Surgeons, Chicago, Illinois, January 24, 1968.

† 1180 Beacon Street, Brookline, Massachusetts 02146.

‡ 125 Parker Hill Avenue, Boston, Massachusetts 02120.

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plasty as a procedure "which can give great satisfaction both to the patient and the surgeon."

In 1923 MacAusland reviewed the literature and described his own operative technique. He cited instability of the knee as the most significant postoperative complication, but did not report his findings or estimate the incidence of instability. To improve the stability of the joint, Albee fashioned the distal end of the femur into the shape of a shallow V and in 1928 reported good results in ten cases in which this technique was used.

Campbell in 1940 first reported on the use of metal in the reconstruction of the human knee. He inserted a curved Vitallium plate which covered the femoral condyles and was fixed to the distal end of the femur with a screw. His first two operations resulted in failure, and the procedure was abandoned. Smith-Petersen, in 1942, attempted two knee arthroplasties using a movable Vitallium mold over the femoral condyles, but the results in both cases were disappointing.

In 1949 Speed and Trout revived interest in fascial arthroplasty when they reported 44.6 per cent good results in sixty-five cases, but they excluded patients with multiple joint involvement, infection, obesity, or osteoporosis.

Samson in his review of fifty fascial arthroplasties found that twenty-six were stable and painless with 45 to 90 degrees of motion. Miller and Friedman in their review of thirty-seven fascial arthroplasties, including twenty cases of rheumatoid arthritis, found that only eleven (30 per cent) had more than 45 degrees of stable, painless motion.

In 1950 Kuhns and Potter<sup>13</sup> reported encouraging results after twenty-five knee arthroplasties performed with nylon as the interposing membrane, but later<sup>11</sup> noted deterioration of the nylon and recurrence of the deformity.

The Smith-Petersen mold for the femoral condyles was modified in 1952 to include an intramedullary stem, and the results using this prosthesis were presented by Jones in 1967.

In the past fifteen years various joint replacement prostheses have been proposed by Majnoni d'Intignano, Moeys, Shiers<sup>31</sup>, Anstett, Walldius, von Hellens, and Young. These prostheses are basically hinged joints with intramedullary fixation in the femur and the tibia by means of proximal and distal stems. These authors reported good to excellent results in from 42 to 74 per cent of the knees.

Townley in 1964 described a procedure in which the articular surfaces of the tibial plateaus were covered with a curved stainless-steel plate fixed to the tibia by two screws. His findings in nineteen knees, which were evaluated more than two years after surgery, were fourteen (74 per cent) good to excellent; two (10 per cent) fair, and three (16 per cent) poor.

In the late 1950's McKeever began to replace each tibial plateau with a metallic implant. He died before he could report his findings, but Elliott<sup>19</sup> reviewed his cases in 1960 and found good results in thirty-nine of forty knees.

MacIntosh<sup>17</sup> designed a tibial plateau prosthesis which was made first of acrylic and later of Vitallium. In 1967 he reported on his experience with 103 knees followed for more than six months. Seventy-two were rated good; five fair, and twenty-six poor. Murray in the same year found sixteen good to excellent results after twenty knee arthroplasties in which the MacIntosh prosthesis was used.

Knee arthroplasties have been performed at the Robert B. Brigham Hospital in Boston, Massachusetts, for many years. Osgood and Wilson performed approximately forty fascial arthroplasties in the 1920's, but abandoned the procedure because of the high rate of failure. Over a hundred arthroplasties, using nylon as the interposing membrane, were performed by Kuhns and associates<sup>12</sup> from 1944 to 1958 but a high rate of recurrent deformity prompted the discontinuation of this procedure.

Records processed under FOIA Request #2016-622; Released by CDRH on 08-29-2016.

From 1958 to 1967, 142 arthroplasties, using metallic implants to replace the tibial plateaus, were performed on 119 patients. Ninety-five of these patients had rheumatoid arthritis; the other twenty-four had findings consistent with osteoarthritis. This study being reported here was undertaken to evaluate the results of these procedures after follow-ups of from one to nine years.

### Indications and Contraindications

Relief of pain and maintenance or restoration of function in the severely damaged arthritic knee constitute the prime indication for arthroplasty. Pain in an arthritic knee is usually due to loss of cartilage on the articular surface of the tibia and femur. Loss of cartilage can be detected by applying varus and valgus stress to the knee as it is moved through a passive range of motion. When the cartilage is absent, a dry grinding crepitus is noted as the bone on the surface of the tibial plateau slides over the exposed bone of the femoral condyle. This is the most significant clinical finding and is a more accurate diagnostic sign of loss of articular cartilage than roentgenographic evidence of joint narrowing. Arthroplasty is not necessary if non-narcotic medication and use of a cane for longer walks are sufficient to relieve discomfort.

Varus or valgus deformities and instability of the knee may be produced by either arthritis or injury. Correction of these conditions by using plateau prostheses of appropriate thickness is the second indication for arthroplasty. Roentgenograms made while corrective forces are applied permit an estimate of the amount of correction which can be obtained by arthroplasty. Use of plateau prostheses of appropriate height will improve stability in most instances, provided the capsular and ligamentous structures are intact. If the corrective forces do not eliminate the deformity, osteotomy may be required. When valgus or varus deformity of the knee has been present for a long time, the tibia will often be subluxated medially or laterally on the femur. Arthroplasty cannot be expected to correct medial or lateral subluxation and should not be performed when subluxation is present. Complete loss of integrity of the collateral ligaments was not observed in any of the knees in this series. The anterior cruciate ligament was frequently destroyed or attenuated in the rheumatoid knees, but the posterior cruciate was intact in every instance. Loss of the anterior cruciate is not a contraindication to arthroplasty.

Flexion contractures of the knee may result from either incongruous joint surfaces or contracture of the soft tissues. Traction, exercises, and a series of bivalved plaster casts, each applied with the knee in maximum extension, should be used prior to surgery in an effort to minimize this deformity. If the flexion contracture is primarily due to incongruous joint surfaces, much of the deformity may be corrected as a result of the arthroplasty. When the preoperative flexion contracture cannot be corrected to less than 30 degrees, a posterior capsulotomy or osteotomy of the distal end of the femur may be required. These procedures should be considered if a postoperative knee flexion contracture is greater than 20 degrees or if knee function is significantly impaired by the contracture.

Quadriceps power is difficult to evaluate accurately in the severe arthritic knee, since pain inhibits normal contraction of the muscle. By relieving the pain, strength at a functional level can be achieved. If there is quadriceps weakness because of a neural deficit, arthroplasty should not be performed.

Typical roentgenographic findings in rheumatoid arthritis (Fig. 5) of the knee are demineralization, cyst formation, soft-tissue swelling, and narrowing of the cartilage space. Narrowing of the cartilage space may be overlooked unless either weight-bearing or varus stress and valgus stress roentgenograms are made. Roentgenographic findings in osteoarthritis are similar to those mentioned previously ex-

cept that there is sclerosis rather than demineralization and the subchondral cysts are likely to be much smaller or absent. Hypertrophic spurs on both the tibia and the femur are also more frequently observed in the osteoarthritic knee. If subchondral cysts in the tibia are visible on roentgenograms, the possibility of the prosthesis sinking into the cysts must be carefully considered. If the cysts are too large, arthroplasty is contraindicated. Large cysts in the weight-bearing area of the femoral condyles also constitute a contraindication to arthroplasty with plateau prostheses.

### The Implants

Vitallium prostheses of both the McKeever (Fig. 1) and the MacIntosh (Fig. 2) design were used in this series. The McKeever prosthesis is semicircular with a smooth concave superior surface, and on the inferior surface, a T-shaped fin with the transverse limb of the T anteriorly. Five thicknesses of the prosthesis, ranging from three to fifteen millimeters, are available for the correction of varus and valgus deformities (Fig. 3). Medial and lateral components (according to the orientation of the fins) are used.

When McKeever described the design of his prosthesis he emphasized the importance of the following features. The area of contact between the prosthesis and bone should be as large as possible, fixation of the prosthesis should be ensured by its shape and in a joint in which there is reciprocating motion, the stress should be continuous and of the same type so far as possible. In the normal knee the amount of the joint surface in contact varies with the position of the joint. The area of contact is maximum in the extended position when the concave tibial plateaus approximate the convex femoral condyles. McKeever measured forty tibial condyles, and found considerable variation in total surface area but little variation in the central weight-bearing area. He concluded that only one size of prosthesis is needed to conform to

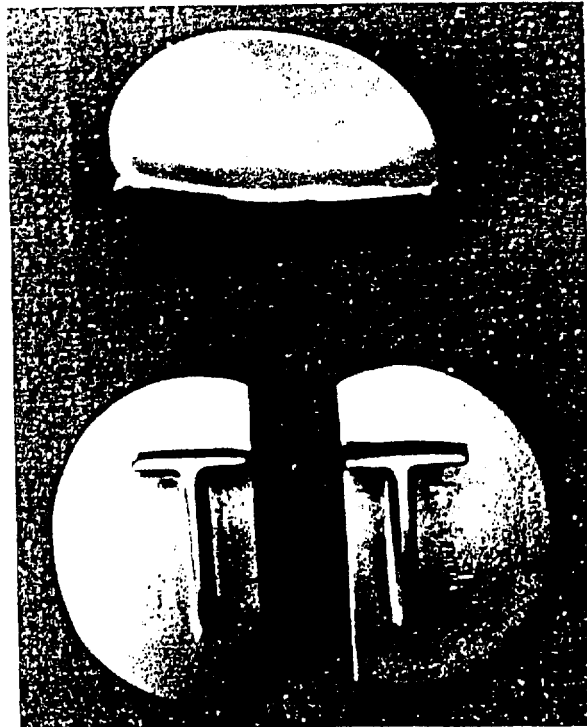


FIG. 1

McKeever prostheses. Upper surface (above) smooth and concave; inferior surface (below) with T-shaped fin.

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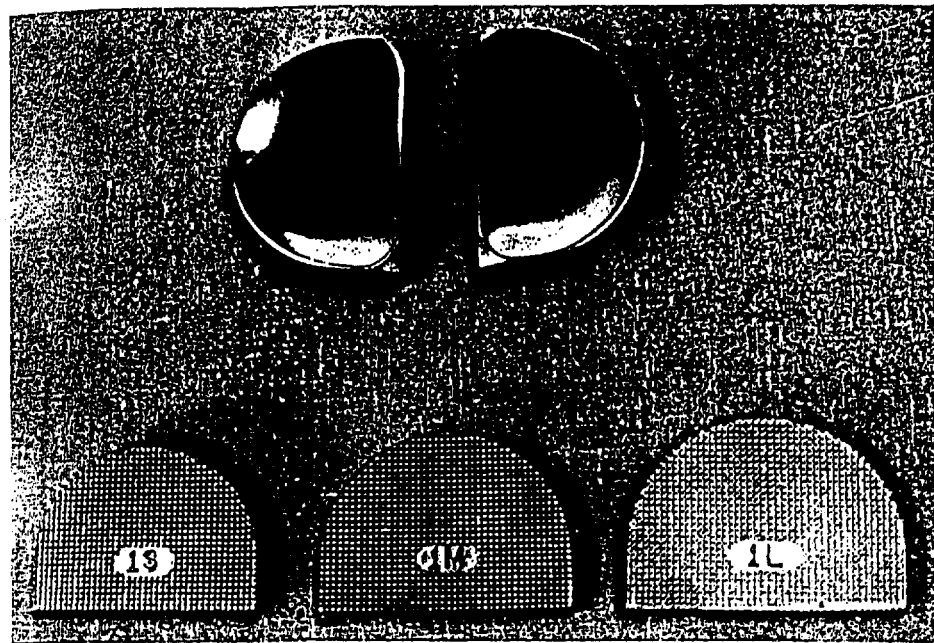


FIG. 2

MacIntosh prostheses. Upper surface (above) smooth and concave, lower surface (below) with serrated surface showing small, medium and large (left to right) prostheses.

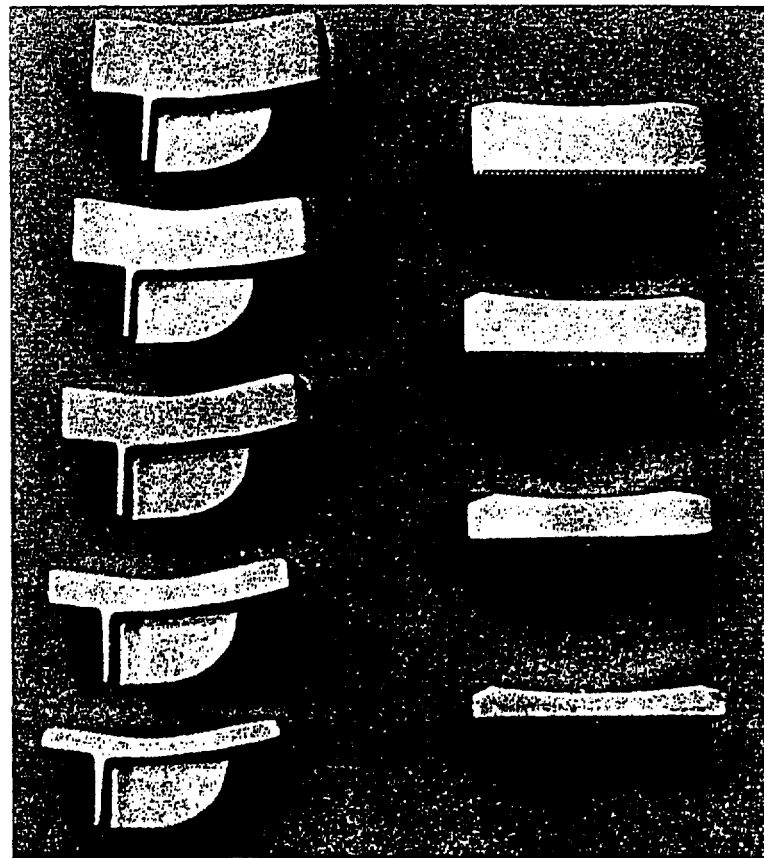


FIG. 3

McKeever (left) and MacIntosh (right) prostheses, showing variety of available thicknesses.

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this central area and, therefore, his prostheses are all the same size with respect to surface area. Fixation is provided in part by the T-shaped fin which maintains the alignment of the prosthesis, but fixation for the most part is dependent on the forces acting on the joint during function. The stress produced by these forces at the prosthesis-bone interface is primarily compression in the direction of the axis of the tibia in all positions of the knee, due to the flat configuration of the implant. When a prosthesis is attached to the femur it must be convex and hence the stress produced by forces on the knee must vary as the position of the knee changes.

The MacIntosh (Fig. 2) prosthesis has a similar design except that its inferior surface is flat with multiple serrations. The stability of the MacIntosh prosthesis depends on the difference in the coefficient of friction of the serrated inferior surface resting on the tibial plateau and that of the polished superior surface of the prosthesis in contact with the femoral condyle. This implant is made in three sizes to conform as closely as possible to the total surface area of the tibial plateau. The same prosthesis can be used in either the medial or the lateral compartment of the joint, and prostheses are available in four basic thicknesses ranging from three to twelve millimeters with additional thicknesses up to twenty-one millimeters obtainable on request (Fig. 3).



FIG. 4

Operative view of femoral condyles of left knee of forty-five-year-old woman with rheumatoid arthritis showing complete loss of articular cartilage over the weight-bearing area and a ridge of bone and cartilage on the anterior part of medial femoral condyle.

#### Operative Technique

The operation is usually performed using a tourniquet and a long medial parapatellar incision. The vastus medialis with a narrow strip of its tendinous attachment is reflected medially to expose the capsule. After opening the joint, it is thoroughly examined to evaluate the extent of destruction of the articular surfaces of the tibia, femur, and patella. In every case, the operative findings (Fig. 4) showed more extensive destruction than had been anticipated from either the appearance of the joint on the roentgenograms (Fig. 5) or the clinical findings during the preoperative examination.

Initially a synovectomy (Fig. 6) is performed, starting in the suprapatellar re-



FIG. 5

Anteroposterior and lateral roentgenograms of the same knee as the one shown in Fig. 4. Note narrowing of the joint space in both medial and lateral compartments and the marked cyst formation in both tibia and femur.



FIG. 6

Excision of hypertrophic synovium beginning in supracondylar area and dissecting distally along the sides of the condyles to the menisci.

gion and removing all visible synovium including that in the posterior part of the joint. In cases of osteoarthritis, a synovectomy is performed only when there is marked hypertrophy or proliferation of the synovium. The menisci are also excised, since they are generally involved by the arthritic process. The anterior cruciate ligament is often absent or attenuated. If it is markedly involved by the synovitis, it may be removed since loss of the anterior cruciate ligament in these patients does not noticeably interfere with joint function.

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Large marginal spurs along the femoral condyle are excised, but since the resulting raw bone surfaces provide potential sites for adhesions, smaller spurs and those which do not interfere with motion are left intact. There is usually a transverse ridge along the anterior aspect of both femoral condyles which appears to be the result of repeated impingement of the anterior margin of the tibia against the femoral condyles. This bone ridge is excised in order to improve knee extension. A bone rasp is used to smooth each femoral condyle and provide it with a rounded contour. Multiple parallel straight cuts three millimeters apart are made with a thin straight osteotome in the areas of exposed eburnated bone on the femoral condyles. Then by directing additional parallel cuts at right angles to the first set of cuts, a crosshatched appearance is produced. We believe that cutting through the eburnated cortical bone facilitates vascularization and the formation of fibrocartilage on the femoral condyles.

#### McKeever Prosthesis

A slotted template (Fig. 7) is used to determine the appropriate site of insertion of the McKeever prostheses. Each component should be placed so that it forms a posteriorly opening angle of about 10 degrees with the mid-sagittal plane (Fig. 8) to conform to the angulation of the femoral condyles (Fig. 9). The curved outer margins of each prosthesis should not protrude beyond the outer margin of the corresponding tibial plateau or impinge on the collateral ligaments. The inner margins of the medial and lateral prostheses when properly placed should outline on the tibia a wedge-shaped area which encompasses the tibial spines and is pointed anteriorly. An osteotome is used to mark the tibial surface along the straight side of the template which is placed in one side of the joint. A vertical cut is then made along this mark to form a buttress against which the straight side of the prosthesis will impinge. A horizontal anteroposterior cut is then made with a slightly curved 12.7 millimeter osteotome so that it joins the vertical cut. This cut surface should be slightly concave paralleling the surface of the tibial plateau and conforming to the shape of the under-

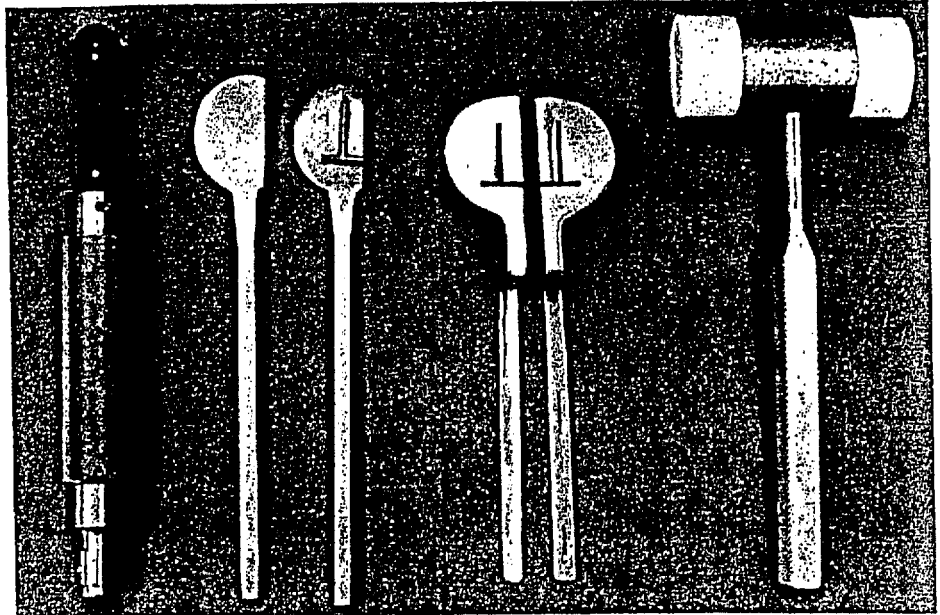


FIG. 7

Special instruments used in knee arthroplasties (left to right): sagittal saw, template with raised fin in location of McKeever fin, template with slots in similar orientation, and nylon headed hammer to prevent damage of prosthesis (see text).

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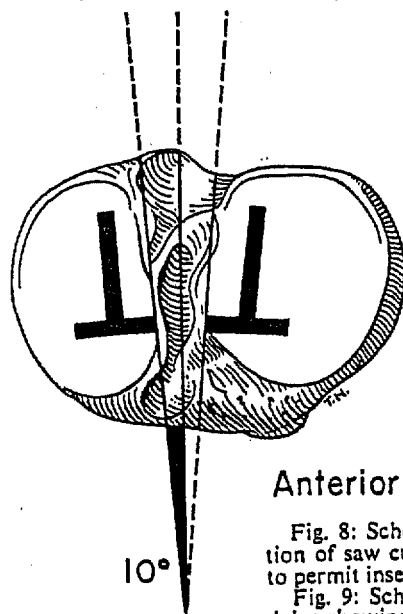


FIG. 8

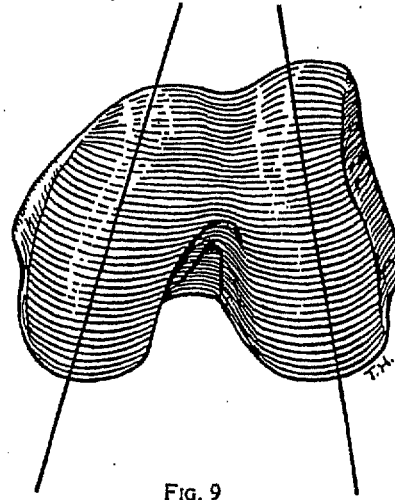


FIG. 9

Fig. 8: Schematic view of tibial plateaus showing proper orientation of saw cuts made to outline the tibial bone fragments removed to permit insertion of the prosthesis.

Fig. 9: Schematic view of weight-bearing surface of femoral condyles showing normal alignment (distal femoral condyles of a right knee).

surface of the prosthesis. In making the horizontal cut an effort should be made to preserve the subchondral bone. After the fragment formed by the osteotomies is removed a similar fragment is removed from the opposite joint compartment using the same technique. The template is then reinserted to determine the sites of the slots for the fins of the medial and lateral prosthesis. The longitudinal (sagittal) slots are six millimeters from the corresponding inner vertical buttress near the base of the tibial spines while the transverse (frontal) slots are twelve millimeters behind the anterior margin of the tibial plateaus. A small reciprocating saw (Fig. 7) is useful to cut these T-shaped slots to prevent fracture of the tibial plateaus; however, a thin osteotome can be used if a saw is not available. The cuts should extend through the subchondral cortex into cancellous bone.

With the knee in maximum flexion the longitudinal fin of the McKeever prosthesis is inserted into the appropriate longitudinal slot in the tibia. The prosthesis is then tamped in a posterior direction using a nylon hammer (Fig. 7). When the transverse fin overlies its tibial slot, the knee is gently extended to seat the prosthesis firmly in place. A similar procedure is carried out in the other compartment. To correct a valgus deformity, the medial prosthesis should be inserted first. The lateral prosthesis, which should be sufficiently thick to correct the deformity yet still permit full knee motion, is then inserted in the same manner. If there is difficulty inserting the implant due to a narrow joint space, a few millimeters of bone may be removed from the posterior non-weight-bearing portion of the corresponding femoral condyle. Similarly, if the anterior tibial spine impinges against the femur in the intercondylar notch, full extension of the knee is prevented. Under these circumstances a rectangular block of bone should be removed from the femoral intercondylar area to create a sufficient space to accommodate the tibial spines when the knee is in full extension.

Once inserted (Fig. 10) the prosthesis should be stable and not move as the knee is flexed and extended through an arc of at least 90 degrees. The anterior edge of the implant may project just beyond the edge of the tibial plateau. If this edge of the implant is too far posteriorly, it will abut against the femoral condyle and block full extension. The prosthesis must be inserted correctly the first time. A new set of slots should not be made because the prosthesis may then be unstable.



FIG. 10

Medial and lateral McKeever prostheses in proper position following synovectomy and excision of hypertrophic spurs from femoral condyles. Note slight toeing-in of prostheses.

#### MacIntosh Prosthesis

For insertion of the MacIntosh prosthesis, the buttresses along the tibial spines are cut initially in the same manner as for the McKeever device. Bone is then removed from each tibial plateau to provide flat surfaces. These cuts should not be made so deeply that they extend entirely into cancellous bone. It is important to remove the posterior lip of each tibial plateau so that the prosthesis can be seated far enough posteriorly to prevent anterior displacement of the implant during knee flexion.

A patelloplasty is performed when there is loss of patellar articular cartilage and extensive marginal osteophytes. To do this the soft tissues are dissected subperiosteally away from the periphery of the patella, and using a reciprocating saw, the posterior two-thirds of the patella is removed, leaving a slight central ridge, corresponding to the femoral intercondylar groove. The cancellous surface of the patella is usually covered with fascia lata. However, the infrapatellar fat pad or articularis genu muscle has also been used. The layers of the wound are then closed with interrupted silk sutures, and the extremity is immobilized in a long plaster cast with the knee in maximum extension. The cast is bivalved on the day of surgery.

#### Postoperative Regimen

The patient is started on quadriceps setting exercises on the first postoperative day. The bivalved cast is removed for active assisted exercises two or three days after operation. The cast is then lined and used as a night cast for eight to twelve weeks. If there is a residual flexion contracture, or the quadriceps is weak, the bivalved cast holding the knee in maximum extension is worn intermittently during the day. Additional casts to maintain the knee in maximum extension are made as the flexion contracture diminishes. If the patient does not attain 60 degrees of flexion by two weeks, a gentle manipulation to 90 degrees is carried out under general anesthesia. During the third week, the patient begins limited weight-bearing, using two crutches. Use of crutches is continued with a gradual increase in weight-bearing for a minimum of three months. At that time, crutches may be discontinued provided the patient has smooth painless motion to more than 70 degrees of flexion, adequate stability, good

quadriceps power, and no residual deformity. If these criteria have not been met, some form of support should be continued.

#### Method of Evaluation

The evaluation of postoperative results is difficult under any circumstances, especially when there is progression of the disease process or recurrence of disease activity. Any bias caused by the enthusiasm of the surgeon for the procedure or by the loyalty of the patient to his surgeon must be minimized if accurate reproducible assessments of the results are to be obtained. We have devised a system for the evaluation of knee arthroplasties which attempts to diminish subjective factors, and to provide a reproducible numerical score which accurately reflects the success of the procedure. The scoring system is based on demerits which are assigned in seven categories: pain, motion, flexion contracture, varus or valgus deformity, medial-lateral instability, quadriceps power, and need for support (Table I). The final rating is determined by adding up the demerit points assigned in each of the categories and rating the result as excellent, good, fair, or poor according to the total demerit scores as shown in Table I.

The one subjective factor which cannot be eliminated from the final result rating is pain. Since relief of pain is a primary goal of the procedure, the method of scoring must weigh heavily any residual pain, considering at the same time the well known tremendous individual variation in the tolerance of pain. The severity of the pain, of course, can be evaluated to some extent by determining how much the pain limits the patient's activities. If the patient has pain only after prolonged walking and otherwise has no limitation of his usual activities, one demerit is assigned. If the patient occasionally limits his ordinary activity due to pain or has pain after walking short distances, he is assigned three demerits and eliminated from the excellent group. For the occasional use of narcotics to relieve pain, six demerits are assigned which would still qualify the patient for the good category if there were no other demerits. However, such a patient would be advised to use support and the added demerits would place the result in a lower category.

Range of motion, deformity, and instability can be measured in degrees in a reproducible fashion and hence are objective factors which aid in the quantitative assessment of the results. Demerit values are assigned according to the severity of the deformity and the amount of limitation of motion.

The measurement of quadriceps strength provides a reliable assessment of knee function. If no motion is present, quadriceps power cannot be measured, and six demerits are assigned in both the quadriceps-power and knee-motion categories so that the ankylosed knee falls in the poor category. In assigning demerits for the use of support, the reason for the use of support is disregarded. Thus, even if crutches are required because of disability in the hip of the opposite extremity, demerits are assigned in the rating of the result of the knee arthroplasty.

In this study an excellent result denoted a virtually painless knee that enabled the individual to perform most of his activities without the need for support. This rating does not imply, however, that an excellent knee is normal and able to withstand all the forms of stress tolerated by a normal knee.

The roentgenographic findings are important and cannot be disregarded in the evaluation of the results after arthroplasty, since they indicate how the bone has reacted to the presence of the prosthesis and also show if there has been any loosening or displacement of the prostheses. However, for the numerical grading of the results we decided that a system based only on function and the clinical findings would be more meaningful and more practical to use. Accordingly, the numerical rating system makes no allowance for the roentgenographic findings.

TABLE I  
 KNEE ARTHROPLASTY EVALUATION

	Demerit Points
<b>Pain</b>	
None; no limitation of activity	0
Occasionally with prolonged walking; no limitation of usual activity	1
Pain after walking short distances; some limitation of usual activity	3
Pain, sufficient to require narcotics for relief; marked limitation of activity	6
Pain at rest; patient incapacitated	7
<b>Knee Motion</b>	
80 degrees or more	0
60 to 80 degrees	1
30 to 60 degrees	3
Less than 30 degrees	6
<b>Flexion Contracture</b>	
None to 5 degrees	0
5 to 15 degrees	1
15 to 30 degrees	2
30 to 45 degrees	4
More than 45 degrees	6
<b>Varus or Valgus Deformity</b>	
Less than 10 degrees	0
10 to 20 degrees	2
20 to 30 degrees	3
More than 30 degrees	4
<b>Medial-Lateral Instability</b>	
Less than 10 degrees	0
10 to 20 degrees	2
More than 20 degrees	4
<b>Quadriceps Power</b>	
Normal to good	0
Good minus to fair plus	1
Fair	2
Poor	4
No motion	6
<b>Support</b>	
None	0
Occasionally uses cane	
Cane all the time	2
Crutches	4
<b>Final Rating</b>	
Excellent	0 to 2
Good	3 to 6
Fair	7 to 10
Poor	11+

Roentgenograms were made in the immediate postoperative period prior to discharge from the hospital, and after approximately three months, when an increase in weight-bearing was anticipated. Subsequent examinations were made at six months, one year, and annually thereafter unless the clinical condition warranted additional studies. The roentgenograms made in the immediate postoperative period permitted evaluation of the placement of the prostheses. When properly placed, the prostheses should not extend medially or laterally beyond the margins of the tibial condyles on the anteroposterior roentgenogram (Fig. 11) but should extend to or slightly beyond the anterior margins of the tibial condyles. Correction of valgus or varus deformity by prostheses of appropriate thickness was evident on the postoperative roentgenograms. Roentgenograms made later showed reactive changes in the bone in contact

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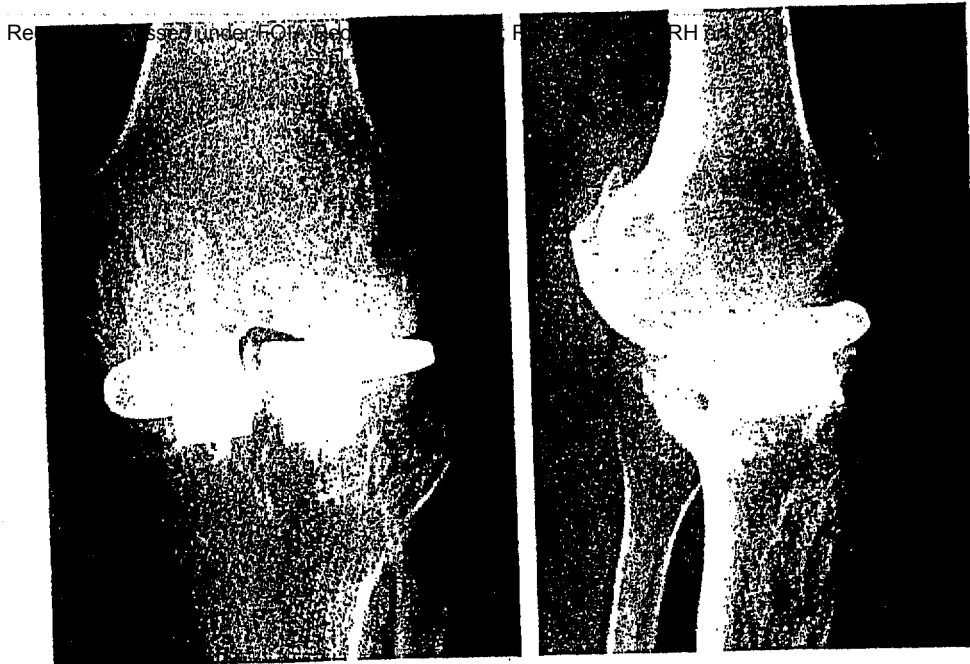


Fig. 11

Anteroposterior and lateral roentgenograms of same patient as in Figs. 4, 5, and 6, eight years following knee arthroplasty with McKeever prostheses. Note area of sclerosis beneath fins and prostheses. This patient had an excellent result by the rating system described.

with the prosthesis. With the McKeever prosthesis the observed changes were a line of sclerosis about the fins and along the undersurface of the prosthesis.

None of the McKeever prostheses in this study migrated distally more than one to two millimeters into the tibial plateau. It is impossible to assess minute changes in angulation of the prostheses due to the technical difficulty of reproducing exactly comparable roentgenograms. No gross changes in the position of the prostheses were noted except for two MacIntosh and one McKeever prosthesis which are discussed in the section on complications. Significant progressive changes were also noted in the lateral femoral condyle of one patient whose clinical course is discussed in the section on results.

#### Material

Since 1958, 142 knee arthroplasties have been performed on 119 patients who have been followed for from one to nine years after surgery. Twenty-three of these patients had a bilateral procedure. Ninety-five patients fulfilled the accepted criteria for the diagnosis of rheumatoid arthritis, and the remaining twenty-four had pathological changes consistent with degenerative joint disease. Included in the latter group were one case each of ochronosis, pseudogout, and traumatic arthritis, secondary to a gunshot wound. The age (Chart I) of the patients at the time of surgery ranged from twenty-two to seventy-six years for the rheumatoid group with a median age of fifty-three, and from twenty-nine to eighty-one years for the osteoarthritic group with a median age of sixty-four. The sex distributions were sixty-nine women and thirteen men in the rheumatoid group and twelve women and five men in the osteoarthritic group. All patients had some form of medical therapy prior to knee surgery. The use of anti-inflammatory drugs did not adversely affect the postoperative course of any patient with one exception to be described.

Of the total group of 142 knee arthroplasties, 118 (ninety-nine rheumatoid and nineteen osteoarthritic) in ninety-nine patients (eighty-two rheumatoid and seventeen

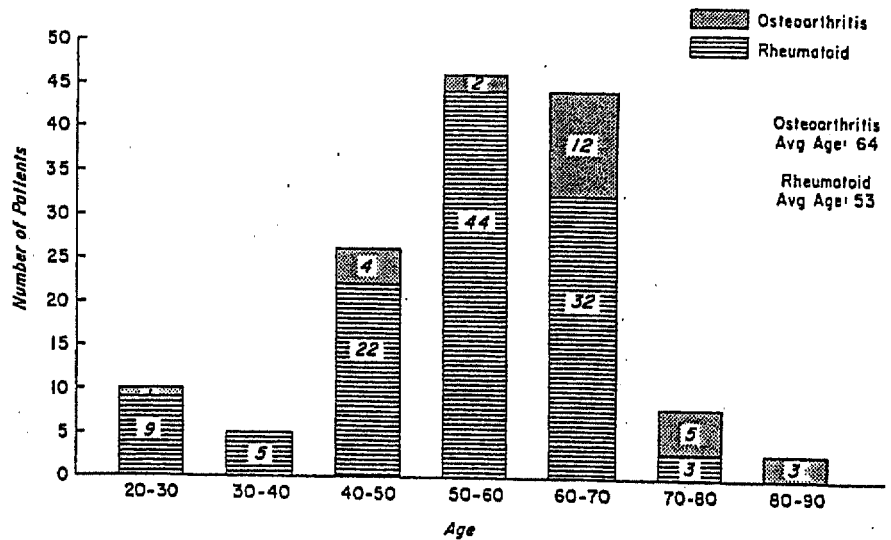


CHART I  
 Age at operation.

osteoarthritic) were evaluated one to nine years after operation. Seven patients with eight knee arthroplasties died before this study was carried out and thirteen patients with sixteen operations were not available for follow-up. The average follow-up was three years; the range, from one to nine years. All of the knees evaluated had been examined by one of the authors within six months of the time of writing.

Many of the patients had extensive involvement. Forty of the ninety-nine patients with rheumatoid arthritis had operations on the opposite knee. These included synovectomy and débridement in ten, arthroplasty with metallic implants in twenty, arthrodesis in eight, and meniscectomy and arthroplasty using nylon in one each. Four of the nineteen patients with osteoarthritis also had contralateral knee operations. These were arthroplasties with metallic implants in three and an arthrodesis in one.

In addition, many patients also had involvement of one or both hips. The resulting disability was sufficient to necessitate surgical treatment in thirteen patients with rheumatoid arthritis and in one with osteoarthritis. Vitallium mold arthroplasties were performed in thirteen patients: on both hips in two of the thirteen rheumatoid patients and in the contralateral hip of the patient with osteoarthritis. One patient had a bilateral Moore arthroplasty for rheumatoid arthritis.

### Results

The results were analyzed in three ways:

1. The over-all results were assessed comparing the postoperative status with that before operation by means of the rating system described;
2. The preoperative and postoperative status were compared in terms of some of the rating categories; and
3. The influence of specific factors on the results was explored by appropriate correlations.

#### Over-All Results

By the described method of evaluation (Table I) the postoperative ratings in the ninety-nine rheumatoid knees were excellent in thirty-six, good in twenty, fair in sixteen, and poor in twenty-seven. The preoperative ratings for these same knees were

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eight good, twenty-three fair, and sixty-five poor, leaving three unrated before operation because of insufficient preoperative information. (The postoperative results in these three were two good and one poor.) The postoperative ratings in the nineteen osteoarthritic knees were fourteen excellent, three good, one fair, and one poor, in contrast to their preoperative ratings that were eight good, six fair, and five poor (Table II). Thus, 70 per cent of the rheumatoid knees and 89 per cent of the osteoarthritic knees were improved according to this method of evaluation.

TABLE II  
RATING BEFORE AND AFTER ARTHROPLASTY

Rating	Rheumatoid		Osteoarthritic	
	Preoperative	Postoperative	Preoperative	Postoperative
Excellent	-	36	-	14
Good	8	20	8	3
Fair	23	16	6	1
Poor	65	27	5	1
	<u>96*</u>	<u>99</u>	<u>19</u>	<u>19</u>

\* For three rheumatoid knees there was insufficient preoperative information. Their postoperative results were two good and one poor.

Of the ninety-six knees in the rheumatoid group, two-thirds were in the poor category preoperatively, while postoperatively only slightly more than one-fourth were in this category, 28 per cent remained unchanged, and 2 per cent were made worse. Of the nineteen osteoarthritic knees, 89 per cent were improved and 11 per cent were unchanged. The changes in rating as a result of arthroplasty according to preoperative ratings are shown in Table III. Considering the rheumatoid and osteoarthritic knees together, eighty-four of 115 knees were improved, two were made worse dropping from a fair to a poor rating, and twenty-nine were not changed, twenty-five remaining at a poor rating, three at a fair rating, and one at a good rating.

TABLE III  
CHANGE IN RATING AS RESULT OF ARTHROPLASTY

Ratings	Rheumatoid	Osteoarthritic
Poor to Poor	24	1
Poor to Fair	13	1
Poor to Good	13	
Poor to Excellent	15	3
Fair to Poor	2	
Fair to Fair	3	
Fair to Good	5	2
Fair to Excellent	13	4
Good to Poor		
Good to Fair		
Good to Good		1
Good to Excellent	8	7
Totals	<u>96*</u>	<u>19</u>

\* Three knees of the ninety-nine rheumatoid knees were not evaluated because of insufficient preoperative information. The postoperative results in these knees were two good and one poor.

Of the eighty-four knees that improved, twenty improved from poor or fair to good, and thirty-five from poor or fair to excellent, while fifteen improved from good to excellent. The remaining fourteen (thirteen rheumatoid and one osteoarthritic)

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knees improved only from poor to fair. Of these fourteen knees, twelve (eleven of the rheumatoid and the one osteoarthritic knee) were assigned four of their demerit points because support was used. Nine of these twelve knees were in limbs with only fair quadriceps power. In the other two knees (of the fourteen which improved only from poor to fair) the slight improvement was due to an increase in motion and quadriceps power.

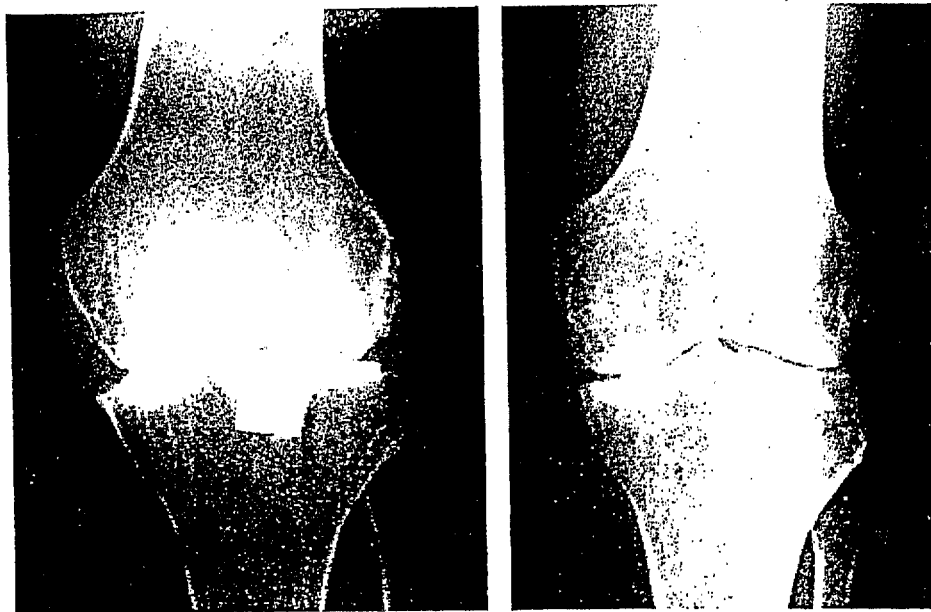


FIG. 12

Anteroposterior roentgenograms of the left knee of rheumatoid patient preoperatively (left) and nine years following lateral McKeever arthroplasty (right). At the time of evaluation this patient had a good result by the rating system.

Of the two patients whose ratings dropped from fair to poor following knee arthroplasty, one had large (1.5 centimeter) cystic defects in both the lateral femoral condyle and the lateral tibial plateau. An attempt was made to fill these defects with bone grafts but further collapse of the femoral condyle led to instability and pain necessitating the use of crutches. The other patient who dropped from fair to poor had a 30-degree flexion contracture following arthroplasty and a supracondylar osteotomy was performed two months postoperatively. Although the deformity was corrected, the knee was painful after prolonged walking. In addition the patient had little knee motion and poor quadriceps power, and required crutches for ambulation.

Of the twenty-five knees which were poor preoperatively and remained so after operation, nine had complications. These were: two supracondylar fractures as the result of manipulation, four postoperative infections, one varus and one valgus deformity both of which were corrected by reoperation and insertion of a thicker prosthesis but without improvement in rating, and one torn medial capsule, the result of a fall four weeks after arthroplasty. The torn medial capsule in this knee was repaired but quadriceps power remained poor and residual instability necessitated the use of crutches.

Thirteen more of the twenty-five knees with poor ratings preoperatively had severely limited motion (less than 45 degrees) before operation. They gained no motion following arthroplasty and, indeed, none of the knees in this series with severe limitation of motion preoperatively gained satisfactory motion after arthroplasty.

The three remaining knees (of the twenty-five which continued to have a poor

ARTHROPLASTY OF THE KNEE

rating) were distributed as follows: One was in a patient with spasticity; another, in a patient with Wernicke's encephalopathy and the third, in a patient in whom no explanation for the poor result was apparent.

Of the three knees which rated fair both before and after operation, the first had a poor quadriceps both preoperatively and postoperatively and continued to require a cane for support, the patient with bilateral arthroplasty had less pain but continued to have only fair quadriceps power bilaterally and hence required two crutches.

The one patient whose rating was good before operation and remained so postoperatively was improved in regard to the knee but required two crutches for progressive hip symptoms.

Sixteen knees (eight rheumatoid and eight osteoarthritic) had good ratings preoperatively. All of the eight rheumatoid and six of the eight osteoarthritic knees had arthroplasties because of pain which came on after short walks (three demerit points in the pain category). The other two osteoarthritic knees were operated on because of valgus deformity in one knee and increasing pain, although still in the 0 to 1 category, requiring continual use of a cane in walking. Of the fourteen knees, thirteen had sufficient improvement to be placed in the excellent category postoperatively. The remaining patient had decreased pain but required two crutches in walking after a Vitallium-mold hip arthroplasty, maintaining the result in the good category.

*Comparison of Preoperative and Postoperative Status*

The result categories used for this comparison were pain, range of motion, flexion contracture, varus or valgus deformity, need for support, and stability.

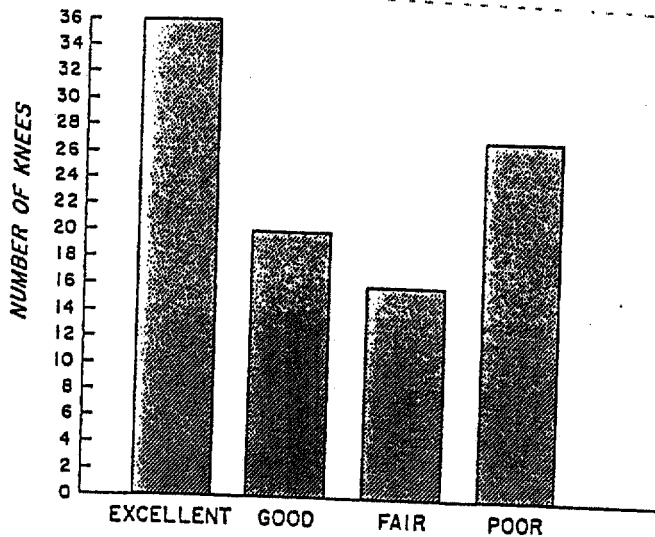


CHART II

End results of knee arthroplasty in rheumatoid arthritis.

*Rheumatoid Group (Eighty-two Patients with Ninety-nine Arthroplasties)*

Prior to arthroplasty, four patients with six knees had a rating for pain of 0 to 1, whereas at follow-up sixty-eight patients with eighty-one knees had this rating. The results in the four patients with a preoperative pain rating of 0 to 1 were as follows: The first with bilateral fibrous ankylosis in 45 degrees of flexion before operation had fibrous ankylosis in 20 degrees of flexion and no change in the poor rating of both knees. The second with flexion contractures of 45 degrees, only 35 degrees of knee motion, and poor quadriceps power, had bilateral arthroplasty and posterior capsulotomy with reduction of both flexion contractures to 20 degrees but insufficient

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gain in motion or quadriceps power to change the over-all ratings. The third had a flexion contracture of 30 degrees, a valgus deformity of 15 degrees, limited motion, and fair quadriceps power, and walked with two crutches preoperatively. At follow-up this knee had no demerit points and an excellent rating. The fourth patient with increasing pain (still at the 0 to 1 level), quadriceps weakness following a nylon arthroplasty on one knee six years earlier, and using two crutches in walking had sufficient improvement in these categories to attain an excellent rating.

Before operation fifty-two knees had 80 degrees of motion or more; postoperatively seventy-one had this range of motion.

Preoperatively the flexion contractures were less than 5 degrees in twenty-one knees, 5 to 15 degrees in thirty-four, and 15 degrees or more in forty-one. Postoperatively, the contractures were less than 5 degrees in sixty-one knees, 5 to 15 degrees in fourteen, and more than 15 degrees in twenty-four.

Before arthroplasty varus or valgus deformity of more than 10 degrees was present in thirty-five knees; postoperatively, nine knees had deformities of this severity.

Preoperatively fifty-three knees were given four demerit points for required external support (two crutches); postoperatively, forty-two knees were so rated.

Preoperatively sixteen knees showed medial-lateral instability greater than 10 degrees; postoperatively, nine knees had instability of this severity.

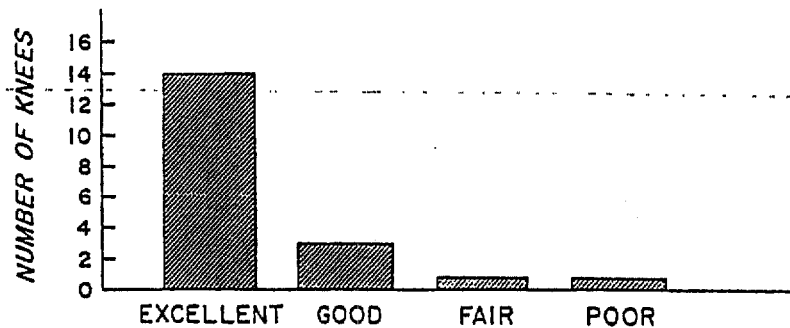


CHART III

End results of knee arthroplasty in osteoarthritis.

#### *Osteoarthritic Group (Seventeen Patients with Nineteen Arthroplasties)*

Before arthroplasty two patients with two knees had pain ratings of 0 to 1, while postoperatively all seventeen patients (nineteen knees) had this rating.

Preoperatively seventeen knees had motion of 80 degrees or more, whereas after arthroplasty sixteen had this amount of motion. The one that lost motion was a patient with chronic spasticity whose over-all rating of poor did not improve after arthroplasty. The two knees with less than 80 degrees of motion preoperatively had increased motion after operation. They improved from fair to one good and one excellent rating.

Initially the flexion contractures were less than 5 degrees in nine knees, 5 to 15 degrees in seven knees, and more than 15 degrees in three. Postoperatively the contractures were less than 5 degrees in fourteen knees, 5 to 15 degrees in two, and more than 15 degrees in three.

Before arthroplasty, varus or valgus deformity of more than 10 degrees was present in ten knees; postoperatively, one knee had such a deformity.

Preoperatively seven knees were given four demerit points for required external support; postoperatively, three knees were so rated.

None of the knees in this group was unstable either before or after operation.

### *Influence of Specific Factors*

The results of knee arthroplasty were correlated with whether prior surgery had been performed in the same knee, the type of knee prosthesis used, and whether a patelloplasty had been performed at the time of arthroplasty. Other factors investigated were bilateral arthroplasty, fusion of the contralateral knee, hip involvement, and the patient's age at the time of operation.

Twenty-seven of the 142 knees studied had been operated on prior to their arthroplasty with tibial plateau prostheses. These operations were: synovectomy and débridement in ten rheumatoid and two osteoarthritic knees, arthroplasty with nylon membrane in one rheumatoid and one osteoarthritic knee, arthrotomy with or without meniscectomy in four rheumatoid and three osteoarthritic knees, posterior capsulotomy in five rheumatoid knees, and supracondylar osteotomy in one rheumatoid knee. Twenty-one of the twenty-seven knees which had had previous operations were available for evaluation. The other six were lost to follow-up for reasons previously noted. The results were four excellent, four fair, and eight poor in the rheumatoid group, and two excellent and three good in the osteoarthritic group. Prior surgery, therefore, did not appear to have an adverse effect on the results of arthroplasty for the osteoarthritic group. In the rheumatoid knees, on the other hand, prior surgery did seem more likely to be associated with a poor result after tibial plateau arthroplasty.

The results with the McKeever and MacIntosh prostheses were also compared. Of the ninety-nine rheumatoid knees, sixty-three were treated with the McKeever, twenty-nine with the MacIntosh, and seven with a medial McKeever and a lateral MacIntosh prosthesis. Both types of prosthesis were used in the same knee before McKeever prostheses of varying heights were available. The ratings with the McKeever prostheses were: twenty-four excellent, twelve good, eleven fair, and sixteen poor, and with the MacIntosh, ten excellent, six good, three fair, and ten poor. With the medial McKeever and lateral MacIntosh the ratings were two excellent, two good, two fair, and one poor. Of the nineteen osteoarthritic knees, eleven were treated with the McKeever and eight with the MacIntosh. With the McKeever the ratings were nine excellent and two good, and with the MacIntosh, five excellent, one good, one fair, and one poor. There was, therefore, no significant difference in the results with the two prostheses although the incidence of poor results was slightly higher when the MacIntosh prosthesis was used.

The results in the twenty-one patients who had patelloplasty were analyzed separately to determine the effect of this additional procedure. There were eighteen rheumatoid and three osteoarthritic knees in which this procedure was performed. In the rheumatoid knees the ratings were five excellent, three good, six fair, and four poor. In the osteoarthritic knees the results were excellent in all three. Patelloplasty, therefore, did not appear to influence the final rating.

Of the twenty-three patients who had bilateral arthroplasty with a McKeever or MacIntosh prosthesis, nineteen could be evaluated: seventeen with rheumatoid arthritis and two with osteoarthritis. The results of the thirty-four knee arthroplasties in the seventeen patients with rheumatoid arthritis were good to excellent in sixteen knees (47 per cent), while the results of the four arthroplasties in the two patients with osteoarthritis were excellent. The results in the bilateral cases were therefore essentially the same as those in the whole group.

Nine patients had an arthroplasty in one knee and an arthrodesis in the other. Of these nine arthroplasties, two were rated excellent, two good, two fair, and three poor, after follow-ups ranging from one to seven years. The findings in these nine patients suggest that arthrodesis of the opposite knee, although not desirable, is not a definite contraindication to arthroplasty.

Fifteen knee arthroplasties were performed on thirteen patients who had Vitallium-mold arthroplasty of the hip. The ratings of these knees were: one excellent, three good, four fair, and seven poor. One patient had bilateral Moore arthroplasties for her hips and bilateral knee arthroplasties, which were both poor.

One knee arthroplasty was performed on the same extremity as the Vitallium-mold arthroplasty, and eight on the contralateral side. Two patients had bilateral knee arthroplasty and two had bilateral hip arthroplasties with one knee arthroplasty.

Fourteen of these seventeen knees had a significant diminution in pain. Of the three in which pain was not decreased, two had postoperative infections, and there was no explanation for the lack of improvement in the third patient. All fourteen patients were using crutches at the time of evaluation.

Age at the time of surgery did not appear to influence the results significantly in either group. For the patients with rheumatoid arthritis, the ratings of the thirty-four, less than fifty years old, were twelve excellent, four good, five fair, and thirteen poor, while the ratings of the sixty-five patients, fifty-one years old or more, were twenty-four excellent, sixteen good, eleven fair, and fourteen poor. For the patients with osteoarthritis, the ratings of the six, less than sixty years old, were two excellent, three good, and one poor, while the ratings of thirteen patients, sixty-one years old or more, were twelve excellent and one fair.

### Complications

Manipulation under anesthesia after arthroplasty was performed on forty-one (36 per cent) of the 118 knees and was considered a second stage of the procedure rather than treatment of a complication. Two manipulations performed more than three weeks following arthroplasty resulted in supracondylar fractures necessitating prolonged immobilization. Both of these knees had a poor result. Otherwise the knees which were manipulated had the same over-all ratings as those which were not.

Four wounds became infected with *Staphylococcus aureus*. Two of these were treated by débridement, drainage, and antibiotics without removal of the implants. Both of these knees showed no evidence, clinical or roentgenographic, of recurrent infection but both were in the poor category at follow-up, one and three years, respectively, after arthroplasty.

The two other wound infections were treated by removal of the prosthesis and arthrodesis of the knee. One of these infections followed a secondary procedure necessitated by a tibial plateau fracture in a patient with a McKeever prosthesis. This patient fell from her bed two weeks after arthroplasty and surgical elevation of the plateau using an autogenous bone graft was followed by a wound infection. After removal of the prosthesis and débridement the wound healed and arthrodesis of the knee occurred.

The other knee treated by removal of the prosthesis and arthrodesis was operated on early in the series. A MacIntosh prosthesis thick enough to correct the valgus deformity was not available and an iliac graft was inserted beneath the implant. A postoperative infection developed followed by resorption of the graft and dislocation of the prosthesis. After removal of the implant the wound healed and the patient was left with a fibrous ankylosis and a poor result.

In recent years we have routinely administered a single dose of parenteral antibiotics (streptomycin one gram and oxacillin one gram) immediately prior to surgery, unless the patient is allergic to these medications. A bacitracin solution (twenty-five units per milliliter) is used to irrigate the wound prior to closure. Only one of the four patients with infections had received preoperative antibiotics.

Four arthroplasties, which were performed before prostheses of different heights were available, had to be revised to correct residual varus or valgus deformities. One

of these patients was lost to follow-up; the other three had one fair and two poor results.

Three patients had re-explorations of their knees for lysis of adhesions after closed manipulations had failed to increase knee motion. Their results were one excellent, one good, and one poor.

One patient had a transient peroneal palsy first noted one week postoperatively and presumably caused by pressure from the plaster cast. Peroneal function returned spontaneously and the patient had a good result when last seen one year after arthroplasty.

There was one postoperative death. This patient had been on large doses of steroid prior to arthroplasty and death was attributed to adrenal insufficiency and gram negative septicemia. No organisms were cultured from the knee.

### Discussion

Comparison of our results with those from other centers is difficult. In many studies the criteria used for evaluation are not well defined and in very few are the results in rheumatoid and osteoarthritic knees separated. In those studies in which arthroplasties on rheumatoid knees were analyzed separately it was generally found that the results in the rheumatoid knees were less satisfactory. The results in some of the recent studies warrant consideration. In 1960 Shiers<sup>30,32</sup> reviewed the world literature pertaining to knee arthroplasty and found an over-all incidence of 42.7 per cent good results in the 831 cases collected. At that time he reported his own results after twenty-eight arthroplasties, in which a joint replacement prosthesis of his own design was used. He found good to excellent results in 42 per cent of the twenty-eight knees. In 1963 Young reported on eight cases of his own and on eleven supplied by other surgeons in which the Young prosthesis had been used. In these nineteen knees, the ratings were 42 per cent good and 37 per cent poor. Eleven of these nineteen patients had rheumatoid arthritis, and only three of these eleven received a good rating. In 1960 Walldius reported his results in sixty-four knees treated with his total joint replacement. The results in 74 per cent of these knees were classified as good to very good with a maximum follow-up of eight years. Wilson in 1968 presented his preliminary findings in eleven patients treated with the Walldius prosthesis and found that seven had a satisfactory arthroplasty after a maximum follow-up of twenty-one months. When Young discussed Wilson's paper he noted that prolonged observation after joint replacement prosthesis revealed many complications due to mechanical failure, loosening of the prosthesis, or local tissue reaction.

In 1967 Jones reported the over-all results from the Massachusetts General Hospital where a Vitallium mold replacement for the femoral condyles had been used. Seventy-five per cent of the sixty-five patients evaluated had rheumatoid arthritis. The over-all results were 51 per cent good to very good and 30 per cent poor. In McKeever's posthumous report of results in forty patients, there was only one unsatisfactory result in a knee which had had a recurrence of an old infection. One other patient had moderate pain, but all others were walking without support and had at least 90 degrees of flexion. Murray found good to excellent results in sixteen of twenty rheumatoid knees (80 per cent) treated by tibial plateau replacement with the MacIntosh prosthesis, but the maximum follow-up in his series was three years.

In our series of ninety-six rheumatoid knees, the results (56 per cent good to excellent ratings) are only slightly better than the previously reported average results, and are not nearly as good as the results in some of the smaller series. Results in our osteoarthritic patients, on the other hand, compare quite favorably with those in previous studies. If our two groups are combined, the over-all results were good to excellent in 62 per cent.

Since the McKeever prosthesis has become available in different heights, we have seldom used the MacIntosh because we prefer the greater stability provided by the T-shaped fin. The MacIntosh prosthesis has been used when an extremely tight joint space has made it technically difficult to insert the McKeever prosthesis. For this reason all sizes of both implants should be available to the surgeon when arthroplasty is contemplated. It is advisable to insert prostheses in both the medial and the lateral compartment in rheumatoid knees.

Patelloplasty, done in twenty-one patients with severe changes in the patella (loss of cartilage and spur formation), did not have a deleterious effect on the results since the ratings in these knees were essentially the same as those in the entire group. Patelloplasty would therefore seem to be indicated whenever there is gross irregularity of the patellofemoral articulation.

Involvement of other joints in the rheumatoid group undoubtedly lowered the result ratings in some patients who used support because of the involvement of other joints and hence received demerits in the rating of their knee.

It is noteworthy that synovectomy and débridement preceded arthroplasty in ten rheumatoid patients and in two patients with osteoarthritis. In each of these, progressive joint destruction and pain necessitated arthroplasty. This finding should not be construed as a condemnation of synovectomy but it suggests that the stage of the disease at which synovectomy should be performed needs further study.

Prior surgery, including synovectomy and débridement, nylon arthroplasty, arthrotomy with or without meniscectomy, posterior capsulotomy, and supracondylar osteotomy did not appear to influence the results in this series. However, there were too few cases to permit definite conclusions.

Secondary surgical procedures were performed following knee arthroplasty in twenty-one of the knees evaluated. Twelve of these were necessitated by complications and were discussed in that section. The remaining nine included: posterior capsulotomies in five rheumatoid and one osteoarthritic knee, two supracondylar osteotomies in one rheumatoid and one osteoarthritic knee, and one arthrodesis in a rheumatoid knee with residual pain, limited motion, and marked flexion deformity.

Posterior capsulotomy or supracondylar osteotomy is likely to be required when the preoperative flexion deformity is more than 30 degrees despite non-operative measures to correct it. In this series surgical correction of flexion contractures was carried out both before and after arthroplasty. Flexion contractures are frequently improved as a result of knee arthroplasty after maximum correction has been obtained by conservative measures preoperatively. If the flexion contracture is greater than 45 degrees, however, it should be corrected surgically prior to arthroplasty. When there is a flexion contracture of 30 degrees or more following knee arthroplasty, a secondary surgical procedure will be required to correct the deformity. The secondary procedure should not be performed until the patient has regained good mobility and active control of his knee.

Arthrodesis of the contralateral knee did not seem to compromise the early or long-term result after arthroplasty. However, since the patients with bilateral arthroplasty in general did quite well, arthrodesis of one knee would not seem to be indicated if both knees are favorable for arthroplasty.

Hip disease had a definite deleterious effect on the results of knee arthroplasty as evaluated by our rating system. However, despite these less satisfactory results the diminution of knee pain after arthroplasty was sufficient to justify arthroplasty.

### Summary

The literature related to arthroplasty of the knee is reviewed and the surgical technique and postoperative management for knee arthroplasty using the McKeever

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and MacIntosh prostheses are described. The results after follow-ups ranging from one to nine years in eighty-two patients with rheumatoid arthritis and seventeen patients with osteoarthritis are presented using a method of evaluation based on demerits assigned for pain, limitation of motion, deformity, instability, quadriceps weakness, and need for support.

Using the described method of evaluation, fifty-six of the ninety-nine rheumatoid knees and seventeen of the nineteen osteoarthritic knees which could be evaluated, had good or excellent results. From these findings it is concluded that knee arthroplasty of the type described when performed in properly selected patients is an effective method to relieve pain and restore function.

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# EXHIBIT 12

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## Unicompartmental and Bicompartamental Arthroplasty of the Knee with a Finned Metal Tibial-Plateau Implant\*

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**ABSTRACT:** We followed a series of ten patients (ten knees) who had a unicompartmental and twenty patients (twenty-two knees) who had a bicompartamental arthroplasty of the knee, in which a finned metal tibial-plateau implant had been used, for two to fourteen years (average, five years) postoperatively. According to the modified criteria of MacIntosh and Hunter, thirty knees (94 per cent) had a good result and two (6 per cent), a fair result. There were two complications: one intraoperative and one postoperative fracture of the tibial plateau. One patient with rheumatoid arthritis required a revision to a total knee arthroplasty at six months because of rapid progression of disease in the contralateral, untreated compartment. Our results suggest that with the proper indications this arthroplasty has a place in reconstructive surgery of the arthritic knee joint.

Prior to the advent of total arthroplasty for treatment of the arthritic knee, the senior one of us (A. B. S.) had used either the MacIntosh or McKeever tibial-plateau hemiarthroplasty in 112 patients. As in other published series<sup>2-8</sup>, the results were often good, but it was his experience that these implants were occasionally unstable or difficult to place.

In 1969, the senior one of us designed and first used a finned metal tibial-plateau implant (Howmedica; Rutherford, New Jersey) for hemiarthroplasty of the knee<sup>10-12</sup>. A short, sagittally directed fin on the undersurface of the metal implant, designed to fit into a slot in the tibial plateau, was provided for stabilization. With the single sagittal fin, this

was found to be easier to insert than the McKeever implant, with its T-shaped stem, and to be more stable than the stemless MacIntosh implant. It was designed in various thicknesses so that angular deformities or ligament loosening and instability could be corrected by selecting the appropriate height of the tibial plateau. We have found this relatively simple and limited arthroplasty to be of value in the treatment of the arthritic knee, especially in certain patients with rheumatoid arthritis and osteoarthritis and in younger patients when the bone stock of the tibial plateau and the femoral condyles are adequate. The procedure is salvageable in that it can be revised to a total knee arthroplasty if necessary.

### Materials and Methods

Between 1969 and 1983, a finned tibial-plateau implant was used in fifty-three knees in forty-nine patients. This report, however, deals with only thirty-two knees in thirty patients who were followed for two to fourteen years (average, five years). A total of fifty-four implants were used, as twenty-two knees (twenty patients) had bicompartamental implants. The patients ranged in age from thirty-two to seventy-two years (average, fifty-five years). Twenty-four patients (twenty-six knees) had rheumatoid arthritis and six patients (six knees) had osteoarthritis. In all of the patients with osteoarthritis a unicompartmental replacement was used.

### Design of the Implant

The implant is made of cobalt-chromium alloy. The surface of the tibial plateau is slightly concave, and there is a fifteen-millimeter vertical fin on the inferior surface that is offset slightly toward the straight intercondylar side of the implant. The implant is available in four diameters (forty-three, forty-six, forty-nine, and fifty-two millimeters) and four thicknesses (four, six, nine, and twelve millime-

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ters) (Fig. 1). The surgical instrumentation includes four templates, representing the available diameters of the implants, and they have a slot through which the tibial plateau can be marked for cutting. A guide with a detachable handle is used to determine the required thickness of the implant.

**Surgical Considerations**

The goals for the use of the finned tibial-plateau implant are pain relief, an increase in the functional range of motion of the knee, improvement of stability, and correction of angular deformity. The advantages of the implant include: (1) replacement of one or both surfaces of the tibial plateau without sacrifice of adequate femoral condyles, (2) minimum removal of bone, so that the procedure may be salvaged later if necessary, (3) less operative time than a total

**Contraindications**

The contraindications to the arthroplasty are: (1) previous sepsis or ankylosis; (2) extensive joint destruction including cystic and erosive changes, particularly of the femur, and poor bone stock at either the tibial or the femoral surface and associated with patellofemoral arthritis (these are indications for a total knee-arthroplasty procedure); (3) neuropathic arthritis; (4) poor motivation of the patient; and (5) angular deformity that cannot be corrected by passive stress testing, for which an associated osteotomy or total knee procedure is indicated.

**Surgical Technique**

The procedure is carried out under tourniquet control. The extremity is draped to expose the entire circumference

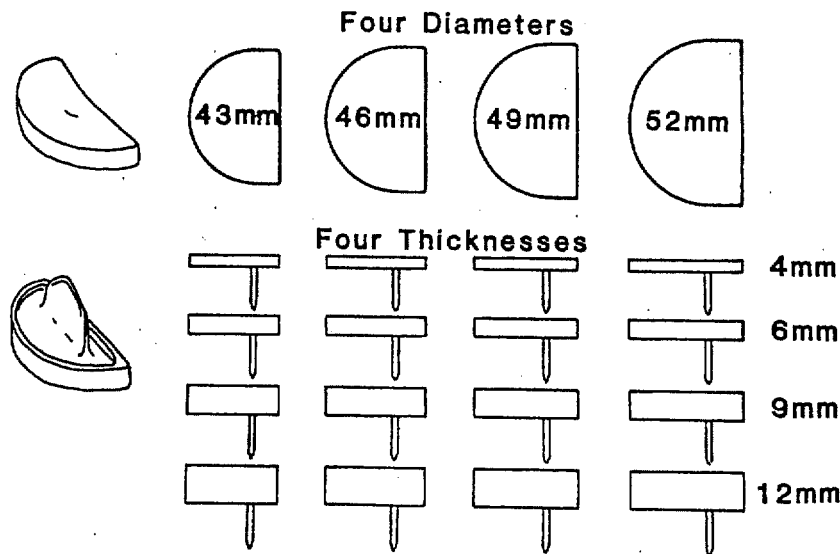


FIG. 1  
The finned metal tibial-plateau implant.

knee procedure and minimum blood loss, (4) the feasibility of use in the young adult, and (5) simple postoperative rehabilitation.

**Indications**

A unilateral or bilateral finned tibial-plateau arthroplasty can be indicated when the disability is due to rheumatoid arthritis, osteoarthritis, or post-traumatic arthritis, providing there is adequate bone stock without erosive or cystic changes in either the tibial or the femoral surface. When these conditions are met, it can be done: (1) after synovectomy in the rheumatoid arthritic knee when joint-space narrowing from degeneration of the tibial or femoral articular cartilage is present (a bicompartamental replacement is preferred, to preclude symptoms from the later development of degenerative change on the other side), and (2) in knees with unicompartamental osteoarthritis when there is loss or depression of the bone of the tibial articular surface, provided angular deformity can be corrected by passive stress testing.

of the distal part of the thigh, the knee, and the proximal part of the leg, so that the alignment of the lower limb can be visualized.

A fifteen to twenty-centimeter medial parapatellar skin incision is used for both the single and bilateral compartment replacements. The quadriceps muscle and patellar tendon are exposed. Starting proximally, a longitudinal incision is made on the medial aspect of the quadriceps tendon, extended into the suprapatellar pouch, and continued distally around the medial side of the patella and through the joint capsule of the knee to the tibial tubercle. The medial quadriceps mechanism is released so that lateral eversion of the patella can be obtained as the knee is flexed. The knee joint is then exposed and inspected. A subperiosteal dissection is carried to the level of the collateral ligaments. Any necessary débridement of the joint and condyles is then done, including trimming and smoothing of the patella, excision of osteophytes from the femur and tibia, and thorough synovectomy. Both tibial plateaus are evaluated. The meniscus, if present, is excised from either one or both compart-

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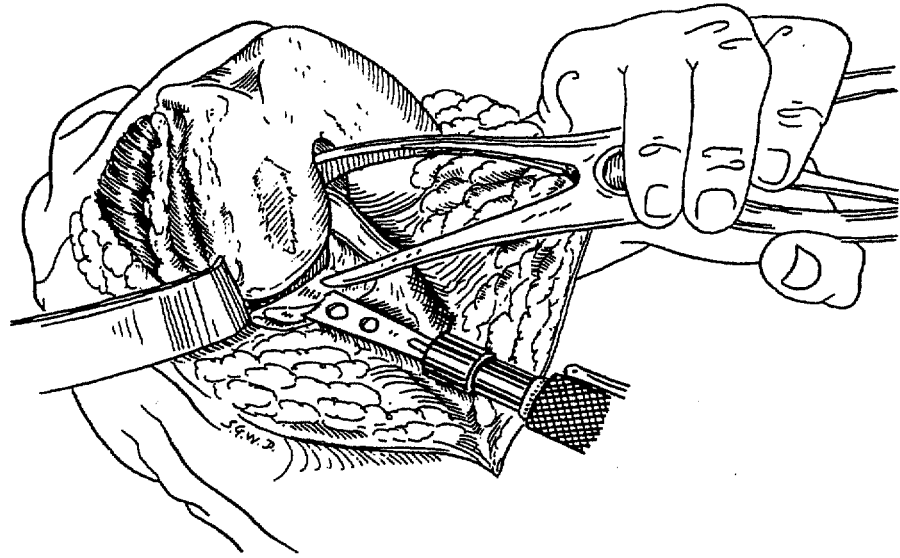


FIG. 2-A

Figs. 2-A through 2-E: The surgical technique.

Fig. 2-A: The surface of the tibial plateau is leveled, removing as little bone as possible. A laminar spreader can be used to improve the exposure.

ments, as indicated, and the stability and alignment of the joint are assessed. One or both tibial compartments, as indicated, are prepared to receive the implant. In patients with rheumatoid arthritis a bicompartamental reconstruction is recommended, with the lateral plateau being prepared first.

The first cut in bone is made vertically and parallel to the intercondylar eminence, which is carefully preserved. The second cut is made parallel to the tibial plateau, trimming osseous irregularities and removing as little cortical bone as possible along a plane at a right angle to the long axis of the tibia (Fig. 2-A). With the knee extended and the

wound edges retracted, one can determine how much joint space is necessary to obtain proper alignment of the knee by laterally stressing the knee into either a valgus or a varus position to visualize the joint space of the medial or lateral compartment. The optimum diameter and thickness of the implant are determined by using the diameter and thickness-sizing templates. The knee should be aligned in 3 to 5 degrees of valgus angulation, and this may require additional preparation of the joint space. Through the slot of the template, a third cut is marked on the surface of the tibial plateau, parallel to the intercondylar cut. This sagittally

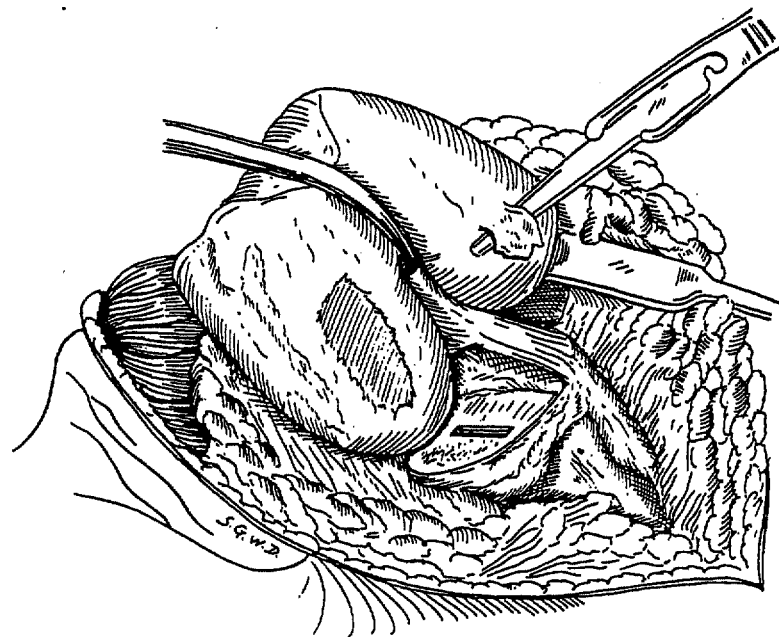


FIG. 2-B

The surface of the tibial plateau, in which a slot has been prepared to receive the fin of the implant. Synovectomy and joint débridement are done as necessary.

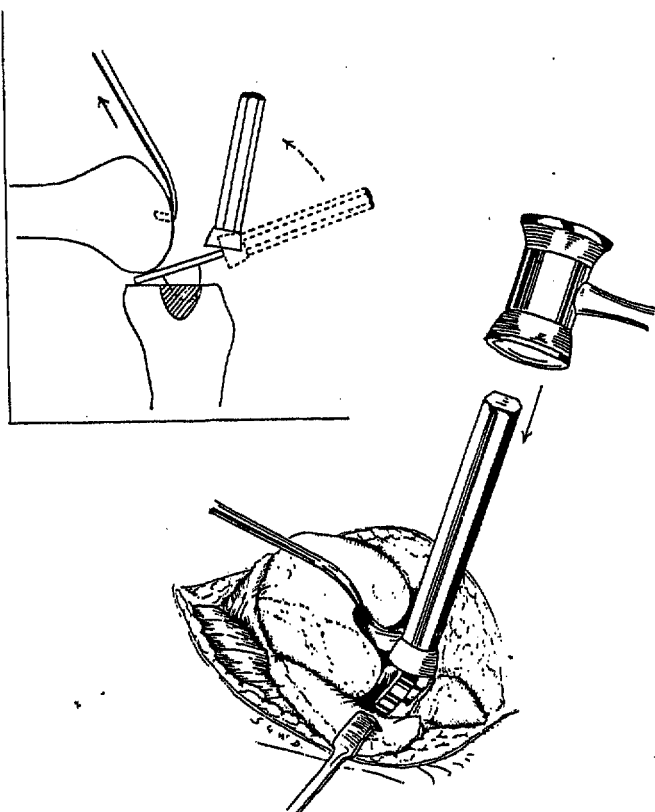


FIG. 2-C

Placement of the implant is facilitated by pulling the tibia anteriorly and lifting the femur vertically with a bone-hook inserted in the intercondylar notch while the knee is flexed. A fine-pointed impactor is used to start placement of the fin, and a blunt polyethylene-tipped impactor is used to complete placement of the implant.

oriented slot is fashioned with a side-cutting burr to receive the fin of the implant and it should be directed more toward the posterior aspect of the cortex to avoid fracturing the anterior aspect of the cortex (Fig. 2-B). With the knee

flexed, the tibia is pulled anteriorly by an assistant and the femur is lifted vertically with a bone-hook inserted in the intercondylar notch. The implant is then inserted with its fin resting in the sagittal slot and its edges on the cortical bone of the plateau. The diameter of the implant should be sufficient to cover the articular surface of the tibial compartment and its thickness should provide proper height of the tibial plateau to provide stability and correction of deformity. A fine-pointed impactor is applied to the fin to start the placement of the fin correctly, and a blunt polyethylene-tipped impactor is used to complete the placement of the implant (Fig. 2-C).

The passive range of motion of the joint, the stability of the implant, and the tracking of the femoral condyle on the implant are tested with the knee in both extension and flexion. If the implant is congruous without pistoning or tilting on movement and the joint is stable, the insertion is satisfactory (Figs. 2-D and 2-E). The wound is then thoroughly irrigated with normal saline solution and a triple antibiotic solution (bacitracin, 100,000 units; polymyxin B, 2.5 million units; and neomycin, one gram in 250 milliliters of normal saline solution) and is closed in layers. Suction drainage is routinely used. Blood transfusions are rarely needed.

Prophylactic intravenous antibiotics, preferably of the cephalosporin family, have been used routinely, administered one day preoperatively, intraoperatively, and one day postoperatively.

The bulky dressing is removed three days after the operation. The postoperative management includes early active and passive movements, which are usually started on the third postoperative day. The goal is to gain 90 degrees of flexion before the patient is discharged from the hospital. Very rarely, a postoperative manipulation under anesthesia is required to gain flexion. A muscle-strengthening program,

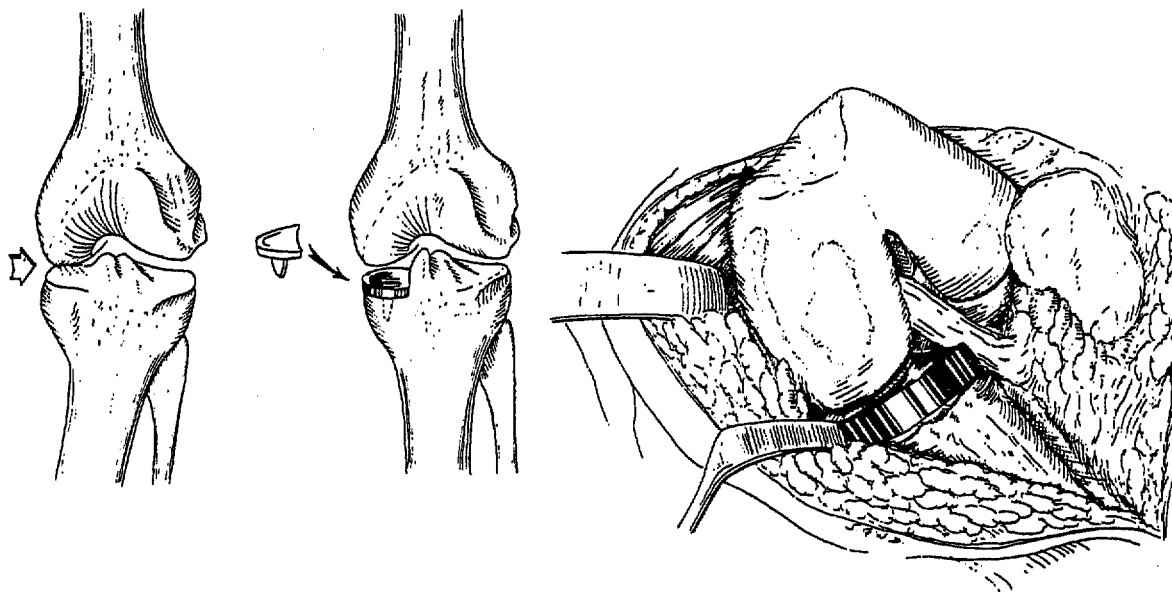


FIG. 2-D

Proper selection of the thickness of the implant will allow correction of alignment with minimum bone resection. A satisfactory insertion allows smooth flexion and extension without pistoning or tilting of the implant.

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emphasizing development of the quadriceps, and gait-training with aids such as crutches, a walker, or a cane, are used. The patients are allowed partial weight-bearing on the involved extremity as soon as tolerated, and they progress to full weight-bearing as tolerated over a period of four to six weeks postoperatively. Bracing of the knee in extension is used at night for six to eight weeks, especially for patients who had a knee-flexion contracture. As soon as the patient can walk without a limp, usually after two to three months, the assistive devices are discarded. Muscle-strengthening programs are continued until the knee has adequate flexion and extension power and its full range of motion. Similar postoperative management is used for both the unicompartmental and bicompartmental tibial-plateau replacements. As would be expected, the recovery period is slightly longer for the patients with bicompartmental tibial-plateau replacement.

A tibial wedge osteotomy had been done prior to this procedure to correct an angular deformity in two patients. In four patients, an osteotomy was done concomitantly with the tibial plateau arthroplasty. The postoperative therapy was compromised in those four patients because of the need for plaster-cast immobilization of the osteotomy site. Angular deformity in a rheumatoid knee that is not correctable by passive stress testing is an indication for total joint replacement.

The clinical factors of pain, motion, stability, angular deformity, and gait were recorded on a specially designed form preoperatively, six months postoperatively, and an-

TABLE I  
MODIFICATION OF THE SYSTEM OF MACINTOSH AND HUNTER<sup>5</sup> FOR  
EVALUATION OF THE RESULTS OF THE ARTHROPLASTY

Result	No. of Criteria Met*
Good	4
Fair	3
Poor	<3, or later revision required

\* The four criteria are: (1) no pain with activity or pain with only heavy activity, (2) extension to -15 degrees or less and flexion to 75 degrees or more, (3) no subjective or objective instability of the knee, and (4) 3 to 5 degrees of valgus alignment.

nally thereafter. At each visit standing anteroposterior and non-weight-bearing lateral radiographs of the knee were made. The results were classified as good, fair, and poor according to a modification of the method of MacIntosh and Hunter<sup>5</sup> (Table I).

### Results

#### Pain (Table II)

Pain was rated on a scale of five classes. Preoperatively, all patients had Class-III pain or greater. Postoperatively, twenty-eight knees (87.5 per cent) were not painful with activity; three knees were painful with heavy activity only (one was rheumatoid, with bicompartmental replacement, and two were osteoarthritic, with unicompartmental

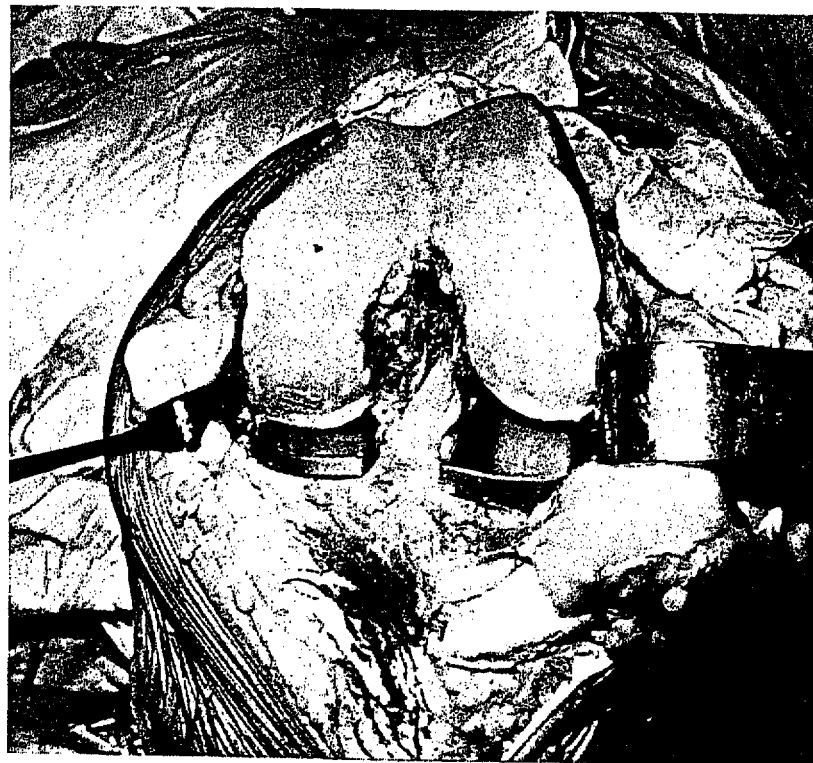


FIG. 2-E

The stability of the implant is tested in both extension and flexion of the joint and by evaluating the tracking of the femoral condyles on the implant. If the joint is stable, without pistoning or tilting of the implant on movement, the insertion is satisfactory.

TABLE II  
PREOPERATIVE AND POSTOPERATIVE PAIN RATINGS  
IN THE THIRTY-TWO KNEES

Class	Pain	No. of Knees	
		Preop.	Postop.
I	None with activity	0	28
II	With heavy activity only	0	3
III	With moderate activity	11	1
IV	With minimum activity	20	0
V	At rest	1	0

replacement); and one knee was painful with moderate activity (a rheumatoid knee, with bicompartamental replacement).

#### Range of Motion (Table III)

The range of motion (flexion and extension) was classified as good, fair, or poor. The average preoperative arc of motion was 91 degrees (-13 degrees of extension to 104 degrees of flexion). The average postoperative arc of motion was 95 degrees (-5 degrees of extension to 100 degrees of flexion).

#### Clinical Angulation Deformity

Good alignment of the knee was considered to be the normal anatomical range of 3 to 5 degrees of valgus angulation. An angulation deformity was present preopera-

tively in seventeen knees (53 per cent) and postoperatively in none. Preoperatively a valgus deformity ranging from 7 to 17 degrees (average, 12 degrees) was present in fifteen knees, twelve of which had rheumatoid arthritis and three, osteoarthritis. A tibial wedge osteotomy was carried out concomitantly with the arthroplasty in the three osteoarthritic knees and in one rheumatoid knee in which the valgus angle exceeded 15 degrees. A varus deformity of 10 degrees was present preoperatively in two osteoarthritic knees, both of which had a tibial wedge osteotomy prior to the unicompartmental arthroplasty. All of the tibial wedge osteotomies resulted in anatomical alignment postoperatively.

TABLE III  
PREOPERATIVE AND POSTOPERATIVE RANGE OF MOTION  
IN THE THIRTY-TWO KNEES

	No. of Knees	
	Preop.	Postop.
Extension		
Good (0 to -10 degrees)	17	29
Fair (-11 to -15 degrees)	3	2
Poor (> -15 degrees)	12	1
Flexion		
Good (>90 degrees)	30	25
Fair (75 to 89 degrees)	2	6
Poor (<75 degrees)	0	1
Average flexion/ extension (degrees)	-13/104	-5/100

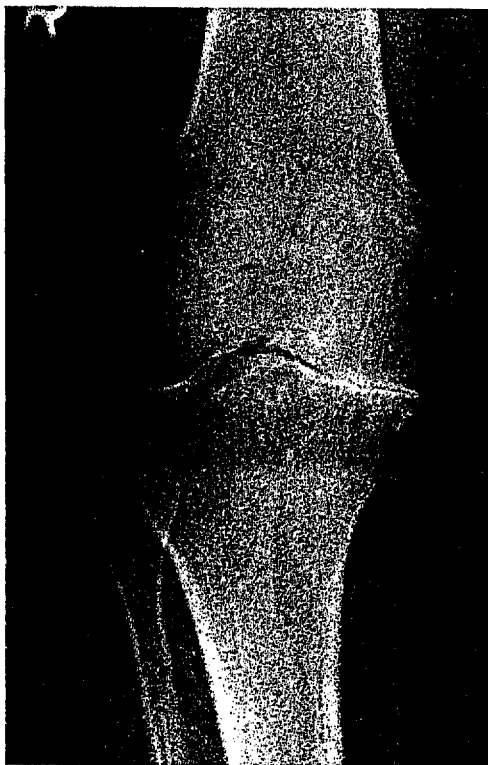


FIG. 3-A



FIG. 3-B

Fig. 3-A: Preoperative standing anteroposterior radiograph of an eighty-two-year-old woman with degenerative changes in the medial compartment, an 8-degree varus deformity, and Class-IV pain.

Fig. 3-B: Radiograph made two years postoperatively, showing tolerance of the underlying bone to the implant and no signs of loosening. The patient had no pain and the range of motion was from -5 degrees of extension to 100 degrees of flexion.



### Stability

Instability of the knee was tested medially, laterally, and anteroposteriorly. It was present in twenty-two (69 per cent) of the knees preoperatively but in none postoperatively.

### Gait

The patients were considered to have an independent gait if they did not require, in order to walk, aids such as a cane, crutches, or a walker because of the surgically treated knee. Our analysis did not include the use of assistive

lateral radiographs of two knees.

### Complications and Revision

No patient had an infection or wound breakdown. A non-displaced fracture of the tibial plateau occurred intraoperatively in one knee during insertion of the implant. This was treated with a bone staple and the patient had a good result. Because of this complication, the design of the implant was changed by shortening the fin and placing it closer to the medial edge of the implant, which is next to the intercondylar eminence. No further problems have occurred



FIG. 4-A

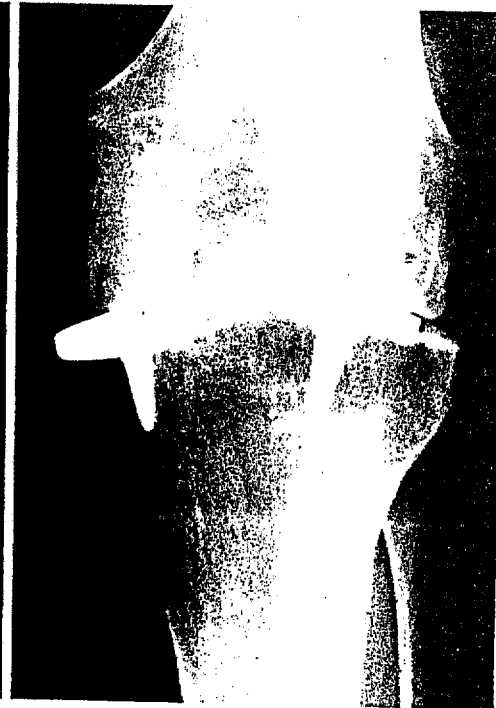


FIG. 4-B

Fig. 4-A: Preoperative standing anteroposterior radiograph of the knee of a thirty-three-year-old man with rheumatoid arthritis. The range of motion was from -20 degrees of extension to 100 degrees of flexion and the pain was Class IV.

Fig. 4-B: Radiograph made fourteen years postoperatively, showing a continued satisfactory position of the implant as well as bone formation around the implant and stems, without signs of resorption. The range of motion was from -15 degrees of extension to 105 degrees of flexion and the knee was pain-free.

devices for problems not involving the surgically treated knee. Preoperatively twenty-four patients had an independent gait, while postoperatively twenty-nine (97 per cent) had an independent gait.

### Radiographic Findings

None of the tibial plateau implants showed radiographic evidence of fracture or displacement, and no absorption of bone was seen beneath the implant (Figs. 3-A through 4-B). No patient had collapse of the tibial plateau on the surgically treated side of the knee. A favorable bone-remodeling process, as evidenced by production of bone beneath the implant and around its fin, was noted in all patients, and we think that it was due to favorable force-loading of the bone on weight-bearing across the implant. The arthroplasty is contraindicated in the presence of poor cortical-bone stock and erosive or cystic changes. Asymptomatic flattening of the femoral condyle was noted on the

since this modification of the design was implemented. In one knee, a fracture of the medial plateau beneath the implant occurred six weeks after operation, and a high tibial osteotomy was done three years later to correct an 8-degree varus deformity, with a subsequent good late result.

A total replacement was required six months postoperatively in one rheumatoid arthritic knee with a unilateral tibial-plateau arthroplasty because of rapid progression of the disease in the untreated compartment. Although that patient was not followed for long enough to be included in our long-term series, the case illustrates that rheumatoid arthritis in the knee is a bicompartamental disease, and we now reconstruct both compartments in such patients.

In the thirty-two patients who were followed for two years or more, the results were graded using a modification of the criteria of MacIntosh and Hunter<sup>5</sup> (Table I). Thirty knees (94 per cent) were graded as having a good result and two (6 per cent) had a fair result. Both of the knees with a

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fair result were rheumatoid and had bicompartamental replacement, with one having poor motion and the other, Class-III pain. The patient who had a total knee replacement at six months because of rheumatoid arthritis had a poor early result.

### Discussion

We think that the finned tibial-plateau arthroplasty of the knee is a useful procedure in selected patients with osteoarthritis or rheumatoid arthritis, cartilage degeneration, and adequate cortical-bone stock. When angular deformity is correctable by passive stress testing, this procedure can provide resurfacing of the tibial plateau and correct its level and height. A later total revision is feasible, as the bone of the tibial plateau is preserved and no cement is used. The most probable causes of early failure are poor selection of

patients (see Contraindications) and technical failures such as inadequate sizing of the implant and poor postoperative therapy. Late failures are likely to be due to progression of disease in the untreated contralateral compartment, especially in patients with rheumatoid arthritis.

Our review of a long-term follow-up of patients with an arthroplasty employing a tibial plateau implant has led us to re-evaluate the worth of this method. We think that both arthroplasty with a finned tibial-plateau implant and total knee-replacement procedures have a place in the care of the arthritic knee joint. When a tibial plateau arthroplasty is done in a rheumatoid patient, both compartments of the knee should be reconstructed. If the proper indications and recommended techniques are followed, tibial plateau arthroplasty should find its proper place in the orthopaedic armamentarium.

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# EXHIBIT 13

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# McKeever Metallic Hemiarthroplasty of the Knee in Unicompartamental Degenerative Arthritis

LONG-TERM CLINICAL FOLLOW-UP AND CURRENT INDICATIONS

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**ABSTRACT:** Forty patients with forty-four unicompartamental McKeever metallic uncemented hemiarthroplasties were followed for five to thirteen years (average, eight years). Thirty-nine knees had a medial and five, a lateral arthroplasty. The age at surgery ranged from thirty-two to eighty-two years (average, sixty-seven years). At the final follow-up, 70 per cent of the knees were rated as good or excellent. Seventy-nine per cent of the knees in patients who were less than sixty-five years old at the time of surgery were in these categories. Six knees (14 per cent) had required revision to either a unicompartamental or a bicompartamental total knee replacement. The average preoperative and postoperative knee flexion did not change, but knees with initially poor motion improved. The average preoperative flexion contracture of 10 degrees improved postoperatively to 5 degrees. Complications were rare and no cases of infection, peroneal palsy, or clinically detectable phlebitis occurred. Obesity did not seem to adversely affect the outcome. This study indicated that the McKeever unicompartamental metallic hemiarthroplasty can provide an attractive alternative in the treatment of unicompartamental degenerative arthritis when proximal tibial osteotomy is contraindicated or has failed or when the patient is too young, heavy, or active to consider total knee replacement.

The surgical options that currently are available for the treatment of advanced unicompartamental osteoarthritis of the knee include tibial osteotomy, metallic hemiarthroplasty, and metal-to-plastic unicompartamental, bicompartamental, or tricompartmental knee replacement. If tibial osteotomy is contraindicated or has failed, most surgeons do not consider metallic hemiarthroplasty but proceed directly to metal-to-plastic knee replacement.

In the late 1950's, McKeever introduced a metallic hemiarthroplasty to resurface the tibial plateau. He reported good initial results in thirty-nine of forty knees. MacIntosh designed a similar interpositional hemiarthroplasty and reported good initial results in seventy-two of 103 knees with

a minimum six-month follow-up<sup>5,6</sup>. Potter et al. followed nineteen osteoarthritic knees that had either a McKeever or a MacIntosh prosthesis for an average of three years (range, one to nine years) and noted good to excellent results in seventeen. Despite these early encouraging reports, metallic hemiarthroplasty never became popular, possibly because of the advent of metal-to-plastic cemented total knee replacement. However, as the rate of loosening of cemented prosthetic components increases with both time and higher stresses across the bone-cement interface, younger, heavier, and more active patients risk a higher failure rate than do older, lighter, and less active patients. Bone stock is compromised by the insertion of the total knee components and by the effects of loosening, which makes revision surgery difficult. The revised knee arthroplasty is then in turn subjected to the same risks of failure as the initial knee arthroplasty. "Bridges have been burned", and the opportunity to take advantage of subsequent technological advances with the second operation may have been compromised.

For this reason, we believe that metallic hemiarthroplasty should still be considered in a select group of patients before proceeding to total knee replacement. The purpose of this report is to review our long-term results with McKeever arthroplasty in unicompartamental degenerative arthritis and to suggest which patients may be candidates.

## Materials and Methods

At the Robert Breck Brigham Hospital (now Brigham and Women's Hospital), unicompartamental McKeever arthroplasty was performed on fifty-one patients (fifty-five knees) with degenerative arthritis between January 1968 and January 1976 by one of six staff surgeons. Eleven patients were lost to follow-up before the five-year examination could be performed. Two had died within two years after surgery, one had insufficient data to be included in the study, and eight were lost to follow-up within the first three years. This left forty patients (forty-four knees) who had been followed for five to thirteen years (average, eight years). Thirty-nine knees had had a medial and five, a lateral arthroplasty. Thirty-two of the knees were in thirty women and twelve, in ten men. The age at the time of surgery ranged from thirty-two to eighty-two years (average, sixty-seven years). Prior operative procedures had been performed on the ipsilateral knee in four patients, and consisted of

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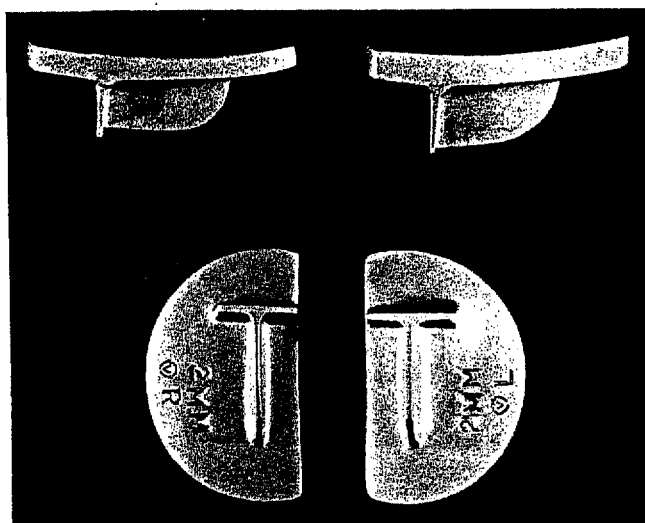


FIG. 1

The McKeever metallic prostheses. They are available in thicknesses ranging from two to fifteen millimeters.

three medial meniscectomies and one proximal tibial osteotomy. In two knees there had been a prior fracture of the tibial plateau. In nine knees the meniscus in the contralateral compartment was found at surgery to be torn and was removed. Eleven patients subsequently had had surgery on the contralateral knee. Four of them had had a contralateral unicompartmental McKeever arthroplasty; four, a unicompartmental metal-to-plastic knee replacement; two, a bicompartamental total knee replacement; and one, a proximal tibial osteotomy.

McKeever Vitallium prostheses were used in this series. Their shape roughly simulates that of a tibial plateau, with a slightly concave and a highly polished superior surface (Fig. 1). The inferior surface has a T-shaped fin that is inserted into a corresponding T-shaped slot made in the tibial plateau for fixation. The transverse limb of the T is anterior, for ease of insertion. The prostheses are designed as right and left mirror-images. A right prosthesis resurfaces either the right lateral or the left medial tibial plateau and a left prosthesis resurfaces either the left lateral or the right medial plateau. Varying thicknesses of the prostheses are available, ranging from two to fifteen millimeters. Three and four-millimeter prostheses were used in twenty-seven (61 per cent) of the knees in this series.

#### Operative Technique

We prefer a slightly median vertical parapatellar incision to expose the joint, such as is used for unicompartmental total joint replacement<sup>10</sup>. The details of the surgical approach and the technique for insertion of the prosthesis have been previously described<sup>8</sup>. An oscillating saw or burr is used to remove any irregularity on the opposing femoral condyle and to shape the tibial plateau so as to achieve maximum surface contact with the tibial prosthesis. It is not necessary to remove all remnants of articular cartilage, but only what is needed to properly shape the tibial plateau. Intercondylar osteophytes should be removed to relieve any

impingement with the tibial spine. All peripheral osteophytes that press against the collateral ligaments and capsule on the concave side of the knee deformity should be removed to assist passive correction of the deformity<sup>10</sup>. The correct thickness of the prosthesis is that which fills the joint space in the arthritic compartment but which is not so tight that it causes subluxation of the tibia on the femur or excessive pressure on the contralateral compartment. As a rule, the correct prosthesis in the medial compartment should allow the medial joint space to be opened approximately one millimeter when a valgus stress is applied with the knee in full extension. The knee must also be tested in flexion, as ex-

TABLE I\*  
KNEE ARTHROPLASTY EVALUATION

	Demerit Points
<b>Pain</b>	
None; no limitation of activity	0
Occasionally with prolonged walking; no limitation of usual activity	1
After walking short distances; some limitation of usual activity	3
Sufficient to require narcotics for relief; marked limitation of activity	6
At rest; patient incapacitated	7
<b>Knee motion</b>	
80 degrees or more	0
60 to 80 degrees	1
30 to 60 degrees	3
Less than 30 degrees	6
<b>Flexion contracture</b>	
None to 5 degrees	0
5 to 15 degrees	1
15 to 30 degrees	2
30 to 45 degrees	4
More than 45 degrees	6
<b>Varus or valgus deformity</b>	
Less than 10 degrees	0
10 to 20 degrees	2
20 to 30 degrees	3
More than 30 degrees	4
<b>Medial-lateral instability</b>	
Less than 10 degrees	0
10 to 20 degrees	2
More than 20 degrees	4
<b>Quadriceps power</b>	
Normal to good	0
Good minus to fair plus	1
Fair	2
Poor	4
No motion	6
<b>Support</b>	
None	0
Occasionally uses cane	1
Uses cane all the time	2
Uses crutches	4
<b>Final rating</b>	
Excellent	0 to 2
Good	3 to 6
Fair	7 to 10
Poor	11+

\* Reproduced from Potter, T. A.; Weinfeld, M. S.; and Thomas, W. H.: Arthroplasty of the Knee in Rheumatoid Arthritis and Osteoarthritis. A Follow-up Study after Implantation of the McKeever and MacIntosh Prostheses. *J. Bone and Joint Surg.*, 54-A: 12, Jan. 1972.

cessive tightness will cause the prosthesis to lift up anteriorly as the femoral condyle rolls posteriorly on the prosthesis during flexion. If this does occur, it can usually be prevented by resecting a little more of the posterior femoral condyle or by contouring the bone of the tibial plateau so that it slopes downward posteriorly 10 or 15 degrees rather than sloping upward.

*Postoperative Regimen*

Postoperatively, the knee is immobilized in full extension with a knee-immobilizer. Quadriceps-setting exercises are initiated on the first postoperative day and active flexion in the side-lying position is begun on the second day. Active knee flexion over the side of the bed is begun after the patient has achieved 45 degrees of active side-lying flexion. Walking is begun on the third or fourth postoperative day using the knee-immobilizer and two crutches. Thirty to 50 per cent weight-bearing is allowed. The splint is discontinued after the patient is able to actively raise the leg with the knee fully extended. When sufficient active flexion has been gained, a stationary bicycle is used for fifteen minutes twice a day. If the patient fails to regain the flexion that was achieved at the end of the operative procedure within two weeks after surgery, manipulation under general anesthesia is performed. Seven (16 per cent) of the forty-four knees in this series required manipulation.

Two crutches are used for a minimum of six weeks. At that time, external support is decreased, as tolerated, to the use of one cane outdoors and no support indoors. By twelve weeks postoperatively, the continued use of any support depends on the patient's progress. Recovery after a McKeever arthroplasty can be expected to be longer than that after a cemented total knee arthroplasty. Some soreness in the resurfaced compartment usually persists for six to nine months, but gradually improves with time. This is often accompanied by an effusion. Support with a cane or crutch is continued as long as either pain or swelling is present.

**Results**

We examined all but three of the patients (four knees) who had retained the McKeever prosthesis at the time of the latest follow-up. For these three patients the last examination had been done within eighteen months by the operating surgeon, but they had moved away, and data on pain and functional status were obtained from these patients by telephone. Preoperative data and intermediate results were obtained from their records and confirmed by the patient.

The over-all results were classified as excellent, good, fair, or poor according to the demerit system used by Potter et al. (Table I). In essence, an excellent knee had no pain and normal function. A good knee had mild, trivial pain related to activities and little or no functional limitation. A fair knee had satisfactory pain relief but moderate functional limitation, and a poor knee had an unsatisfactory level of function.

The results at one year, three years, five years, and the

latest follow-up (five to thirteen years) are shown in Table II. At one year, thirty-eight (86 per cent) of the forty-four knees were in the good or excellent category, but this had gradually diminished to thirty-one (70 per cent) at the final follow-up evaluation. Three knees (7 per cent) had a poor result at the one-year evaluation, and this number gradually increased to seven knees (16 per cent) at the time of the final follow-up.

TABLE II  
 EVOLUTION OF RESULTS (IN PER CENT) AFTER  
 MCKEEVER ARTHROPLASTY IN FORTY-FOUR KNEES

Result	At 1 Yr.	At 3 Yrs.	At 5 Yrs.	At >5 to 13 Yrs.*
Excellent	7	7	7	7
Good	79	72	68	63
Fair	7	14	14	14
Poor	7	7	11	16
Revised	5	5	7	14

\* Average, eight years.

Six knees (14 per cent) required revision because of inadequate relief of pain. Three knees were revised to a unicompartmental total knee replacement and three, to a bicompartamental total knee replacement. All of them were graded as good or excellent when last seen. The revision was accomplished without difficulty, as the McKeever prosthesis did not compromise the bone stock of the tibial plateau. Two revisions were done within the first postoperative year and one each was done at four and a half, five, seven, and ten years.

*Pain relief:* All of the patients had had significant pain on weight-bearing before surgery. In patients who had had preoperative pain at night, this was relieved by the end of the first postoperative year and did not recur except in the patients who required revision. The three knees that had been rated as excellent and had had no pain at the one-year follow-up continued to be pain-free at the final follow-up. Eight of the thirty-five knees that were rated as good at one year had no pain regardless of activity. The remaining twenty-seven knees had some mild discomfort after strenuous activity, but no limitation of function.

*Range of motion:* Preoperative flexion of the knee averaged 110 degrees (range, 70 to 135 degrees). The flexion at final follow-up also averaged 110 degrees (range, 85 to 135 degrees). The average preoperative flexion contracture was 10 degrees (range, zero to 40 degrees), while the average flexion contracture at final follow-up was reduced to 5 degrees (range, zero to 20 degrees).

*Results in younger patients:* As we thought that the McKeever arthroplasty might have particular advantages in younger patients, we singled out, for special study, thirteen patients (fourteen knees) who were less than sixty-five years old at the time of surgery. The average age of these patients was fifty-four years (range, thirty-two to sixty-four years). Five years after surgery, thirteen of the fourteen knees were rated good or excellent. At five to twelve years of follow-

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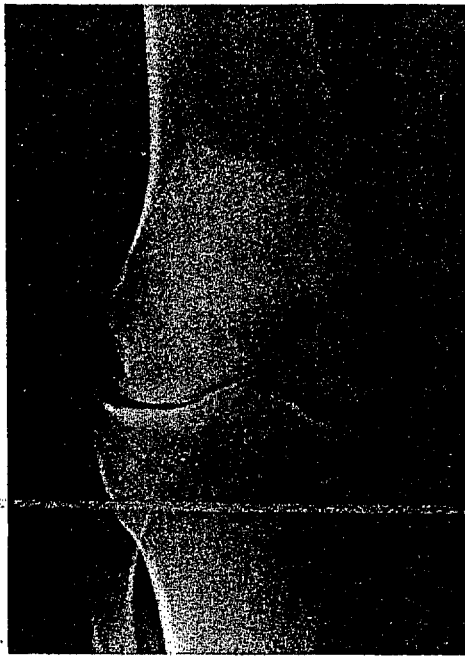


FIG. 2-A

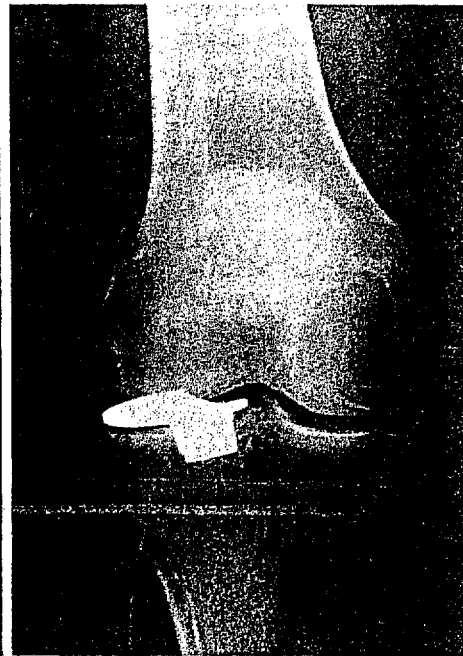


FIG. 2-B

Fig. 2-A: Preoperative radiograph of a knee with osteoarthritis involving the lateral compartment. The patient was fifty-eight years old and worked daily in the winter as a downhill-skiing instructor.

Fig. 2-B: Radiograph made three years after arthroplasty. Eburnated bone on the lateral condyle of the femur was drilled at the time of surgery. Minimum bone stock was sacrificed. The knee had a full range of motion, good stability, no effusion, and no pain. The patient returned to downhill skiing with no difficulty.

up (average, eight years) eleven knees (79 per cent) were still in the good or excellent category, one knee was rated fair, and two knees had been revised.

**Complications:** There were few perioperative complications and no infections. In one patient the surgical drain was retained, and repeat surgery was necessary to remove it. One patient had a large intra-articular hematoma that gradually resolved and did not compromise the result, and one patient had a superficial wound hematoma that drained spontaneously, with no effect on wound-healing. There were no clinically manifested cases of thrombophlebitis.

### Discussion

We are strong advocates of proximal tibial osteotomy as the procedure of choice in the younger, heavy, or active patient with medial unicompartmental degenerative arthritis. The McKeever interpositional arthroplasty, however, can provide an attractive surgical alternative in a knee with unicompartmental degenerative arthritis when proximal tibial osteotomy is contraindicated or has failed and the patient is too young, too heavy, or too active to consider total knee replacement.

In our opinion, the relative contraindications to osteotomy include active flexion of the knee of less than 90 degrees, a flexion contracture of more than 15 degrees, intercondylar osteophyte impingement as shown on a tunnel radiograph, the presence of pain at rest, a history of phlebothrombosis or venous stasis disease in that extremity, or signs of internal derangement (especially episodes of locking). Early degenerative changes in the contralateral joint compartment shown on a standing plain radiograph (per-

ipheral osteophytes, subchondral sclerosis, mild joint-space narrowing, or chondrocalcinosis) or a bone scan showing increased uptake in the opposite compartment are also contraindications.

It is more difficult to define what we mean by "too young, too heavy, or too active to consider total knee replacement", as so many factors must be considered for each individual patient. For example, we would not consider a twelve-year-old bedridden patient with juvenile rheumatoid arthritis who weighs forty kilograms to be too young for total knee replacement<sup>9</sup>, but we might think that a fifty-five-year-old laborer weighing 120 kilograms is too heavy and too active for the procedure.

The McKeever arthroplasty has some distinct advantages over tibial osteotomy, as a torn meniscal fragment and bone impingement can be removed at the time of surgery. After such débridement and the release of intra-articular adhesions, it is possible to gain both flexion and extension in patients who have significant preoperative limitation of motion. As we have not found postoperative immobilization to be necessary after a McKeever arthroplasty, the chance of venous thrombosis is diminished. Also, both knees can be operated on during the same hospitalization, significantly diminishing recovery time in a patient with bilateral involvement. The potential problem of delayed union or non-union of an osteotomy is avoided, and the incidence of peroneal palsy is less<sup>2,4,11</sup>.

In patients who already have early degenerative changes in the contralateral joint compartment of the same knee, the McKeever arthroplasty has an additional advantage over osteotomy. Slight overcorrection of the preoper-

active varus or valgus deformity, which is the goal of osteotomy, transfers extra weight-bearing forces to the contralateral compartment with early involvement. In the knee with preoperative varus alignment that has advanced medial-compartment disease but only early lateral-compartment disease, the correctly chosen width of McKeever prosthesis can adjust the postoperative alignment to neutral or only a few degrees of valgus angulation. This permits the resurfaced medial compartment to share substantial weight-bearing forces while protecting the opposite compartment from overload. It is permissible to allow the patient to engage in vigorous physical activity as tolerated. Finally, at an average of eight years of follow-up, the results in our patients were equal to or better than those that have been reported for osteotomy<sup>1,4,11</sup>.

A McKeever arthroplasty cannot be expected to produce an initial result that is comparable with that after cemented unicompartmental or bicompartamental total knee replacement. All of the patients in this series who had a cemented total knee replacement in the opposite knee or who eventually had a conversion to a total knee replacement preferred the total knee arthroplasty. However, the McKeever arthroplasty has several advantages over unicompartmental or bicompartamental total knee replacement in selected patients. As bone cement is not required, the po-

tential adverse effects on bone of late cement failure are eliminated. The minimum resection of bone stock results in little or no compromise of any later salvage procedure. The patients can resume vigorous physical activity as tolerated, allowing their potential return to a strenuous occupation or avocation (Figs. 2-A and 2-B).

Two categories of patients benefit from these advantages: the obese and the young. The obese patient is at greater risk of component loosening — the heavier the patient, the higher are the stresses that are generated across the bone-cement interface. However, obesity did not appear to adversely affect the outcome of the McKeever arthroplasty in our series and is, perhaps, a relative indication for the procedure. We have obtained good results with three years of follow-up in patients who were as heavy as 170 kilograms.

Youth is a relative contraindication to any prosthetic joint replacement. The McKeever arthroplasty, however, can be used to maintain a good functional knee during the years prior to a probably inevitable total knee replacement. Bone stock is preserved, and the delay will enable the patient to have the advantage of the latest joint-replacement technology.

NOTE: The authors would like to thank Dr. C. B. Sledge, Dr. M. S. Weinfeld, and Dr. R. Poss for their contribution to this study.

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# EXHIBIT 14

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# The Use of the McKeever Metallic Hemiarthroplasty for Unicompartamental Arthritis\*

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**ABSTRACT:** We reviewed the results of sixty-one McKeever unicompartamental arthroplasties performed by the senior one of us (T. P.) for osteoarthritis of the knee. The average follow-up was five years (range, two to thirteen years). Forty-four (72 per cent) of the arthroplasties were rated as good to excellent. The average postoperative range of motion in these knees was 110 degrees. Six knees were rated as fair and eleven knees, as poor. The poor results appeared to be caused by degenerative arthritis involving ipsilateral compartments that had not been resurfaced with an implant.

Osteoarthritis of the knee joint is not infrequently confined to one compartment, usually the medial one, with the lateral compartment being relatively free of disease<sup>7,10,13</sup>. The best treatment for this problem is controversial, and various methods have been proposed, including both tibial and femoral osteotomy<sup>1-3,7,8,10,15</sup>, unicompartamental cemented prosthetic replacement<sup>4,12</sup>, and total joint replacement<sup>9,15</sup>.

osteoarthritis with varus deformity have appeared to be generally satisfactory to date<sup>1-3,7,8,10</sup>. The reported results of tibial osteotomy for lateral compartment disease and valgus deformity have not been as satisfactory, however, and Shoji and Insall have stated that high tibial osteotomy is contraindicated in this situation. The alternatives that they have suggested are a supracondylar femoral osteotomy in the younger patient and a total knee replacement in the older patient. However, it has been reported that motion of the knee is frequently restricted following femoral osteotomy for arthritis<sup>6</sup>. Articular replacement of both joint compartments for unicompartamental arthritis seems excessive, and the results with cemented unicompartamental total joint replacements have been inconsistent<sup>4,5,9,12</sup>.

A series of exclusively unicompartamental uncemented tibial-plateau arthroplasties for osteoarthritis has not been previously reported. Prior reports have combined unicompartamental and bicompartamental implants in both rheumatoid and osteoarthritic patients<sup>11,14</sup>. The senior one of us (T. P.), however, has used the McKeever prosthesis as a

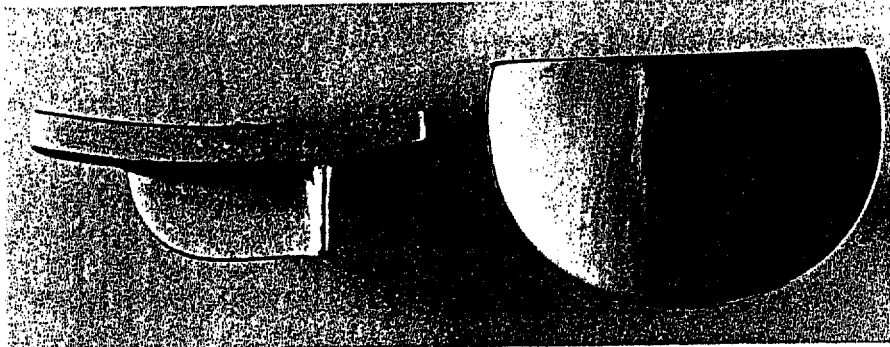


FIG. 1

Two views of the McKeever implant.

With time, it has become clear that the cemented total joint prosthesis, particularly in the young or active patient, has an appreciable risk of failure, primarily because of loosening at the bone-cement interface<sup>5,9</sup>. Salvage of a failed cemented implant is a major surgical challenge<sup>10</sup>. The reported results of tibial osteotomy for medial compartment

hemiarthroplasty in knees with unicompartamental osteoarthritis since 1971 (Figs. 1, 2, and 3).

The purpose of this paper was to retrospectively study this experience in an attempt to determine the role of the McKeever prosthesis in the treatment of unicompartamental osteoarthritis.

## Clinical Material

Seventy-two consecutive McKeever hemiarthroplasties for unicompartamental osteoarthritis were performed by the senior one of us in sixty-nine patients between 1971 and

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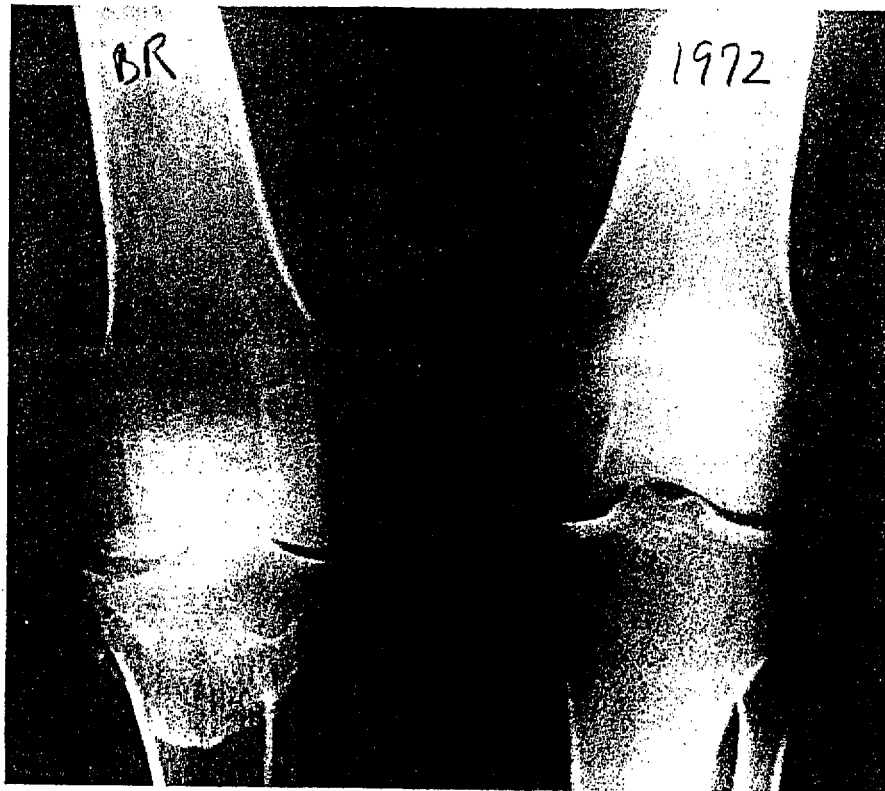


FIG. 2

Preoperative radiograph showing post-traumatic osteoarthritis of the lateral compartment.

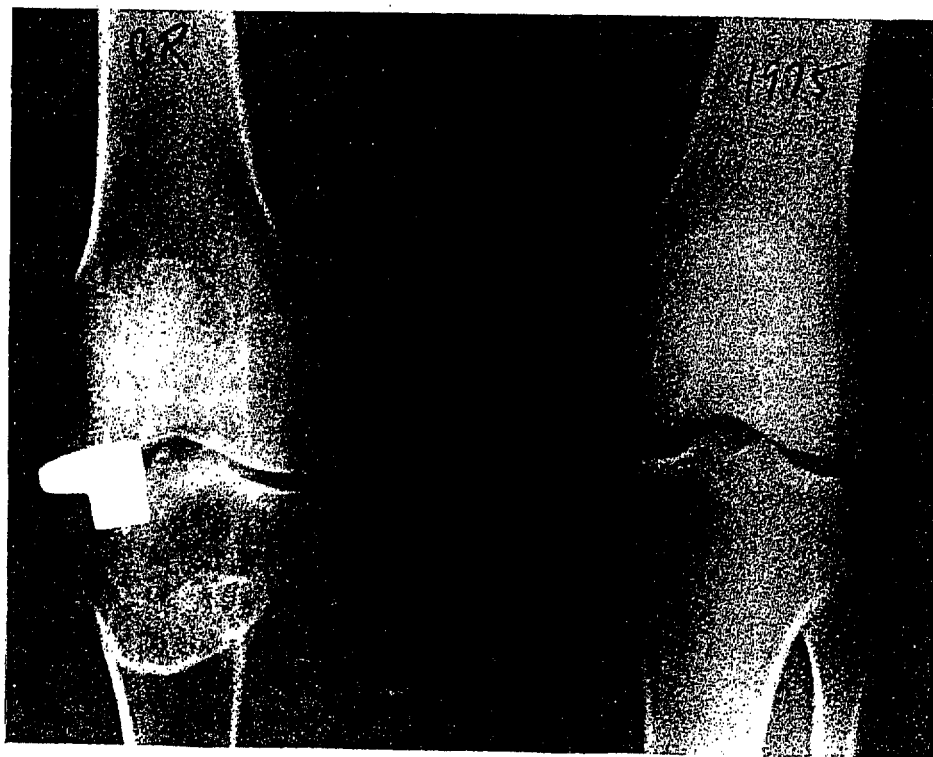


FIG. 3

Postoperative radiograph of the knees shown in Fig. 2, three years after insertion of a McKeever implant in the lateral compartment.

1978. These patients' hospital charts, radiographs, and post-operative office records were reviewed. The patients were interviewed by telephone when necessary to complete the follow-up. All of the patients were personally followed by the senior one of us. Of the seventy-two arthroplasties, sixty-one knees in sixty-one patients were available for follow-

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up at two to thirteen years (average, five years) postoperatively.

The method of knee evaluation used in this study was reported previously by Potter et al. A grade of zero to 2 points is excellent; 3 to 6, good; 7 to 10, fair; and more than 11, poor.

The series consisted of thirty-three women and twenty-eight men, with thirty-five right and twenty-six left knee arthroplasties. The average age of the patients was sixty-one years (range, twenty-eight to eighty-one years).

Forty-eight implants were placed in the medial and thirteen, in the lateral tibial compartment. In the knees with replacement of the medial compartment, the preoperative varus deformity at the knee averaged 7 degrees (range, zero to 15 degrees). In the knees with replacement of the lateral compartment, the preoperative valgus deformity averaged 10 degrees (range, 2 to 20 degrees).

Twenty-four (39 per cent) of the knees had had previous surgery, of which a meniscectomy of the ipsilateral compartment was the most common. A total of forty previous operations had been done, with eight knees having had more than one procedure (Table I). The preoperative arc of motion for all knees averaged 84 degrees. Active flexion averaged 91 degrees (range, 60 to 120 degrees). There was an average flexion contracture of 7 degrees (range, zero to 25 degrees). Osteoarthritic involvement of the contralateral compartment

TABLE I  
PREVIOUS SURGERY  
(TWENTY-FOUR KNEES)

Procedure	No.
Meniscectomy	20
Débridement	3
MacIntosh implant	5
Intra-articular fracture	4
Synovectomy	2
Excision of a Baker's cyst	2
High tibial osteotomy	1
Ligament reconstruction	1

and of the patellofemoral articulation was frequent, fourteen knees (23 per cent) having significant involvement of the contralateral compartment and seventeen (28 per cent) having patellofemoral involvement. Thirteen of the former knees were rated as having mild and one, as having moderate involvement, and four of the latter were rated as having mild; ten, moderate; and three, severe involvement.

The McKeever implants (Howmedica) are available in two, three, four, and six-millimeter thicknesses. Larger sizes are available on special order. The most frequently used size in this study was four millimeters.

#### Surgical Technique

Proper surgical technique and careful attention to the postoperative program is necessary for a good result with this prosthesis. The surgical technique and postoperative regimen have been previously reported on by Potter et al.,

but some details of the technique used for unicompartmental prostheses must be emphasized.

The purpose of the unicompartmental prosthesis is primarily to resurface the arthritic tibial plateau and only secondarily to correct deformity. The least possible amount of bone should be removed, although the meniscus must be excised to accommodate the prosthesis. All osteophytes beneath the joint capsule should be removed to permit realignment of the leg. These osteophytes tent the capsule and produce a fixed deformity. Their removal permits the ligaments to return to their normal relationship with the joint surface. When this has been accomplished, the smallest implant that is stable should be used. The tendency to put in the largest implant to obtain better alignment of the leg should be resisted.

Postoperatively, in the operating room, a long cast is applied in one section from groin to toes to produce a stronger bivalved cast. As the patient must be observed carefully during the postoperative period for development of a flexion contracture, we prefer a bivalved long cast in extension rather than the usual prefabricated knee-immobilizer, which may produce a small flexion contracture. The cast is used in the hospital and, except during physical therapy sessions, is used at home at night for six to eight weeks.

The cast is bivalved in the recovery room about two hours after application to allow for swelling. Quadriceps-setting and gluteal-setting exercises are started on the first postoperative day. The bivalved cast is removed on the second or third day to allow the start of active, assisted range-of-motion exercises. The cast is lined and straps are applied for use as a night splint for the next eight to twelve weeks. Partial weight-bearing with crutches is allowed after 70 degrees of flexion has been attained, usually at about the third postoperative week.

If the patient does not attain 60 degrees of flexion by two weeks postoperatively, the knee is gently manipulated to 90 degrees under general anesthesia. The patient is instructed in a touch-down partial weight-bearing gait, which is used for a minimum of three months. If a residual knee-flexion contracture or excessive quadriceps weakness persists, the bivalved cast, holding the knee in maximum extension, is worn intermittently during the day. Several cast changes may be required to stretch out a residual flexion contracture. The importance of the postoperative regimen for the success of this procedure cannot be overemphasized.

#### Results

The average preoperative score of the sixty-one knees in this series was 9.5 points (range, 3 to 20 points) and the average postoperative score was 4.6 points (range, zero to 22 points). This was an average improvement of 4.9 points over the average preoperative score of 9.5 points (Table II). The results in knees with a medial compartment implant ranged from zero to 16 points (average, 3.7 points) and in knees with a lateral compartment implant they ranged from zero to 22 points (average, 6.8 points). Over-all, forty-four

TABLE II  
Records processed under FOIA Request #2016-622; Released by CDRH on 08-29-2016  
CHANGE IN RATING AS RESULT OF ARTHROPLASTY

Ratings	No. of Knees
Poor to poor	7
Poor to fair	0
Poor to good	6
Poor to excellent	10
Fair to poor	3
Fair to fair	2
Fair to good	7
Fair to excellent	10
Good to poor	1
Good to fair	2
Good to good	3
Good to excellent	10

(72 per cent) of the knees were graded as good to excellent. Thirty-seven (77 per cent) of the knees with a medial compartment implant were rated as good to excellent and seven (54 per cent) of those with a lateral implant attained this rating. The twenty patients who were less than fifty-six years old had an average postoperative score of 4.0 points, which was better than the rating for the over-all series. It should be particularly noted that this was an active group of patients, most of whom worked regularly and engaged frequently in non-strenuous athletics. While some of the younger patients admitted to some aching in the knees that had been operated on, after an extremely active day, none had limitation of their normal activities.

The forty-eight knees with a varus deformity that received a medial implant were corrected to an average of 2 degrees of valgus angulation, and the thirteen knees with a valgus deformity that received a lateral implant were corrected to an average of 6 degrees of valgus angulation.

The average postoperative active flexion in the knees with excellent and good results was 110 degrees (range, 60 to 135 degrees). Only three knees had less than 90 degrees of flexion, and nine had more than 120 degrees. Fifteen patients required manipulation of the knee at two weeks postoperatively, including two who had to have manipulation twice. Three knees had a 5-degree flexion contracture; two, a 10-degree contracture; and one, a 30-degree contracture.

Six knees (9 per cent), all with a medial implant, were rated as having a fair result. None required revision surgery. Eleven knees (18 per cent) were rated as having a poor result at follow-up. Six had had a medial and five had had a lateral implant. Seven of these knees have since had revision to a total knee replacement. One first had revision to a unicompartmental cemented prosthesis, which in turn was revised to a total knee replacement and ultimately to a knee fusion. The average time from unicompartmental surgery to total joint replacement was 2.8 years (range, 1.5 to four years). The knees with a poor result were especially characterized by pain and the need to continue the use of crutches. The average arc of motion in this group was 98 degrees (range, 60 to 130 degrees). All lacked 5 degrees to full extension except for one knee with a 30-degree flexion

contracture and only 60 degrees of flexion. The knees that subsequently required revision were those that had had the most severe arthritic involvement of the contralateral compartment and the patellofemoral joint.

### Complications

Complications related to the implant were rare. One medial implant dislocated several years postoperatively while the patient was engaged in vigorous dancing. This was treated by revision to a larger prosthesis and the patient had continued good function. The other complications were few in number and were typical of any major joint operation. There were five deep-vein thromboses, five hemarthroses requiring aspiration, one superficial infection with *Staphylococcus epidermidis*, one reflex sympathetic dystrophy, and one postoperative cardiac arrhythmia.

### Discussion

The alternative surgical procedures that are available today for the treatment of unicompartmental osteoarthritis include proximal tibial osteotomy, distal femoral osteotomy, and unicompartmental total joint replacement. The reported good to excellent results of high tibial osteotomy have ranged from 59 to 82 per cent<sup>1,3,7,8,10</sup>. The majority of these patients had varus deformity. The results of proximal tibial osteotomy for valgus deformity and lateral compartment osteoarthritis have generally been less satisfactory<sup>15</sup>, although Jackson and Waugh<sup>6</sup> reported that eleven of their patients with valgus deformity experienced considerable relief of pain.

The results of unicompartmental total joint replacement have also been variable. Insall and Walker<sup>4</sup> reported 45 per cent good to excellent results and Laskin, 65 per cent relief at two years of follow-up. Marmor reported 75 per cent good to excellent results at two to four years of follow-up.

The results of unicompartmental tibial-plateau arthroplasty with a McKeever implant have not been previously reported. Only two small groups of patients who received a McKeever implant for bicompartamental osteoarthritis have been reported on. The first such report was published following McKeever's death, from material of his that was assembled by Robert Elliott<sup>11</sup>. Seventy-six implants in forty knees were described and there was only one failure due to infection. Potter et al. reported on nineteen patients with bicompartamental osteoarthritis. Seventeen (89 per cent) of them had good to excellent results with the same knee-evaluation scoring that we used in this series.

The results in our series were similar to the best results reported for the other techniques that have been used to address the problem of unicompartmental osteoarthritis<sup>1,3,7,8,10</sup>. There are, however, several advantages to the McKeever implant. Few complications are directly related to the prosthesis. The loosening problems that are inherent in cemented prostheses do not exist. The McKeever implant does have the capacity to correct some varus or valgus deformity by means of varying implant widths, but it is our opinion that overcorrection must be avoided. It can also be

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used as an interpositional implant without changing the varus or valgus alignment of the joint in an arthritic knee without malalignment or in a knee with a depressed tibial-plateau fracture. A failed tibial osteotomy in a younger patient, in whom a cemented prosthesis could be a liability, can be easily converted to a McKeever hemiarthroplasty. There were two such patients in this series. One patient had an excellent result at the time of his death three years post-operatively, and the other, who has been followed for seven years to date, was working as an athletic coach with no significant pain or limitation of activity. Another significant advantage of the McKeever prosthesis is that its insertion does not require the removal of a significant amount of bone, thus making subsequent total joint-replacement surgery easier, and allowing the use of conventional total joint prostheses. The McKeever prosthesis has the capacity to function as a bicompartamental implant, although indications for this use are fewer in this era of total knee replacement. In special circumstances, however, such as in the younger patient, this use should be investigated.

The chief disadvantage of the McKeever implant is the prolonged rehabilitation that is required for a good result. Many older patients are not able to adhere to the regimen of strict partial weight-bearing. These patients, however, are probably better suited for a cemented joint arthroplasty than for the McKeever implant.

It is our opinion that the McKeever implant acts in a fashion similar to the cup arthroplasty of the hip. Observation of the established implant at surgery reveals a smooth glistening surface on both the tibial and femoral osseous surfaces, and while there is obviously motion on the femoral side, it is our opinion that there is micromotion on the tibial side which is important to the success of the implant. There is, therefore, a biological response of the tissues to the

implant. The exacting and prolonged rehabilitation program is required to obtain this local tissue response. In addition, it is our clinical observation that this biological adaptation appears to be inhibited by too tight a fit between the implant and the joint surfaces.

The chief reason for failure in this series appeared to have been multicompartamental arthritis. As this was more common in the older patients, it may partially explain why the younger patients tended to do better. Also, the younger patients were better able to participate in the rehabilitation program, which is more demanding than that required for a cemented prosthesis. The patients in this series were operated on before the era of reliable total knee arthroplasty, and today many of the older patients would be treated with a total joint replacement. Bicompartamental arthritis or severe patellofemoral arthritis would now be considered a contraindication to the use of the McKeever prosthesis.

There continues to be, however, the occasional patient with limited osteoarthritis of the knee who is not a candidate for total joint replacement, due either to age or to the desire to engage in vigorous activities. Osteotomy continues to be the procedure of choice for this type of patient, in our opinion, since no artificial implant is required. In the patient with unicompartamental arthritis without significant deformity, however, in whom realignment of the limb has no rationale, the McKeever prosthesis offers a feasible alternative to the cemented prosthesis. Another indication for use of the McKeever prosthesis is a failed osteotomy, when avoidance of a cemented prosthesis is desirable. While one may not see a great number of patients who will require the McKeever prosthesis, in our opinion it is the best alternative for a small subset of patients, and if it is properly applied it can provide a reliable solution for the complaints of some patients.

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# EXHIBIT 15

## The Classic

# Tibial Plateau Prosthesis

DUNCAN C. MCKEEVER, M.D., F.A.C.S.

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Duncan Clark McKeever (Fig. 1) was born on September 13, 1905, in Valley Falls, Kansas. After attending local schools, he graduated from the University of Kansas Medical School in 1929. As a naval reservist, he spent the next four years in naval training centers, followed by a residency in pathology at St. Luke's Hospital in Kansas City. While there, he fell under the influence of Drs. Frank Dickson and Rex Divley and became interested in orthopedics. After three years of association with them, he moved to Houston in 1939 to open a private practice. From 1941 to 1945, during World War II, he was back in the navy as chief of several hospitals. After the war, he returned to his private practice.

McKeever's knowledge of engineering principles led to his research interest in stress analysis as it applied to operative procedures on bones. His advanced ideas in orthopedic surgery led him to develop original procedures, and his exacting attention to details helped make them successful. His success led to additional innovative procedures, which included prostheses of the hip, patella, and tibial plateau.

His continuing studies kept him in demand as a teacher. Frequent visits from his many friends included those from Latin American countries. Dr. McKeever enjoyed hunting and fishing, and he was always delighted to be at his ranch.

McKeever was one of the founders of the Association of Bone and Joint Surgeons and became its third president. He was also a member and active participant in many orthopedic organizations and on local hospital boards and staffs.

On a rainy evening, October 13, 1959, when driving someone else's car, he ran out of gas; while filling the tank, he was struck by another car and killed. His untimely death was a great loss to orthopedics as well as a personal loss to his many friends.

JUSTUS C. PICKETT, M.D.

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In the past, when a badly damaged knee joint lost any of its articular surfaces, we destroyed it. If the patella is rough, some surgeons take it out. Usually this is not necessary. If the condyles and the plateaus lose their articular surfaces, we arthrodes

the knee. This is not an answer; it is an escape. A constructive solution must be found to replace this destructive one. Arthrodesis is an easy way out for surgeons and for patients who have trouble in only one knee, but what of those who have two bad knees? Arthrodesis is an admission of defeat. It is an answer that will be accepted less readily as knowledge of endoprostheses accumulates.

The tibial plateaus present a special problem in endoprosthetic restoration. Mechanically, each plateau forms part of a separate joint. They must function synchronously, but the degree of damage of the two may not be identical. Within the same joint space

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The material in this chapter was assembled by Dr. Robert B. Elliott, of Houston, Texas, after Dr. McKeever's death. Part was at Dr. McKeever's home, part was found in his wrecked automobile. Dr. Elliott also read the contents of this chapter at the meeting of the American Fracture Association held in New Orleans, October, 1959.

Reproduced with permission from McKeever, D. C.: Tibial plateau prosthesis. Clin. Orthop. 18:86, 1960.





FIG. 1. Duncan Clark McKeever (1905-1959).

the patellofemoral articulation must function. The knee joint has little structural stability.

### BIOMECHANICS

There are several fundamental considerations applicable to all prostheses intended for functional restoration of joint surfaces. These factors should determine the design and the use of endoprostheses, and must always be given due consideration. The important fundamentals lie within the field of biomechanics. Prosthetic design need not continue to be developed solely by trial and error.

A. There must be an optimal relation between surface area and the range of functional stress to be borne by the prosthesis and transmitted from it to bone. We can obtain a rough idea of the range of these stresses in normal joints by the application of simple mathematical formulas. From this application we can assume that the stresses

must at times exceed 2,000 lbs. per square inch.

In relation to the tibial plateau, the knee is a lever of the 2nd class. The point of action is between the applied force and the fulcrum. If the weight is 150 lbs., the femur is 18 inches long and the fulcrum is 1 inch from the center of application of the force on the tibial plateau, the force exerted is  $17 \times 150$ , or 2,550 lbs. If the area to which it is applied is 1 square inch, the load is 2,550 pounds per square inch.

The object of an endoprosthesis is to achieve functional restoration. If we wish to restore normal function, we must make as close an approach as possible to the surface areas and contours existing in the normal joint, since in nature there is a correlation between these areas and the functional stresses imposed on them when in use. Their contour, design and density are determined by the effect of function during growth.

B. An endoprosthesis must be self-retaining. It must be so designed and inserted that the normal forces existing in the joint in action hold it in place. Any screw, pin, flange or other retention device that functions as anything more than a guide to alignment or to retention of the prosthesis when the joint is at rest must eventually give way as a result of cyclic stress.

C. The direction of stress transfer between the endoprosthesis and the bone on which it rests must be constant. The importance of this factor is very seldom appreciated. Bone will withstand repeated applications of stress, and even increase in sectional density to offer increased resistance to the stress, provided that the stress is constant in direction. If there is an angular variation in direction of stress, absorption certainly will take place. The prosthesis cannot have just anatomic continuity with the bone; it must have functional continuity.

D. The stress transfer from prosthesis to bone must take place at a single level. Any part of a prosthesis that passes this level will

be nothing more than an alignment device to maintain a constant direction of stress. If a significant portion of the stress to be transferred from the endoprosthesis to the bone bypasses one part to reach another level of bone, absorption will occur and will continue until a balance is reached. This absorption will be in proportion to the amount of stress that bypasses the contact point. If all of it bypasses this point, total absorption will occur. Bone that is not functional as a stress-transmitting unit will disappear. We must not lose sight of the fact that endoprostheses transfer stress on two surfaces. The stress is transferred from one articular surface to the prosthesis, is transmitted through it and again is transferred to the bone.

E. Complete functional restoration of the joint by a thorough surgical procedure must be the goal. A prosthesis may play a small, though vital, part in the result. Such problems as range of motion, stability, muscle balance and restoration of periarticular gliding surfaces must be given due attention individually and in relation to each other.

### CLINICAL CHOICE

Case selection is an important consideration in the use of endoprostheses. It is a common error in surgical judgment to use a new procedure, or device, such as a prosthesis, in the most hopeless and difficult case that we can find. This attitude has been responsible for many discouraging failures of good surgical procedures; for instance, in the hip. I have done it, others have done it, and it is so natural that we probably shall continue to do it. But it is not logical. The proper case to select for the first use of an endoprosthesis is one in which the only functional deficit in the joint can be replaced by insertion of the prosthesis. This would suggest that the joint still is functional, or at least that it only recently has lost its function.

The mental attitude of the patient, his tolerance to pain, his economic and psycho-

logical incentives to cooperate may be decisive. Some patients, through sheer will power, continue to get about on a joint that functionally is so deranged that others of weaker moral fiber and lower pain tolerance would long since have ceased to use it. Such people are good patients on whom to try a new surgical procedure.

The physiology of the patient frequently is ignored. To do this is to invite failure. Prostheses are *biomechanical* problems. A functional unit that is satisfactory in a machine may fail in a living body. A machine cannot alter its structure to compensate for variations in stress; its margins of safety are constant. In a healthy body, bone can increase in density and in size to meet the additional strain if the stress is not applied too rapidly or in too great an amount. The direction of application should not change, but its margins of safety may be variable. In an unhealthy body, where the stress is applied too fast and in too great an amount or in a variable direction, bone will melt away. We must ensure a positive reaction to the prosthesis. Bone responds according to certain laws. We must know what they are and apply this knowledge.

### PHYSIOLOGICAL CONSIDERATIONS

We cannot afford to assume that a patient's physiology is normal; we must use every test at our command to detect any possible abnormality. Vital functions for which we have no laboratory or clinical test must be assumed to be subnormal. We should take steps to ensure their function at physiologic levels. Many reconstruction procedures have failed because the doctor did not realize the importance of the general health of the patient and did not take steps to improve it. All aging individuals, and many who have sustained an injury or have had other surgery, are in some degree of catabolism. The essence of degenerative change, the cardinal characteristic of aging, is that catabolism exceeds

anabolism in rate. The body must be made to react positively to the prosthesis. This implies normal physiology, as expressed by rapid healing. Normal osteogenesis will ensure proper arrangement of stress lines for the transfer of strain from the prosthesis to bone and enable the bone to attain optimal cross-sectional density in a minimal time. Unless the patient is in a positive metabolic state, these positive reactions to the prosthesis cannot occur; ultimate failure then is certain.

The metabolic phase of this problem must be considered in the light of the patient's life expectancy. Optimal physiology must be maintained for the remainder of the patient's life. Part of the surgeon's job is to emphasize to the patient and his responsible relatives the importance of this factor, so that they will see to it that the regimen is continued after the patient has been discharged from direct medical supervision.

Muscle function and balance must be restored with proper exercises. In the knee joint the function of the flexors is very important. The extensor mechanism cannot function normally unless it is balanced by hamstrings of good strength and resiliency. The hamstrings must be given adequate progressive exercises, for, paradoxically, the knee will not extend fully if the flexors are weak. Full extension must be restored. Full flexion is not essential, but good functional flexors are.

Occasionally, arthroplasty of an ankylosed knee is indicated and justified, but there are many more knees in which restoration of one or both tibial plateaus for weight-bearing surfaces is indicated. Such restoration will avoid an arthrodesis and restore a functional range of pain-free motion not possible without it. In centrally or totally depressed tibial plateau fractures, restoration of position may not restore a smooth surface. In traumatic and degenerative arthritides, particularly in elderly individuals in whom a gradually developing flexion contracture precludes weight-bearing, a smooth plateau may restore function. Such conditions may follow trauma that occurred many years before. They may

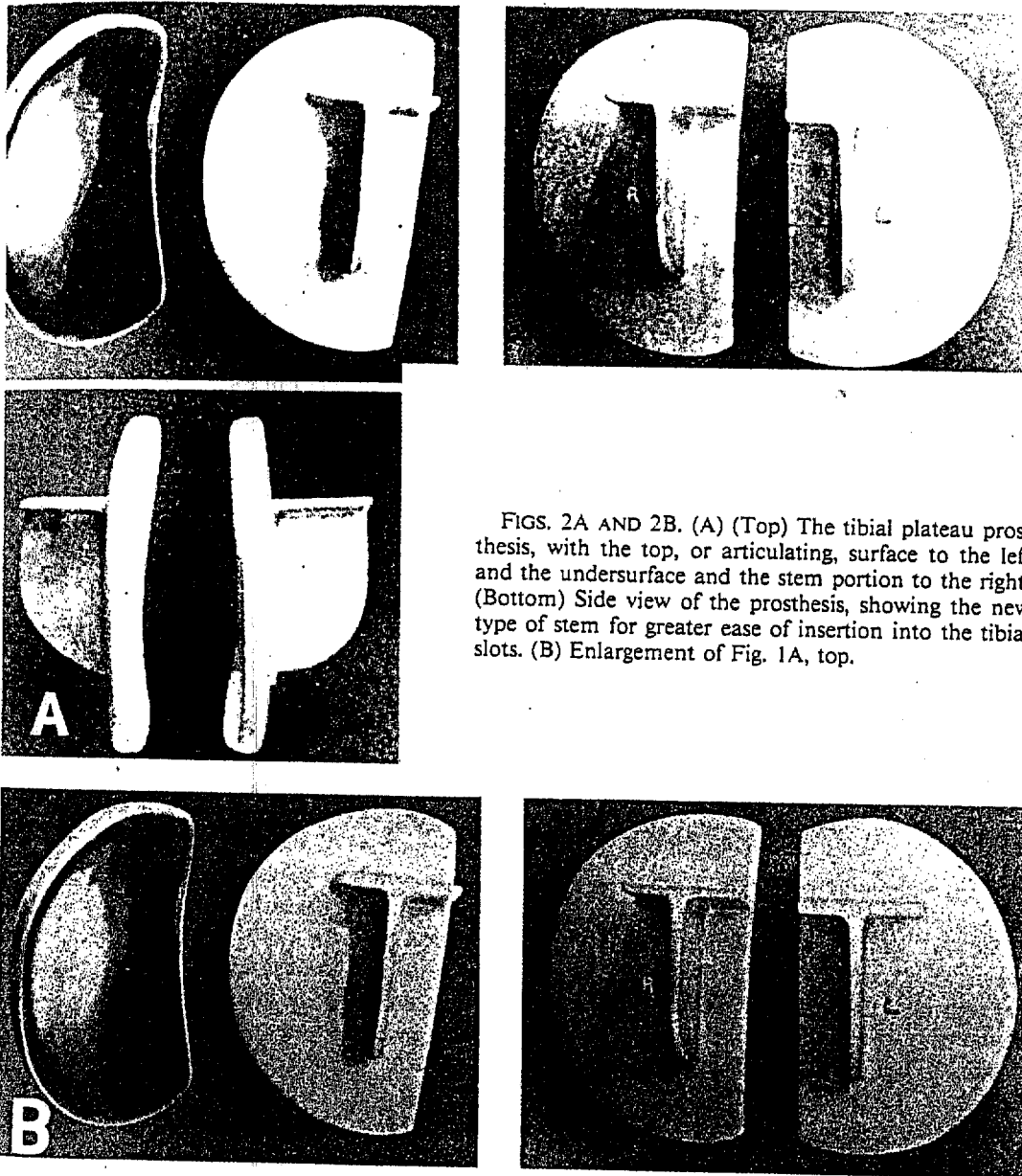
be the end result of osteochondritis dissecans, old untreated cartilage injuries, or the abnormal weight-bearing stresses occurring with a knock-knee or a bowleg. They may occur incidentally in rheumatoid arthritis. Many such cases are subjected needlessly to arthrodesis.

## DESIGN OF PROSTHESIS

For some years I tried to design a prosthesis for application to the lower end of the femur. During this time I made several different drawings with a number of minor variations in each. Instinctively I felt that there was something wrong with them. After several years of study of the mechanical principles, during which time I made more and more application of these principles to the problems of endoprostheses in other locations, the basic fault of this approach to the problem finally occurred to me: Such a prosthesis violates one of the given principles. "There must be a constant direction of stress transfer from the prosthesis to the bone." How does this apply to the knee joint? In the lower end of the femur, stress applied may vary through an arc up to 145° between the limits of flexion and extension. This precludes stress transfer from prosthesis to bone in a constant direction. In such a case extension produces a direct thrust. In flexion, the lower femur becomes the site of application of forces exerted through a lever. Bone will not withstand angular variations of stress at the point of contact with a prosthesis.

The functional stress applied to the surface of the tibial plateau has a constant direction. It is in line with the axis of the tibial shaft no matter what position the knee is in. Any prosthesis applied to the knee and functionally similar joints—for example, the interphalangeal and the metacarpophalangeal joints—should be on the distal side of the joint.

The restoration of the tibial plateau must be accomplished by two separate pieces, one for each tibial plateau. In many knees it is



FIGS. 2A AND 2B. (A) (Top) The tibial plateau prosthesis, with the top, or articulating, surface to the left and the undersurface and the stem portion to the right. (Bottom) Side view of the prosthesis, showing the new type of stem for greater ease of insertion into the tibial slots. (B) Enlargement of Fig. 1A, top.

necessary to restore only a single plateau, in which case it is important to have a single-plateau type of prosthesis. Of importance also is the observation that there is a change in axis at the knee joint as flexion occurs. In many cases, this would cause either rocking or binding of a one-piece prosthesis made to cover both plateaus. The only way to avoid

this with a one-piece prosthesis would be to have the lateral ligament sufficiently loose to prevent binding. Such a joint would be unstable in extension (Fig. 2).

The first prosthesis designed had exactly the same contact articular surface as the present prosthesis. This surface design was achieved by measuring 40 tibias of different

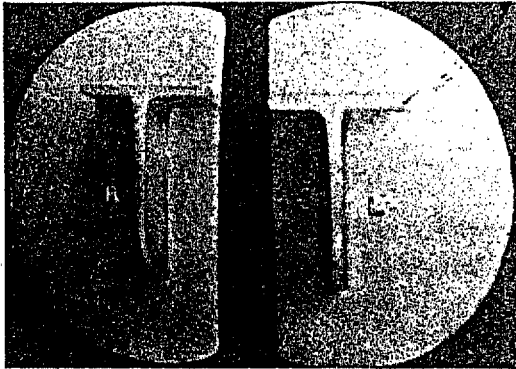


FIG. 3. The undersurface of a pair of tibial plateau prostheses, labeled L and R. This does not refer to the right knee and the left knee but to the right side and the left side of *either* knee as one faces the knee during surgery.

sizes. These measurements disclosed that, while considerable variation existed in the overall diameters of the upper surfaces, there was little variation in the central weight-

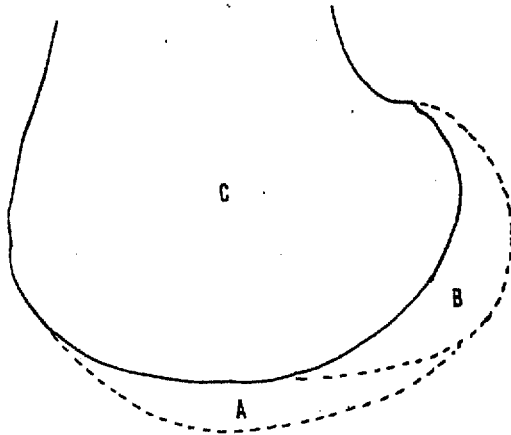


FIG. 4. Diagrammatic lateral view of the distal end of the femur in certain cases. If the femoral condyle has been badly worn away and flattened, then it is necessary to remove some of the posterior condyle to restore the normal elliptical contour of the articular surface to permit normal smooth flexion. "A" represents the portion of the femur worn away and flattened, and in this case "B" represents the portion of the posterior condyle to be removed to restore the normal elliptical contour. "C."

bearing areas. The largest tibia did not exceed the articular surface of the present prosthesis, and its dimensions were within the anatomic limits of the smallest adult tibia of those tested. The articular surface of the larger specimens was found to be an extension of the elliptical contour of the weight-bearing area of the smaller tibias. The central areas were almost identical. Furthermore, in practice, this contour has proven to be satisfactory. The original stem has been altered for greater ease of insertion. The prostheses are made in pairs. A pair will do both sides of either knee. For example, the prosthesis for the right medial plateau fits the left lateral plateau. They are labeled right and left. This is not an anatomic designation but refers to the right or the left side of the knee being operated upon as one faces it. (Fig. 3).

#### OPERATIVE TECHNIQUE

Through a median parapatellar incision the semilunar cartilage, or its remnant on the involved side, is removed. The femoral condyle may be flattened if the weight-bearing surface is worn away badly. This necessitates the removal of a portion of the posterior part of the condyles to restore the elliptical contour of the articular surface and permit smooth flexion (Fig. 4).

With a reciprocating saw, a triangular piece of bone is removed from the tibial plateau and the tibial spines. An anteroposterior cut is made  $\frac{1}{4}$  inch from and parallel to the vertical edge, where the triangular piece of bone was removed. A transverse cut then is made at right angles to the anteroposterior cut and approximately  $\frac{1}{2}$  inch from the anterior edge of the plateau (Fig. 5). It extends medial to the anteroposterior cut and then lateral to it. These cuts need not be deep, but they must penetrate the subchondral bone (Fig. 6). The prosthesis then is inserted so that the anteroposterior flange on the prosthesis rests in the anteroposterior saw cut. It is pushed or driven back into the knee until the transverse flange on the prosthesis

lies directly over the transverse saw cut. It may be necessary to distract the joint in order to do this (Fig. 7). Distraction may be obtained by manipulation of the leg or by placing a lamina spreader in the intercondylar groove. With the flanges on the prosthesis in position over the grooves, the knee is extended. The prosthesis will seat itself as the joint tightens in extension. Flexion of the joint then can be tested. If it is smooth and the joint is stable in extension, the insertion is satisfactory.

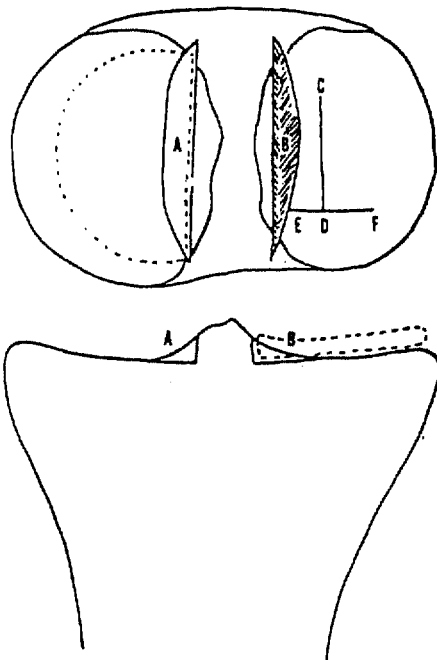


FIG. 5. (Top) View of the superior articulating surface of the tibia showing (A and B) the portions of the tibial plateaus and the tibial spines removed for insertion of the tibial plateau prosthesis. C to D is the anteroposterior slot and E to F is the transverse slot, which are cut into the tibia, by measurement, to allow insertion of the stem of the prosthesis. This is done on both sides of the tibia, of course, for insertion of a pair of prostheses in each knee, although here it has been done on one side only. (Bottom) An anterior view of the same portion of the tibia showing the triangle of bone removed from the tibial plateau and the tibial spine areas to allow insertion of the prosthesis, as represented by the broken line on the right.

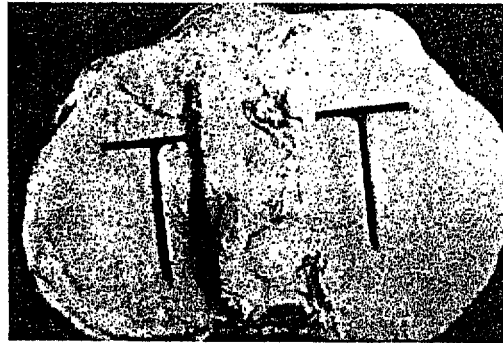


FIG. 6. Gross tibial specimen of the preparation of the tibial plateau prosthesis bed and the slots to receive the stem of the prosthesis.

The patella may show chondromalacia or proliferative changes. If it is badly damaged, it should be restored with a patellar prosthesis.

The other tibial plateau may be restored in exactly the same manner. Any necessary smoothing of the edges of the condyles or debridement of the remainder of the joint should be carried out. I am of the opinion that these overhanging edges should be gently hammered flat rather than cut off. The surface will be much smoother if this is done. The articular margins of the condyles should be treated in this way.

If it is necessary to elevate the tibial plateau to correct valgus or varus deformity, the prosthesis should be inserted first. The collateral ligament and periosteum are elevated, maintaining continuity with the periosteum on the tibial shaft. A transverse saw cut should be made beneath the prosthesis. I prefer to cut it with an osteotome. The entire plateau, in which the prosthesis is embedded, is elevated, and the cut-out piece of bone may be removed and used to fill the defect. The plateau should be held in this elevated position by a carefully fitted autogenous bone graft, preferably formed from a full thickness of ilium with the crest at the tibial cortex (Fig. 8).

#### COMMENTS

Most of the cases in which this prosthesis has been used would otherwise have been

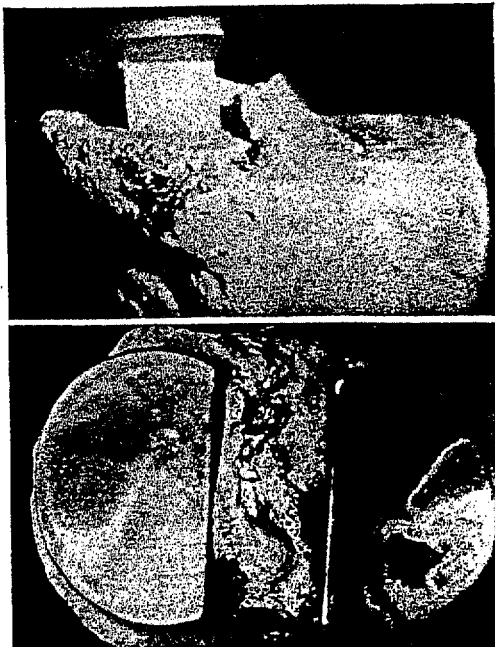


FIG. 7. (Top) Anterior view of gross specimen as would be presented at operation, showing the technique of inserting the prosthesis with the anteroposterior stem in the slot, pushing it backward (posteriorly) until the transverse stem fits into the transverse slot, and then seating the prosthesis by pushing or tapping on it. Extension of the knee joint will also tighten the joint, and the pressure of the femoral condyles will aid in seating the prosthesis. Insertion of the prostheses initially may be aided by distraction of the joint by manipulation or by use of a lamina spreader in the intercondylar notch region. (Bottom) Superior view of articular end of the tibia (knee joint) showing the prostheses seated in correct position and alignment.

subjected to an arthrodesis. At least one of them could not have been ambulatory except in so far as one is able to be ambulatory with both knees arthrodesed. Both knees of the woman were involved in a very advanced rheumatoid arthritic process, the degenerative changes of which had been accentuated by decalcification incident to long-continued administration of large doses of cortisone.

The first case was operated on in April, 1952. This was an almost hopeless joint, due to an advanced villonodular synovitis. This

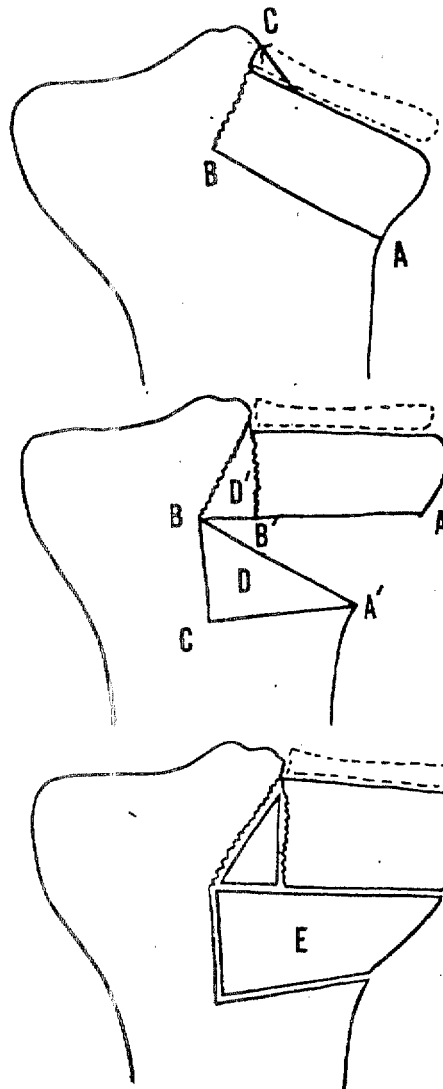


FIG. 8. (Top) Technique of using the prosthesis and elevating the tibial plateau when markedly depressed from old fracturing, bone disease, or erosion. (A) Prosthesis is inserted first, and the tibial plateau is elevated by making an anteroposterior saw cut from A to B and then breaking or cutting the attachment between B and C as the plateau is elevated with the prosthesis in place. (Center) Next, a triangle of bone (D) is removed by cutting from A' to C and from B to C; then this piece (D) is placed at D' to fill the gap and to add stability. (Bottom) Finally, a piece of autogenous iliac bone, shown as E, is cut and fitted carefully into place, as illustrated, to complete the elevation and the support of the tibial plateau and prosthesis.

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woman was such a case as I have said should not be chosen for trial of a new device or procedure; she had been in flexion contracture, partially disabled for 11 years, and on crutches for 5 years. She had a restoration of both tibial plateaus by a prosthesis, a patellar prosthesis and an extensive joint debridement. Cellophane was interposed to restore the periarticular gliding surfaces and the suprapatellar pouch. Eight days after operation she had a smooth range of passive motion from 30° of flexion to complete extension. Three weeks later she had almost 90° of flexion and lacked a very few degrees of complete active extension against gravity. This patient had taken her medication in a rather haphazard fashion. In spite of this, she continued to be quite active. When seen 1 year later, she had a range of motion, voluntary and against gravity, from 80° to 180°. She walked with a cane outside the house and without a cane in the house. Two years after the operation she had lost some motion. She had stopped all medication and had had an acute exacerbation of her general arthritic process. Six years postoperatively, after resuming her medical regimen, she was walking without a crutch or cane, has 70° of flexion and complete extension against gravity. She did not have any pain unless she was on her feet all day.

When it is considered that this patient, aged 57, had a villonodular synovitis of 11 years' duration and a generalized rheumatoid and degenerative arthritis with almost complete destruction of all joint surfaces of the knee, that she had been on crutches for several years, and that she had a 30° flexion contracture when first seen, this result seems quite satisfactory. She is still quite active, walks without a crutch or a cane and drives her own car.

Another case was a woman of 34. She had had rheumatoid arthritis for 8½ years. She had taken 150 mg. of cortisone daily for 5½ years. She could walk a few steps with crutches. She had advanced chondromalacia of the patella and extensive destruction of

the joint surfaces. There was flexion contracture in both knees, also valgus deformity of 40° on the left knee and about 20° on the right knee.

On February 14, 1955, a partial synovectomy and excision of the semilunar cartilages were carried out on the left knee. A lateral tibial plateau prosthesis was inserted, and the plateau was elevated to correct the valgus deformity as much as possible. A patellar prosthesis was inserted.

Extensive alterations in her medical regimen were instituted, and all activity of her arthritic process ceased. About 6 weeks after the first operation the right knee was operated on in a similar manner, a lateral tibial plateau prosthesis and a patellar prosthesis being used. Extensive debridement and synovectomy were done. It was not considered necessary to elevate the tibial plateau on this side because the prosthesis itself produces some correction, and it seemed sufficient in this knee. The result might have been better if it had been raised enough to correct the valgus completely. The patient gets about without crutches or a cane. She goes up and down stairs with some difficulty. She is working full time as a secretary. She has had no acute exacerbation of her rheumatoid arthritis in spite of very unusual stress due to the prolonged serious illness of her husband. She has continued to carry most of the load of family activity.

Similar operations have been carried out on other patients. To date, I have inserted 76 plateaus in 40 patients. In most of these, patellar prostheses have been used in conjunction with the plateau prostheses. All of them were badly damaged knee joints, and varying degrees of debridement and contouring of the edges of the condyles were carried out. Excision of one or both semilunar cartilages was necessary in every case.

There has been one failure due to recurrence of an old infection. This necessitated the removal of both plateau prostheses and the patellar prosthesis, and the patient now has an ankylosis.



All the other cases are ambulatory without cane or crutches, though some of the older patients are encouraged to carry a cane for safety. All have a satisfactory functional range of motion, from complete extension to 90° or more of flexion. In one patient recurrent pain has persisted. Because it is relieved completely by a small injection of 1 percent procaine, administered every 2 or 4 months, this pain is believed to be of functional stress origin. Several other cases are in varying

stages of convalescence but are not considered to have reached an end-result status.

#### CONCLUSION

With this prosthesis it is possible to restore satisfactory function to most of the badly damaged knee joints that ordinarily would be subjected to an arthrodesis. If this prosthesis will function satisfactorily in these severely damaged knee joints, it will function in any case other than that with an infection.

# EXHIBIT 16

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## THE USE OF THE HEMIARTHROPLASTY PROSTHESIS FOR ADVANCED OSTEOARTHRITIS AND RHEUMATOID ARTHRITIS OF THE KNEE

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*From the Orthopaedic Service of the Toronto General Hospital*

The surgery of advanced arthritis of the knee joint is attracting considerable attention, and the value of osteotomy (Jackson and Waugh 1961, Gariépy 1964, Coventry 1965, Benjamin 1969) and of arthroplasty (Walldius 1957, McKeever 1960, Shiers 1960, Young 1963, Platt and Pepler 1969, Turner and Aufranc 1969) has been discussed in the recent orthopaedic literature.

MacIntosh gave a preliminary report on the value of hemiarthroplasty in 1958 and in 1966 reported a review of fifty-eight rheumatoid knees. This further review was undertaken to make an independent assessment of the results of the operation and to determine its place in the surgical treatment of advanced osteoarthritis and rheumatoid arthritis of the knee.

### AIMS OF HEMIARTHROPLASTY

The aims of hemiarthroplasty are to correct the varus or valgus deformity by inserting a tibial plateau prosthesis of appropriate diameter and thickness to build up the worn side of the joint, and thus to restore normal stability of the knee, to relieve pain and to improve function and gait.

The collateral ligaments usually maintain their own length in spite of long-standing varus and valgus deformity, and stability is maintained by a prosthesis that is thick enough to correct the deformity and take up the slack in the collateral ligaments.

The operation should be considered only when more conservative methods such as meniscectomy, synovectomy, joint debridement and tibial osteotomy would be of no value, and when the disease has progressed to a stage at which all the articular cartilage on the weight-bearing surfaces of the knee has been destroyed and bone is articulating with bone.

### HISTORY OF HEMIARTHROPLASTY

In 1954 a seventy-three-year-old woman was admitted to the Toronto General Hospital for proposed fusion of an arthritic knee with severe valgus deformity. At operation it was noticed that the valgus deformity could be passively corrected; the lateral ligament then became taut, restoring stability. In the operation theatre at that time there happened to be an acrylic prosthesis for replacement of the whole upper end of the tibia, as used by Dr Sven Kiaer and Dr Knud Jansen of Copenhagen. The prosthesis was cut in two, and one half was inserted in the lateral space to correct the deformity. This produced a stable straight knee which flexed to 90 degrees, and the patient lived free from pain for a further twelve years.

Acrylic was later abandoned, mainly because of widespread dissatisfaction with the use of this material in the hip. In the knee it showed only slight wear, and four of six patients who are still alive, but not included in this series, have a good result more than ten years after the operation.

A trial was then made with Teflon, but this wore badly and promoted an acute foreign body reaction. Only five knees out of sixteen reviewed showed a good result, and fusion or total knee replacement was soon necessary in over half of this group.

Titanium implants were then used, but discontinued because the polished surface of the prosthesis appeared to score and metallic dust discoloured the entire synovium.

Since 1964 Vitallium has been used exclusively and no further change in the design of the prosthesis has been found necessary. The prosthesis is available in three diameters and in serial thicknesses from six to twenty-one millimetres. It can be used in the medial or lateral compartment of either knee. The prosthesis is held in position by the anatomy of the knee joint, and stability depends upon the taut collateral ligaments. No additional fixation is necessary. The top of the prosthesis has a contoured surface with rounded edges to provide the condyle with a permanent low friction area. The undersurface is flat with multiple serrations to ensure a snug fit and stability (Fig. 1).

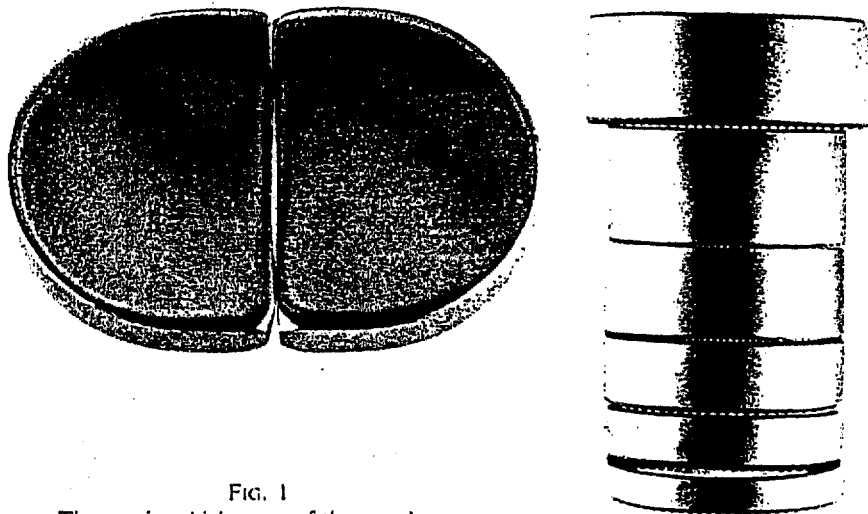


FIG. 1  
The varying thicknesses of the prostheses.

#### ASSESSMENT BEFORE OPERATION

The principal complaints were pain, deformity, instability and limitation of function.

Clinical examination revealed painful bone-on-bone crepitus in one or both compartments of the knee. Most knees in the osteoarthritic group showed varus deformity and most of those in the rheumatoid group had a valgus deformity, but this was not invariable.

Radiographs taken with stress applied to the affected knee were found to be of more value than standing films in assessing the cartilage space of each tibio-femoral compartment (Figs. 2 and 3).

A final decision on whether one prosthesis or two should be inserted often could not be made until both joint surfaces had been examined at operation. Preliminary arthroscopy or arthrography had not been found helpful.

#### TECHNIQUE OF OPERATION

The operation is done on the exsanguinated limb usually through a medial parapatellar incision with complete lateral displacement of the patella. If there is flexion deformity of over 30 degrees the patellar tendon is detached with a small rectangular block of bone before transfer downwards and medially to be dovetailed into the medial border of the tibia. If this transfer is done it is combined with release of the lateral expansion, and in these patients a lateral parapatellar incision may be preferred.

A thorough examination is done to determine the extent of synovial proliferation and cartilage destruction. In rheumatoid arthritis the synovium is often thin and atrophic at this advanced stage and is preserved. If, however, it is hypertrophic, synovectomy is done. A

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flare-up in a rheumatoid knee after prosthetic hemiarthroplasty with or without synovectomy, is rare.

The meniscus, when present, is excised. In rheumatoid arthritis both cruciate ligaments are usually absent or attenuated. If a taut anterior cruciate ligament prevents extension it is divided (Somerville 1960). Loss of either cruciate ligament has not interfered with stability.

After a long-standing knee flexion deformity, an unworn ridge of bone along the anterior aspect of the medial femoral condyle may have to be cut away to improve knee extension (Fig. 4); at the same time marginal osteophytes, if present, are excised from each femoral condyle. Flexion deformity of up to 30 degrees can be corrected at arthroplasty in the cutting of the bed for the prosthesis and by freeing the capsule at the back of the joint. More severe flexion deformities may need posterior release, but this is best done some months later.



FIG. 2

FIG. 3

The value of stress radiography in the assessment of the cartilage space in each tibio-femoral compartment before operation is shown by comparing Figures 2 and 3.

A level bed is cut for the prosthesis on one or both tibial plateaux. The first osteotomy cuts are vertical, protecting the intercondylar area, and the plateau shaped accurately to a level bed, using an air-powered drill with reciprocating saw, as little bone as possible being removed (Figs. 5 to 7). The bed should be at right angles to the coronal and sagittal planes. No lateral or posterior ridge need be left to stabilise the prosthesis; stability is ensured by the rough undersurface of the prosthesis and a perfectly flat bed.

Varus or valgus angulation is corrected by the insertion of a prosthesis of appropriate thickness and diameter in each compartment (Figs. 8 to 15). If there has been a long-standing varus or valgus deformity the femoral condyles may have acquired a medial or lateral slope, and the prominent margins will have to be cut back.

If on flexing the knee to a right angle tilting of the prosthesis occurs, it is essential to ensure that the beds are level in both planes. Rarely it is necessary to reshape the femoral condyles posteriorly to prevent their impinging on the prosthesis when the knee is flexed.

No attempt is made to correct the lateral rotation deformity so commonly associated with a valgus knee in rheumatoid arthritis. This rotation deformity is caused by a combination of flexion deformity and a tight ilio-tibial band. It is thought that the knee establishes its own plane of motion in lateral rotation, and that no correction need be attempted.

Trimming of marginal osteophytes from the patella is often needed, but excision of the patella should be avoided at the time of hemiarthroplasty whenever possible because it delays rehabilitation.

The tourniquet is released before closure. The wound is irrigated with Bacitracin solution and closed in layers with catgut and subcuticular wire. Blood transfusion is seldom needed. Prophylactic antibiotics have not been routinely used in this series.

#### MANAGEMENT AFTER OPERATION

The knee is kept in extension for five days after operation in a massive compressive bandage or very occasionally in a Thomas splint. Static quadriceps exercises are started on the first day after operation, even if the patellar tendon has been transferred. The patient is

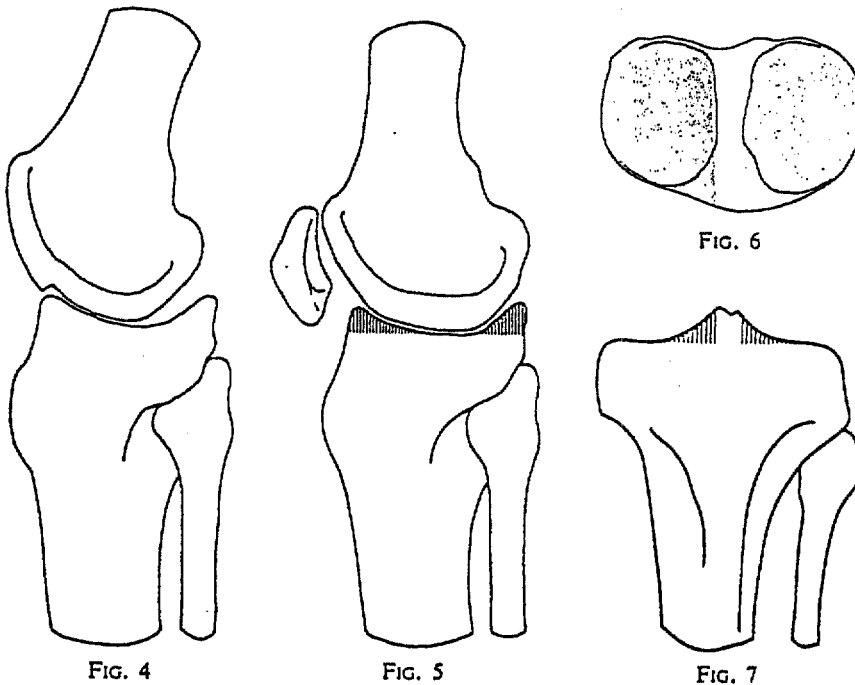


FIG. 4  
FIG. 5  
FIG. 6  
FIG. 7  
Figure 4—The unworn ridge of bone on the medial femoral condyle is often present after a long standing flexion deformity. Figures 5 to 7—The direction of osteotomy of the upper surface of the tibia.

allowed up fully weight-bearing in a walking frame or with crutches after two days and active flexion is encouraged after five days if wound healing is adequate, initially in the ward and later in a hydrotherapy pool.

If movement is slow to return a gentle manipulation under anaesthesia to 90 degrees of flexion, with an intra-articular injection of a corticosteroid, is given in the second week after the operation; the manipulation is repeated after a further week if progress continues to be slow.

Crutches are replaced by walking sticks as soon as the patient can safely manage with them, and may be necessary for two or three months after the operation.

#### ANALYSIS OF CLINICAL MATERIAL

In the ten years from 1959 to 1969, 122 patients were operated upon by the senior author. Eleven patients were not available for review, ten had died from intercurrent disease and two had revision procedures too recent for review.

Records processed under FOIA Request #2016-622; Released by CDRH on 08-29-2016.

Of the ninety-nine patients available for review, sixty-eight had had arthroplasty of one knee and thirty-one had had arthroplasties of both knees, making a total of 130 knees to be assessed.

Sixty patients fulfilled the accepted criteria for the diagnosis of rheumatoid arthritis, and the remaining thirty-nine had pathological and radiological findings consistent with osteoarthritis.

There were thirty medial, fourteen lateral and eighty-six double hemiarthroplasties.

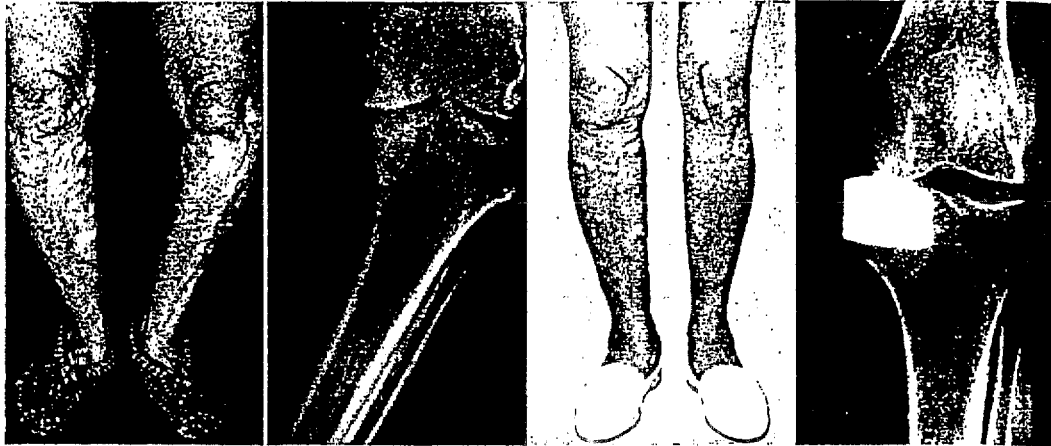


FIG. 8

FIG. 9

FIG. 10

FIG. 11

The correction of a varus deformity by a single plateau in the medial compartment of an osteoarthritic knee.



FIG. 12

FIG. 13

FIG. 14

FIG. 15

The correction of a valgus deformity by a single plateau in the lateral compartment of an osteoarthritic knee.

*Sex*—There were twenty men and seventy-nine women.

*Age*—The age at the time of operation was between twenty-one and seventy-eight years, with an average age of fifty-six years. The age distribution is shown in Figure 16. The patients with rheumatoid arthritis were much younger than those with osteoarthritis.

*Side*—The operation was performed on the right knee on seventy-two occasions and the left knee on fifty-eight occasions.

*Type of prosthesis*—A titanium prosthesis was in use until 1964, but since that time only Vitallium has been used (Table I). Five patients who previously had a hemiarthroplasty performed by other surgeons but who required revision are included in this series.

*Duration of symptoms*—The duration of symptoms before operation ranged between three and forty years, with an average of fifteen years.

HEMIARTHROPLASTY FOR ADVANCED ARTHRITIS OF THE KNEE

*Length of follow-up*—The follow-up period was from one to ten years, with an average of three and a half years (Fig. 17).

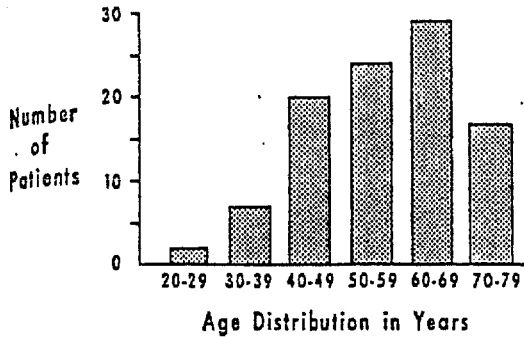


FIG. 16

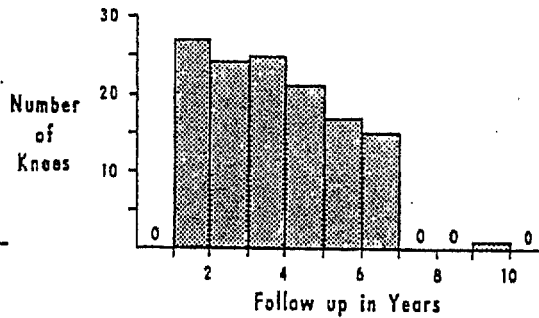


FIG. 17

Figure 16—Age distribution (ninety-nine patients). Figure 17—Duration of follow-up (130 knees).

METHOD OF ASSESSMENT

All patients were assessed personally by one of the authors (G. A. H.). It was necessary to travel more than 5,000 miles in Ontario to ensure adequate follow-up; the patients were interviewed, their knees examined, their gait studied, and radiographs were made available locally where appropriate.

TABLE I  
TYPES OF PROSTHESIS (130 KNEES)

Metal	Number
Titanium .	17
Vitallium .	107
Mixed .	6

TABLE II  
RANGE OF MOVEMENT (130 KNEES)

Range (degrees)	Number of knees	Result
More than 90.	70	53 Good 17 Poor
60 to 89	49	41 Good 8 Poor
Less than 60	5	Poor
Later fusion or total replacement	6	

TABLE III  
FLEXION DEFORMITY (130 KNEES)

Flexion deformity (degrees)	Number of knees	Result
0 to 10	104	87 Good 17 Poor
11 to 20	12	7 Good 5 Poor
More than 20.	8	Poor
Later fusion or total replacement	6	

The assessment of results after operation is difficult. In both groups the disease is subject to periods of remission and recurrent activity. "The enthusiasm of the surgeon for the procedure and the loyalty of the patient towards his surgeon must be minimised if accurate reproducible results are to be obtained" (Potter 1969). For this reason we felt that the surgeon's or the patient's assessment would be inaccurate.

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The aims of arthroplasty are fivefold. 1) To relieve pain so that no analgesics are required for the knee joint itself. 2) To increase range of movement. All the patients with good results were found to have at least 60 degrees of flexion from the extended position (Table II). In seven patients there was a good result in spite of fixed flexion deformity of 15 to 20 degrees (Table III). The range of movement was recorded by the zero neutral method. 3) To provide stability. This was assessed subjectively by the patient, who complained of giving way at the knee, and objectively by assessment of the stability of the cruciate and collateral ligaments, and the power of the quadriceps muscle. 4) To improve function and gait. Enquiry into the activities of daily living after the operation and to that before operation as estimated by the patient and from the records. Most patients found it impossible to kneel and had difficulty in descending stairs normally both before and after the operation. No patient was considered to have a good result if two crutches were still used. Many patients used one stick outside the house. 5) To correct the lateral deformity to within 5 degrees of varus or 10 degrees of valgus. The actual degree of valgus in a normal knee, when measured from the mid-inguinal point is only 3 degrees (Hall 1965). The degree of lateral deformity was measured clinically from the mid-inguinal point and allowance made for 7 to 8 degrees in either direction.

Radiographic measurements before operation, often in the presence of a flexion and external rotation deformity, were thought to be too unreliable to make any valuable comparison with those after operation.

For the operation to have achieved a good result, all five of the above criteria had to be fulfilled. If one or more of these aims had not been achieved the result was poor. The operation was recorded as a failure when subsequent fusion or total knee replacement was necessary.

A knee that needed revision was assessed at least one year after the revision.

The results were assessed for each knee rather than for each patient. It must be emphasised that this report is a continuing review of experience with hemiarthroplasty. The overall results are shown in Table IV.

Most of the poor results needing revision or other operation were apparent within two years. If a patient continued to have pain after the operation the cause was determined and a revision advised when possible, rather than proceeding directly to total replacement or arthrodesis.

The percentage of good results was almost constant over each two-year period after operation, suggesting that the good results are maintained (Table V).

If the principle of hemiarthroplasty is sound, then the analysis of the poor results and failures should give more information than an analysis of the good results.

#### CAUSES OF POOR RESULTS

The causes of the poor results, often multiple, are shown in Table VI. This analysis includes an assessment of a further fifty-two knees operated on by other surgeons at the Toronto General Hospital using the metallic prosthesis.

*Lateral subluxation* of the knee cannot be corrected by hemiarthroplasty and is a contra-indication to the operation (Fig. 18). It may be that in this group hemiarthroplasty should be combined with tibial osteotomy.

*Patello-femoral disease* probably causes a poor result because of continuing pain and limitation of flexion.

*Deep infection after operation* occurred in four knees to give two poor results and two arthrodeses.

*Failure to correct deformity* to within 5 degrees of varus or to within 10 degrees of valgus occurred in eight patients. If the angular deformity is greater than 20 degrees, replacement by a tibial prosthesis may have to be combined with a tibial osteotomy (Figs. 19 and 20).

HEMIARTHROPLASTY FOR ADVANCED ARTHRITIS OF THE KNEE

*Previous ankylosis or fusion*—If the knee has previously been arthrodesed or is ankylosed from previous disease, the results have been poor. The pericapsular structures are too tight and the quadriceps muscle too weak to produce efficient knee function.

TABLE IV  
OVERALL RESULTS IN 130 KNEES

Result	Number	Per cent
Good .	94	72.3
Poor .	30	23
Failure .	6	4.6

Rheumatoid Arthritis			Osteoarthritis		
Result	Number	Per cent	Result	Number	Per cent
<i>Details of 89 knees</i>			<i>Details of 41 knees</i>		
Good . . .	61	68.5	Good . . .	33	80.5
Poor . . .	24	27	Poor . . .	6	14.6
Failure . . .	4	4.5	Failure . . .	2	4.9
<i>Details of single plateau</i>			<i>Details of single plateau</i>		
Good . . .	7		Good . . .	27	
Poor . . .	3		Poor . . .	6	
Failure . . .	0		Failure . . .	1	
<i>Details of double plateaux</i>			<i>Details of double plateaux</i>		
Good . . .	54		Good . . .	6	
Poor . . .	21		Poor . . .	0	
Failure . . .	4		Failure . . .	1	

TABLE V  
FOLLOW-UP PERIOD RELATED TO RESULTS

Time (years)	Good results		Poor results	
	Number	Per cent	Number	Per cent
1 to 3 .	42	78	12	22
3 to 5 .	32	76	10	24
5 to 7 .	20	74	7	26
7 plus .	0	—	1	—
Total .	94		30	

TABLE VI  
CAUSES OF POOR RESULTS

Lateral subluxation of the knee
Patello-femoral disease
Infection after operation
Failure to correct varus or valgus deformity
Ankylosis before operation
Excessive joint destruction
Failure of operative technique
Poor motivation

*Excessive joint destruction* of both femoral and tibial condyles, often with subluxation of the joint, is a contra-indication to hemiarthroplasty, and such a knee would be better managed by arthrodesis or total replacement. Recently, in such severe cases the plateau has been built

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up with methyl methacrylate. Stability is restored by use of the cement as a "filler", but the results are too early for assessment. Normally no such additional fixation is necessary.

*Failure of operative technique*—Failure to cut level beds on the tibia, failure to place the prosthesis well back in the knee joint and failure to reshape the femoral condyle when necessary will lead to tilting of the prosthesis with subsequent movement within the knee joint. The prosthesis does not normally move from its bed, and we have confirmed this by cineradiography

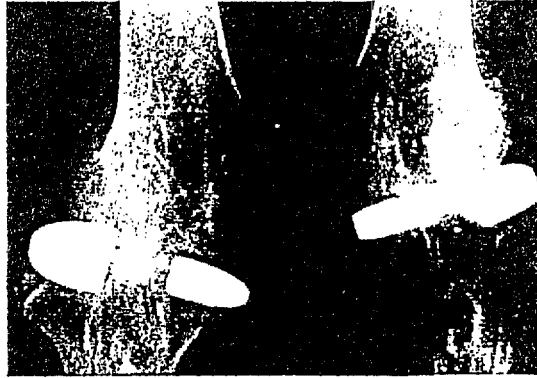


FIG. 18

The prostheses are seen to be unstable because of lateral subluxation of the knee.

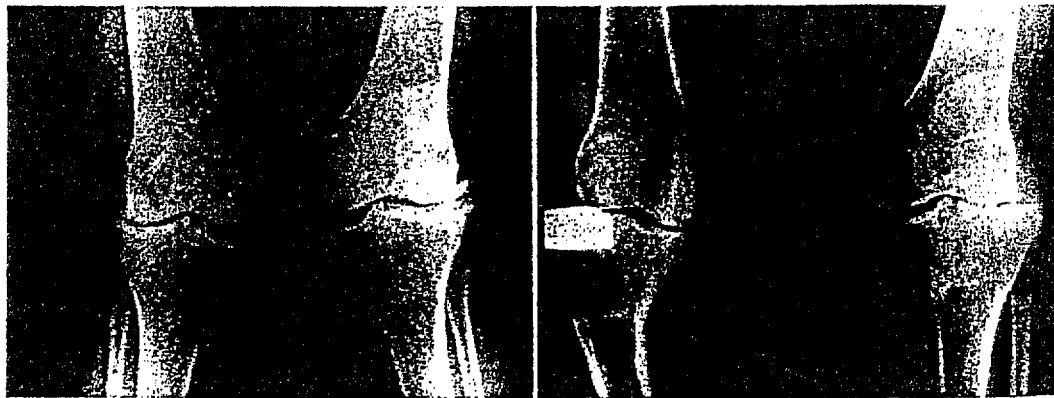


FIG. 19

FIG. 20

Hemiarthroplasty has been combined with tibial osteotomy. The tibial osteotomy alone has not corrected the deformity of the lateral part of the left knee.

and by the fact that at revision the upper tibial surface is cross-hatched to coincide with the serrations on the under-surface of the prosthesis.

*Poor motivation* is a contra-indication to most elective orthopaedic procedures, and particularly to arthroplasty of a knee, for which the full cooperation of the patient is needed.

#### COMPLICATIONS

Complications are shown in Table VII. The late sequelae are shown in Table VIII.

*Detachment of the patellar tendon* occurred twice. On each occasion it was reattached with a successful outcome.

*Lateral popliteal nerve palsy* was noted on five occasions: all recovered within a few months of the operation.

HEMIARTHROPLASTY FOR ADVANCED ARTHRITIS OF THE KNEE

ASSOCIATED OPERATIONS

**Tibial osteotomy**—If the valgus or varus deformity exceeds 20 degrees, hemiarthroplasty should be combined with preliminary tibial osteotomy. This was performed in four patients with good results.

**Excision of the patella**—This should be avoided if possible at the time of hemiarthroplasty, because it interferes with the recovery of knee movement in the period after operation. However, good results were obtained in seven of twelve knees in which it was necessary.

TABLE VII  
COMPLICATIONS

Haemarthrosis . . . . .	2
Superficial wound infection . . . . .	1
Deep wound infection . . . . .	4
Wound dehiscence (sterile) . . . . .	1
Detachment of patellar tendon . . . . .	2
Foot drop . . . . .	5
Thrombo-embolism (non-fatal) . . . . .	3

TABLE VIII  
LATE SEQUELAE

Revision procedure . . . . .	16
Hinge arthroplasty . . . . .	3
Fusion . . . . .	3
Death (intercurrent disease) . . . . .	10

TABLE IX  
REASON FOR REVISION IN SIXTEEN KNEES

Movement of prosthesis . . . . .	8
Failure to correct varus or valgus deformity . . . . .	5
No obvious cause . . . . .	3

**Posterior capsulotomy**—This was done at the same time or soon after the arthroplasty in nine knees, with good results in all but one.

**Quadricepsplasty** was necessary in three knees after operation. It achieved good results in two knees, and flexion of 50, 65 and 80 degrees respectively was obtained.

REVISION

A revision was done in sixteen knees. The reasons are shown in Table IX.

*Movement of the prosthesis* is abnormal and occurs with failure of technique—such as failure to correct lateral deformity—or with a pre-existing subluxation of the tibia on the femur.

*Failure to correct varus or valgus deformity* occurs in osteoarthritis because of undercorrection of the more common varus deformity and in rheumatoid arthritis because of overcorrection of the more common valgus deformity by a single plateau.

*No obvious cause* was found in three knees needing revision for continuing pain. The patients had poor results over one year after the revision.

Nine of the fourteen knees had a good result after revision. Two patients who have had a recent revision are excluded from this series.

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## CONTRA-INDICATIONS

These are summarised in Table X.

Initially hemiarthroplasty was used to replace the fractured lateral tibial plateau. Although a Teflon prosthesis was used in these early cases, eight out of fifteen subsequently had an arthrodesis or total replacement. It is probable that the younger patient expects too much of the operation and that the hemiarthroplasty cannot stand up to the demands of heavy work in young manual labourers. No fractures of the tibial plateau have been included in this series.

## CONCLUSIONS

In osteoarthritis involving a single compartment of the knee, tibial osteotomy is nowadays the procedure of choice. It can be used in young patients at an early stage of the disease and it avoids the introduction of a foreign body into the knee joint. Hemiarthroplasty should only be used in the elderly patient (over seventy years of age) because the rehabilitation after operation is more rapid, and for the rare type of osteoarthritis in which there is loss of articular cartilage in both compartments of the knee joint.

TABLE X  
CONTRA-INDICATIONS TO HEMIARTHROPLASTY

Fractures of the tibial plateau (early or late)
Single compartment osteoarthritis
Previous sepsis or ankylosis
Lateral subluxation of the tibia on the femur
Extensive joint destruction
Neuropathic arthritis
Poor motivation

In rheumatoid arthritis hemiarthroplasty is the procedure of choice because tibial osteotomy does not offer a reasonable alternative. Both tibio-femoral compartments are usually involved and two prostheses are required. It is still thought that, in the rheumatoid knee with the usual valgus deformity, if the cartilage of the medial compartment is still present it should be preserved, but that revision to double hemiarthroplasty may be necessary at a later date.

Occasionally correction of severe deformities in both osteoarthritis and rheumatoid arthritis is best accomplished by a combination of hemiarthroplasty and tibial osteotomy.

## SUMMARY

1. Hemiarthroplasty is a method of dealing with painful deformities of advanced osteoarthritis and rheumatoid arthritis of the knee.
2. The indications and contra-indications for this procedure are discussed. Careful selection of patients is essential.
3. The technique of operation and management after operation are described.
4. The results of such a procedure, as done by one surgeon, are given. Good results have been obtained in 80 per cent of the osteoarthritic knees and in 69 per cent of the rheumatoid knees.
5. The complications, place of associated operations and value of revision procedures are discussed.

We are indebted to Miss Maureen Barnes for secretarial assistance, to the Department of Medical Art of the University of Toronto and to the Department of Photography of the Toronto General Hospital for the figures. This work was done by one of us (G. A. H.) during the tenure of a Bilton Pollard Fellowship, awarded in 1969 by University College Hospital, London, England.

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# EXHIBIT 17

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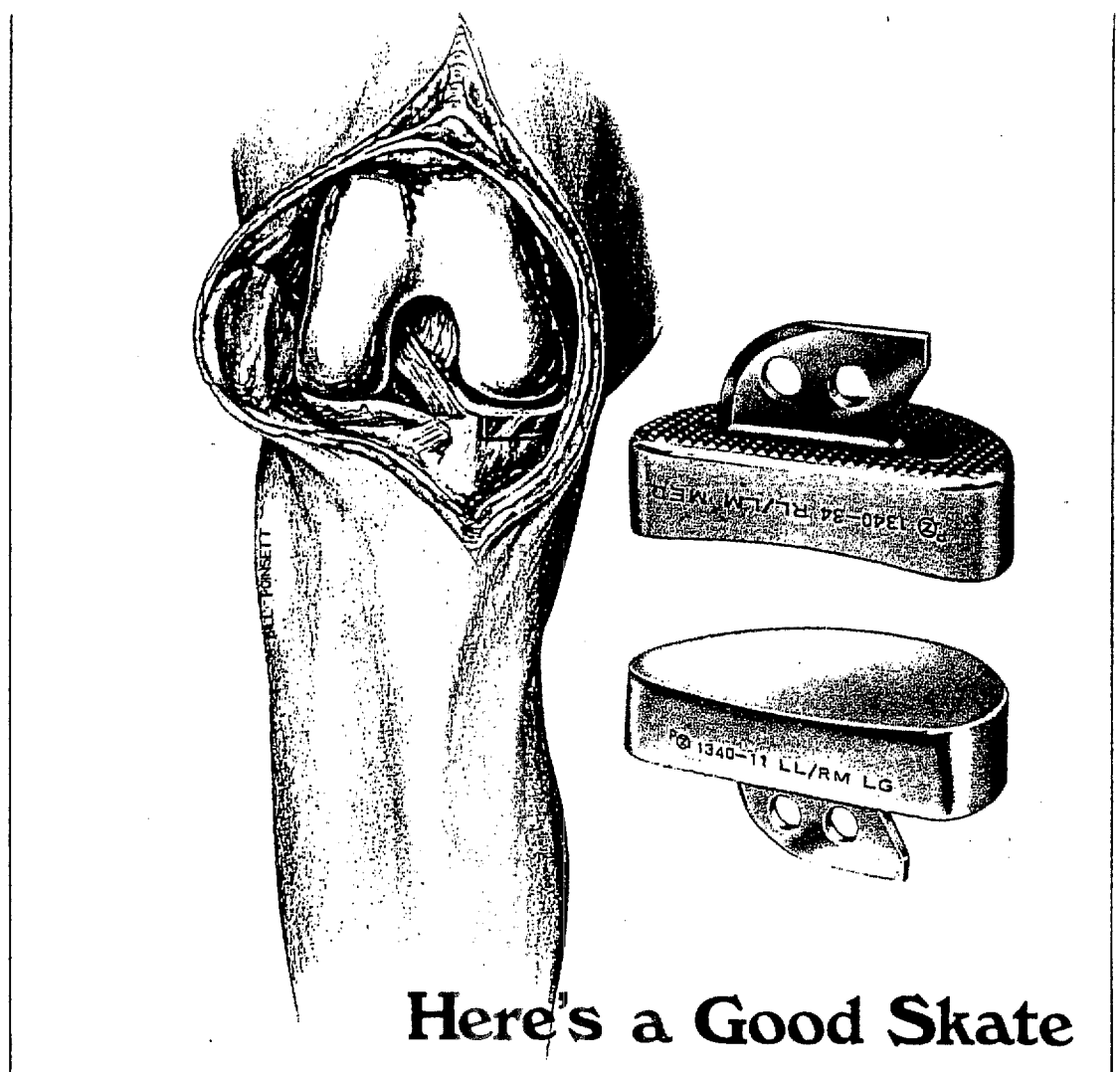
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tibia plateau prostheses

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Designed by John L. Sbarbaro, M.D., this Zimaloy prosthesis is indicated in degenerative arthritis and other instances where replacement of the tibia shelf is required. Anatomically contoured to replace the tibia shelf and to mount solidly with its unique barb and serrations. Dr. Sbarbaro's technique is available.

1340-11



Cat. No.	Description	Size	Width		Depth		Thickness	
			Inch	mm	Inch	mm	Inch	mm
1340-01	Left Lateral/Right Medial	Small	1 1/4	27	1 3/8	41	3/8	9.5
1340-02	Right Lateral/Left Medial	Small	1 1/4	27	1 3/8	41	3/8	9.5
1340-03	Left Lateral/Right Medial	Medium	1 1/2	29	1 3/8	44	3/8	9.5
1340-04	Right Lateral/Left Medial	Medium	1 1/2	29	1 3/8	44	3/8	9.5
1340-05	Left Lateral/Right Medial	Large	1 5/8	33	2	51	3/8	9.5
1340-06	Right Lateral/Left Medial	Large	1 5/8	33	2	51	3/8	9.5
1340-11	Left Lateral/Right Medial	Small	1 1/4	27	1 3/8	41	3/8	9.5
1340-12	Right Lateral/Left Medial	Small	1 1/4	27	1 3/8	41	3/8	9.5
1340-13	Left Lateral/Right Medial	Medium	1 1/2	29	1 3/8	44	3/8	9.5
1340-14	Right Lateral/Left Medial	Medium	1 1/2	29	1 3/8	44	3/8	9.5
1340-15	Left Lateral/Right Medial	Large	1 5/8	33	2	51	3/8	9.5
1340-16	Right Lateral/Left Medial	Large	1 5/8	33	2	51	3/8	9.5
1340-31	Left Lateral/Right Medial	Small	1 1/4	27	1 3/8	41	3/8	9.5
1340-32	Right Lateral/Left Medial	Small	1 1/4	27	1 3/8	41	3/8	9.5
1340-33	Left Lateral/Right Medial	Medium	1 1/2	29	1 3/8	44	3/8	9.5
1340-34	Right Lateral/Left Medial	Medium	1 1/2	29	1 3/8	44	3/8	9.5
1340-35	Left Lateral/Right Medial	Large	1 5/8	33	2	51	3/8	9.5
1340-36	Right Lateral/Left Medial	Large	1 5/8	33	2	51	3/8	9.5
1340-41	Left Lateral/Right Medial	Small	1 1/4	27	1 3/8	41	3/8	9.5
1340-42	Right Lateral/Left Medial	Small	1 1/4	27	1 3/8	41	3/8	9.5
1340-43	Left Lateral/Right Medial	Medium	1 1/2	29	1 3/8	44	3/8	9.5
1340-44	Right Lateral/Left Medial	Medium	1 1/2	29	1 3/8	44	3/8	9.5
1340-45	Left Lateral/Right Medial	Large	1 5/8	33	2	51	3/8	9.5
1340-46	Right Lateral/Left Medial	Large	1 5/8	33	2	51	3/8	9.5
1340-101	Left Lateral/Right Medial	Small	1 1/4	27	1 3/8	41	19/32	15.
1340-102	Right Lateral/Left Medial	Small	1 1/4	27	1 3/8	41	19/32	15.
1340-103	Left Lateral/Right Medial	Medium	1 1/2	29	1 3/8	44	19/32	15.
1340-104	Right Lateral/Left Medial	Medium	1 1/2	29	1 3/8	44	19/32	15.
1340-105	Left Lateral/Right Medial	Large	1 5/8	33	2	51	19/32	15.
1340-106	Right Lateral/Left Medial	Large	1 5/8	33	2	51	19/32	15.

**SBARBARO TIBIA PROSTHESIS DRIVER**

Made of satin finished stainless steel for driving the 1340 Sbarbaro Tibia Prosthesis. Knurled handle provides directional control.

Cat. No.	Diameter		Overall Length		Handle Length	
	Inch	mm	Inch	mm	Inch	mm
1341-06	1/2	13	7 1/2	191	2 1/4	57

**IMPACTOR**

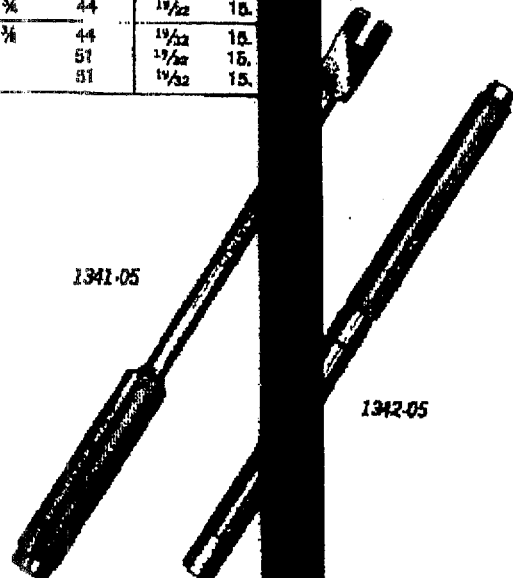
This satin finished stainless steel impactor is provided with a replaceable Teflon cap. For use with 1340 and 1345 Tibia Prostheses.

Cat. No.	Diameter		Length	
	Inch	mm	Inch	mm
1342-06	1/2	12.5	6 1/2	165

**CAP**

Replaceable Teflon cap for Impactor 1342-06.

Cat. No.	Diameter		Length	
	Inch	mm	Inch	mm
1342-10	3/8	9.5	1	25



1342-05



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## SURGICAL RECONSTRUCTION OF THE KNEE JOINT UTILIZING A TIBIAL PLATEAU PROSTHESIS.

John L. Sbarbero, Jr., M.D.  
Hospital of the University of Pennsylvania

The hemitibial plateau prosthesis has been designed for the restoration of the tibial plateau that has been destroyed by disease or trauma.

Experience at the Hospital of the University of Pennsylvania with 100 osteoarthritic knees and 150 rheumatoid knees indicates that this procedure can give improved function and lasting results. This has been confirmed in 85 per cent of cases with an average followup of five years.

The major indication for surgery is uncontrollable pain and effusion. Varus and valgus stability of the knee is evaluated with the knee to 10 degrees. Instability of less than 10 degrees (Class I) (fig. 1) is treated by synovectomy and debridement. Instability of 10 degrees to 20 degrees (Class II) (fig. 2) is treated by synovectomy, debridement, and insertion of a tibial plateau prosthesis on whichever plateau is destroyed. Instability in excess of 20 degrees (Class III) (fig. 3) is treated by hinge arthroplasty.

### SURGICAL TECHNIQUES

Following a routine skin preparation, a tourniquet is inflated high on the thigh and a medial parapatellar incision is placed on the skin and deepened through the subcutaneous tissues, quadriceps expansion and capsule. The incision extends from 5 centimeters above the superior pole of the patella to the tibial tubercle. The capsular incision is parallel to the patellar tendon (fig. 4). A complete anterior synovectomy is carried out and care is employed to remove the suprapatellar pouch as well as the infrapatellar fat pad. A pituitary rongeur is employed to remove synovium from under the collateral ligaments as well as the posterior recesses of the joint. The menisci are destroyed and the remnants are removed. Frequently the cruciate ligaments are destroyed and these may be removed in toto if necessary. The collateral ligaments are intact and are preserved. Hypertrophic bone about the femoral condyles and tibial plateau is removed with a curved osteotome (fig. 5). The patella is revised as needed but preserved.

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The sloping tibial plateau is revised so as to present a flat surface for the prosthesis (fig. 8). Frequently the slope is so contoured that a flat surface can be obtained without removing excessive bone. If such is the case, then enough bone is removed so as to give a 75 per cent seating of the prosthesis. A 0.25 inch straight osteotome is then used to cut a trough into the plateau. A proper sized plateau is then selected and fitted into the trough (fig. 7). A driver is then set against the skate and the plateau is seated in the trough with the knee in 45 degrees of flexion. Final seating is accomplished with a mallet. Stability of the joint is verified and the wound thoroughly irrigated with saline. The capsule is closed with 00 chromic and the subcutaneous tissue with 000 chromic catgut suture. The skin is closed with no. 35 wire and an elastic compression corset applied.

Ankle motion and straight leg raising exercises are started on the day following surgery. Range of motion exercises are started five days after surgery. A waterproof wound dressing is applied and whirlpool therapy is instituted on the seventh postoperative day. Seventy degrees of flexion is usually accomplished by the third postoperative week and partial weight bearing may be instituted at this time. If motion is slow in returning, then a manipulative procedure may be carried out under general anesthesia but this has to be done no later than the third postoperative week.

Transient peroneal palsy can be a frequent postoperative complication. If the patient is not closely observed during the first twelve hours. This palsy is related to postoperative swelling and the patient with a preoperative genu valgum deformity is particularly vulnerable. Splitting of the cotton dressing and release of the knee corset will alleviate the condition.

Another problem to be guarded against is the development of a postoperative knee flexion contracture. The patient should be encouraged to rest the knee in extension with either a sling or a pillow behind the heel.

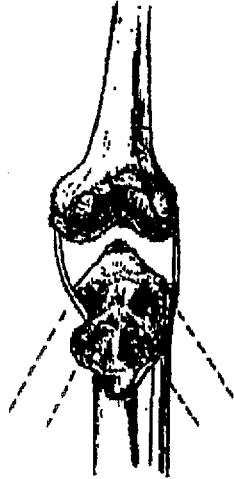
Patients are usually ready for discharge about four weeks following surgery. At that time they should have full extension and 90 degrees of flexion. Partial weight bearing is continued for three months. The knee will exhibit slight swelling, effusion, and warmth for three to six months. An enthusiastic quadriceps exercise program should be continued throughout the convalescent period.



Class I  
Fig. 1



Class II  
Fig. 2



Class III  
Fig. 3



Fig. 4

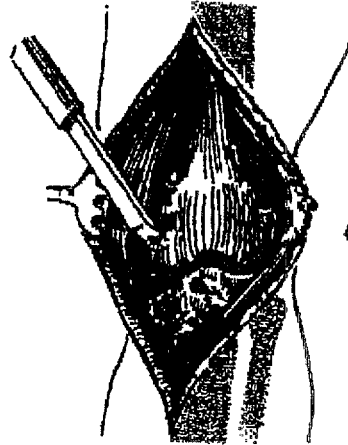


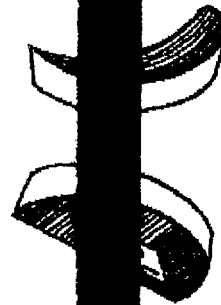
Fig. 5



Fig. 6



Fig. 7



Feb. 1971  
TR 4D

# EXHIBIT 18

**UNICOMPARTMENTAL INTERPOSITIONAL SPACER  
COMPARISON TO COMPETITIVE PREDICATE DEVICES**

FEATURE	SUBJECT DEVICE	PREDICATE DEVICES		
		McKeever Prosthesis	McIntosh Prosthesis	Sbarbaro Prosthesis
Manufacturer	Sulzer Orthopedics	Howmedica	Howmedica	Zimmer
Material	CoCr	Vitallium (CoCr)	Vitallium (CoCr)	Zimaloy (CoCr)
Sizes	7 (34-54mm)	1	3 (S, M, L)	3 (S, M, L)
Thicknesses	5 (1-5mm)	5 (3-15mm)	6 (3-21mm)	5 (3-15mm)
General Shape	Kidney	Semicircular	Semicircular	Semicircular
Femoral Surface	Smooth/concave	Smooth/concave	Smooth/concave	Smooth/concave
Tibial Surface	Smooth/convex <sup>1</sup>	Smooth/convex	Serrated/flat <sup>2</sup>	Serrated/flat
Other Features	N/A	T-shaped stabilization fin	N/A	Blade shaped stabilization fin
Bone resection?	No <sup>1</sup>	Yes, sagittal slots required	Yes, flat tibial surface required <sup>2</sup>	Yes, flat tibial surface required

<sup>1</sup> The largely conforming tibial surface "mates" to the existing tibial plateau without the need for bone resection. This technique has the advantage of requiring a lower level of surgical skill and should minimize the occurrence of technical mistakes.

<sup>2</sup> MacIntosh preferred to prepare the tibial plateau through bone resection in order to accept his flat-bottomed device. He further stated "Failure to cut level beds in the tibia, failure to place the prosthesis well back in the knee joint and failure to reshape the femoral condyle when necessary will lead to tilting of the prosthesis with subsequent movement within the knee joint..."

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# EXHIBIT 19

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SUMMARY OF PUBLISHED LITERATURE ON PREDICATE DEVICES

UNICONDYLAR INTERPOSITIONAL SPACER

Article/Author	Potter (Exhibit 11)	Swanson (Exhibit 12)	Scott (Exhibit 13)	Emerson (Exhibit 14)	Macintosh (Exhibit 16)
No. Patients	99	32	40	61	99
No. Implants	118	30	44	61	130
Diagnosis	99 RA, 19 OA	24 RA, 6 OA	44 Degen. Arthritis	61 OA	60 RA, 39 OA
Follow-up Range (Avg.)	1-9 yrs (3 yrs)	2-14 yrs (5 yrs)	5-13 yrs (8 yrs)	2-13 yrs (5 yrs)	1-10 yrs (3.5 yrs)
Age Range (Avg.)	RA: 22-76 (53); OA: 29-81 (64)	32-72 (55)	32-82 (67)	28-81 (61)	21-78 (56)
Clinical Rating, Postop	RA: 56.5% exc/good OA: 89.4% exc/good	94% good	75% good/exc @ 5 yrs 70% good/exc @ >5yrs	75% good/excellent	RA: 68.5% good OA: 80.5% good
ROM, Postop	RA: 71.7% w/≥80 deg OA: 84.2% w/>80 deg	95 deg (avg.)	110 deg (avg.)	110 deg (avg. in the 46 pts. w/good-exc result)	54% w/>90 deg
Flexion Contracture, Postop	RA: 61.6% w/<5 deg OA: 73.7% w/<5 deg	Not reported	5 deg (avg.)	3 pts. w/5 deg 2 pts. w/10 deg 1 pt. W/20 deg	80% w/0-10 deg.
Revisions	6 (2 for infection, 4 to correct varus/valgus deformity)	1 (RA patient had rapid progression of arthritis to opp. Compartment)	6 (inadequate pain relief - 2 @ < 1yr, 1 ea. @ 4.5, 5, 7 and 10 years)	7 (poor results due to inadequate pain relief and need for support)	16 (8 for failure of technique, 5 for failure to correct varus/valg deformity, 3 for pain)
Complications	4 infections 3 adhesions requiring open exploration 1 plateau fracture (fall) 1 peroneal nerve palsy 1 death (adrenal insuff.)	1 intraop. tib. plat. fracture 1 postop. tib. plat. fracture	1 drain removal 1 intraart. Hematoma 1 superfic. Hematoma	5 Deep venous thromb. 5 hemarthroses 1 dislocation 1 Superficial infection 1 Dystrophy 1 cardiac arrhythmia	5 foot drop 4 deep infections 3 Thromboembolism 2 Detached pat. Tendon 2 Hemarthroses 1 superficial infection 1 wound dehiscence

# EXHIBIT 20

## 510(k) SUMMARY

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807, this is to serve as a Summary of Safety and Effectiveness for the Sulzer Orthopedics Unicondylar Interpositional Spacer.

**Submitter:** Sulzer Orthopedics Inc.  
9900 Spectrum Drive  
Austin, Texas 78717  
(512) 432-9900

**Date:** October 16, 2000

**Contact Person:** Mitchell A. Dhority  
Manager, Regulatory & Clinical Affairs

**Classification Name:** 21 CFR 888.3590 - Knee joint tibial (hemi-knee) metallic resurfacing uncemented prosthesis

**Common/Usual Name:** Hemi-knee prosthesis

**Trade/Proprietary Name:** Unicondylar Interpositional Spacer (UIS)

### PRODUCT DESCRIPTION

Currently, arthroscopic debridements are performed regularly to address the pain and synovitis associated with early stage osteoarthritis; as many as half of those patients treated are estimated to have Grade III-IV chondromalacia. It is also estimated that failure occurs within 2 years in half of those treated. While the effectiveness of arthroscopic debridement is quite variable, it is clear that it does not address the mechanical alignment and laxity problems associated with the joint. Use of other options, such as knee arthroplasty and high tibial osteotomy (HTO), are more invasive, technically challenging and may compromise the joint to future treatment options. Anti-inflammatory medications have also been used to manage pain, but have limited effect on moderate arthritis and offer no solution in terms of repair to the joint.

The Unicondylar Interpositional Spacer was developed as an alternative to arthroscopy, HTO and knee arthroplasty treatments for those situations where limited degeneration/joint destruction exists. Instead of simply debriding soft tissues as in arthroscopy or resecting valuable unaffected bone and cartilage as in total knee replacement, this treatment allows for placement of a metallic "spacer" device into the joint space above the affected medial tibial plateau. The femur then articulates against the polished, curved surface of device. The device is intended to be used without cement and is held in place by its geometry and the surrounding soft tissue structures.

The device will be manufactured from either wrought cobalt chromium alloy (ASTM F1537) or forged cobalt chrome alloy (ASTM F799). The design is kidney shaped to mimic that of the medial tibial condyle; the shallow "dished" geometry allows for articulation with the femur. It is asymmetric (left and right components) and is available in seven sizes (30-54mm) and five thicknesses (1-5mm) to better restore joint alignment, tension and stability.

The surgical procedure to place the device is carried out in two stages. First, the posterior horn of the meniscus is debrided and resected arthroscopically. The device may then be inserted into the joint space above the affected medial tibial plateau via open surgical implantation.

Use of this device raises no new issues relative to safety or effectiveness and provides several potential advantages over other surgical options, including:

- Technically easier to implant than a unicompartmental total knee, high tibial osteotomy or meniscal transplant.
- Facilitates future conversion to total knee arthroplasty by eliminating the need for bone resections.
- Is surgically less invasive (e.g. unicompartmental treatment, smaller incision, fewer implant components required, no bone resection required).

### SPECIFIC DIAGNOSTIC INDICATIONS

The Unicondylar Interpositional Spacer is intended for uncemented use in treatment of the following:

- Moderate degeneration of the medial compartment of the knee (grade III-IV chondromalacia) with no more than minimal degeneration (grade I-II chondromalacia, no loss of joint space) in the lateral condyle and patellofemoral compartments.

### SUBSTANTIAL EQUIVALENCE

Substantial equivalence is based on comparison to the following preamendment devices:

- McKeever Hemiarthroplasty Prosthesis
- MacIntosh Hemiarthroplasty Prosthesis
- Sbarbaro Tibia Plateau Prosthesis

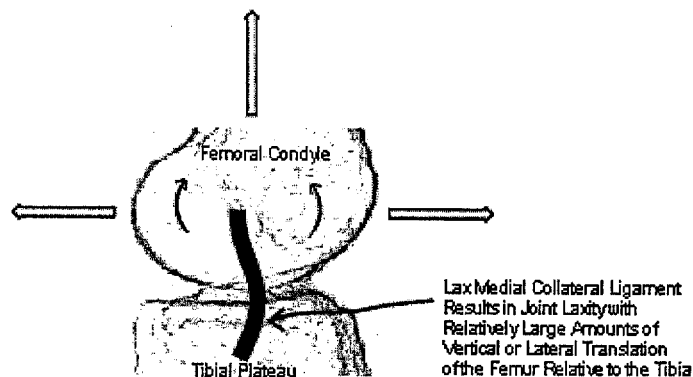
### Design Features

The subject and predicate devices are similar in terms of design features. All of these designs are unicondylar in nature and generally incorporate a metallic tibial resurfacing component of various sizes/thicknesses. The femoral condyle articulates against the curved upper surface of the implant.

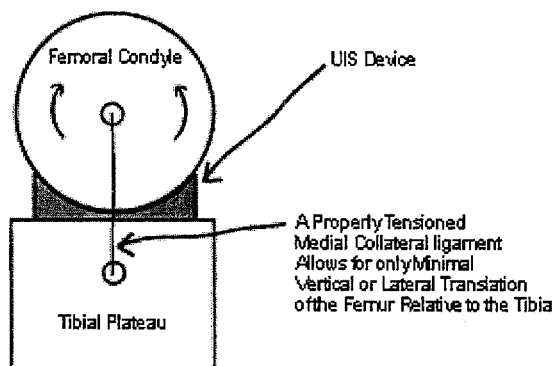
### Stability

Like the MacIntosh tibial prosthesis, the Unicondylar Interpositional Spacer has no obvious means of attachment.

In the osteoarthritic knee, substantial amounts of articular cartilage have been lost as a result of the disease. The knee compartment suffers a subsequent closing of the joint spacing as seen on X-ray. This joint closing allows the collateral ligament to become lax and the joint to become unstable and off-axis (varus deformity). Whereas normal motion of the femoral condyle is largely rotational, if ligament laxity is present, there will be increased translational motion of the femur relative to the tibia



Filling the joint space that was once occupied by the now missing articular cartilage can restore the correct tension of the collateral ligament. When the proper thickness of the Unicondylar Interpositional Spacer is chosen, the tightening of the collateral ligament prevents any excessive translational motion of the femoral condyle. Thus, almost all of the forces against the Unicondylar Interpositional Spacer now become rotational and the Unicondylar Interpositional Spacer will have no forces acting on it that would cause it to "spit" from the joint space. The stability of the joint is restored.



The surface geometry of the Unicondylar Interpositional Spacer also plays a significant role in its inherent stability.

MacIntosh states "The collateral ligaments usually maintain their own length...and that the stability is maintained by a prosthesis that is thick enough to correct the deformity and take up the slack in the collateral ligaments". He further states that "The prosthesis is held in position by the anatomy of the knee joint, and stability depends on taut collateral ligaments. The top of the prosthesis has a contoured surface with rounded edges to provide the condyle with a permanent low friction area."

The Unicondylar Interpositional Spacer has a femoral surface geometry that imitates that of the tibial plateau including an intact meniscus. On the other side, the tibial surface of the Unicondylar Interpositional Spacer imitates the surface of the tibial plateau without the meniscus.

When the Unicondylar Interpositional Spacer is properly placed into the knee compartment, it rests inside the boundaries of the resected meniscus. It has substantially intimate contact with the tibial plateau throughout the entire range of motion. The femoral side of the Unicondylar Interpositional Spacer also has substantially full contact with the femoral condyle when the knee is in full extension.

Thus, when the knee is in full extension, the Unicondylar Interpositional Spacer can only be located in one position in the joint space as determined by the relative position of the femoral condyle to the tibial plateau.

As the knee is flexed and the femoral condyle begins to rotate, since the collateral ligaments remain under tension, the posterior aspect of the femoral condyle remains in contact with the central weight-bearing surface of the UIS

Materials

The subject and predicate devices are similar in terms of materials used. All of these designs use cobalt chrome alloy.

Intended Use

Additionally, the subject and predicate devices share similar indications for use. The subject device, like the predicate devices, are used generically in the treatment of unicompartmental tibial arthritis where total knee replacement is not warranted.

Clinical Safety & Effectiveness

Based on review of the published clinical literature on this type of device, the known potential risks associated with these devices are essentially of the same type and frequency as unicompartmental or total knee replacement, arthroscopy and others. As shown in the publications associated with the predicate devices, these risks include hematoma, infection, nerve palsy, embolus, dislocation, fracture and need for revision. The less invasive nature of the device also lends itself to ease of conversion to the more conventional surgical treatments.

The history with the predicate devices also indicates that the effectiveness of this treatment is at least equal to that obtained with tibial osteotomy in terms of pain relief, correction of deformity and restoration of stability. Furthermore, it provides some added benefits which cannot be recognized with current treatments (e.g., ease of implantation, ease of conversion to other treatments, less invasive).

Testing did not raise any new issues of safety or effectiveness and indicated that this device should provide performance equivalent to commercially marketed products.