found between the tibial articulating surface and the supporting metal tray. This residue could not be adequately removed to give accurate wear-loss measurements. Six of the tibial components showed increased weight, thus negating this part of the study.

SUMMARY

The knee simulator used in this study provides all of the normal degree of freedom and applies representative loading conditions. As a result, it provides a means of evaluating performance characteristics and shock-wear behavior of prosthetic materials. This and previous studies indicated that Poly Two tibial components "wear" significantly less than conventional polyethylene, but carbon fiber-associated damage with Poly Two was the major wear mechanism. This break-up of the fibers is believed to be a "rolling" action of the femoral component on the tibia. This behavior may be observed in the typical pin-on-disk test.

Visual, stereoscopic, and SEM examination of the tibial components showed that the original surfaces of Poly Two components contained relatively large numbers of carbon fibers. In the contact region, these fibers were gradually removed during the course of the test. Areas found on the tibial component tested for 500,000 steps where the fibers were completely depleted of carbon fiber. The most common wear scars, found on all four Poly Two tibial test specimens, were carbon fiber-associated damage and anteroposterior scratching. Three types of fiber damage were found: fibers removed from the wear surface, fibers removed from above the fibers, and fiber breakage. Fiber removal, as served as roughs in the surface where carbon fibers had been. Ultrasonic removal frequently appeared as an area where the polyethylene had been removed from the top of an intersection of several fibers. Anteroposterior scratches were always found in areas of carbon fiber associated with roughness possibly due to the abrasive action of broken carbon fibers. Surfacemation was found on eight of the four Poly Two components with none of these considered excessive. Pins were found on six tibial component bottoms of the pins seemed to be lined with carbon fibers indicating the pin had formed when a piece of material had pulled away from the carbon fibers or fatigue cracks had propagated until a large wear particle had been formed. A pin in the shape of forming was found where a particle, surrounded by an apparent crack, was pulling away from three carbon fibers that were the surface. Observations of minor abrasion were found. No severe wear that could be found between tibial component wear mechanics and the femoral materials.

Visual examination of Ti-6Al-4V femoral components revealed the abnormal or corrosive wear mechanisms that have been noted on Poly Two. There were, however, light surface areas were not present on the Co-Cr-Mo femoral components. From a test similiar, test similar scratches were observed on the uncoated Ti-6Al-4V femoral component run with conventional UHMWPE tibial and patellar components. One Ti-6Al-4V femoral component had a slight transfer layer. Scanning was observed on the titanium nitride coated Ti-6Al-4V femoral components. The titanium nitride coated femoral component tested for 100,000 steps showed no coating breakdown or surface scratching. From the results observed in this study, several conclusions can be made:

1. The original surface of Poly Two components included a relatively low, scratching and carbon fiber associated damage were major wear mechanisms. After the surface fibers were removed, the amount of carbon fiber remained a major wear mechanism.

2. Pitting of the tibial components was found as a major wear mechanism. The root side of the fiber were lined with carbon fibers, but remained a major wear mechanism.

3. No correlation was found between the incidence of tibial surface damage and the femoral component material used.

4. Ti-6Al-4V femoral components did not exhibit signs of the deep scratch or corrosive wear as seen by Galante and Rostoker in their study using sliding-on-flat wear testing device and distilled water as a lubricant.

5. Ti-6Al-4V femoral components, tested with either Poly Two or Co-Cr-Mo wear that were not observed on the Co-Cr-Mo or TIN coated Ti-6Al-4V components.

The TIN coating on a femoral component did not break down or scratch during an extended test of 500,000 steps.

The research was sponsored by Zimmer, USA, Warsaw, Indiana.

References


23. B. M. Hillberry, J. A. Schatz, and D. C. Cullens, "Laboratory knee simulation: A viable option."
Standard Specification for
Unalloyed Titanium for Surgical Implant Applications

1. Scope

This specification covers the standard, nominal, and regulatory requirements for four grades of unalloyed titanium for use in the manufacture of surgical implants.

2. Referenced Documents

2.1 This specification is consistent with the following: FDA and FDA and the relevant federal regulations for medical devices.

3. Terminology

3.1 Definition: This specification shall conform to the requirements of the latest revision of ASTM B 200, B 240, and B 291.

4. Ordering Information

4.1 Inquiries and orders for material shall include the following information:

4.1.1 Quantity, weight, or mass, in pounds (kg); and

4.1.2 Finish

4.1.3 Condition (O, T, H); and

4.1.4 Other special requirements.

5. Manufacture

5.1 Material and-manufacturer shall be the best available on the market at the time of manufacture.

6. Chemical Composition

6.1 The chemical analysis shall be determined according to the requirements of the latest revision of ASTM B 200, B 240, and B 291.

7. Tensile Properties

7.1 The tensile properties shall be determined according to the requirements of the latest revision of ASTM B 200, B 240, and B 291.

8. Heat Treatment

8.1 The heat treatment shall be determined according to the requirements of the latest revision of ASTM B 200, B 240, and B 291.

9.1 F-67 standard specification means the standard, nominal, and regulatory requirements for four grades of unalloyed titanium for use in the manufacture of surgical implants.

10.1 When used in both-patented units shall be to the requirements of the latest revision of ASTM B 200, B 240, and B 291.

11.2 The requirements and orders for material shall include the following information:

11.2.1 Quantity, weight, or mass, in pounds (kg); and

11.2.2 Finish

11.2.3 Condition (O, T, H); and

11.2.4 Other special requirements.

12. Manufacture

12.1 Material and-manufacturer shall be the best available on the market at the time of manufacture.

13. Chemical Composition

13.1 The chemical analysis shall be determined according to the requirements of the latest revision of ASTM B 200, B 240, and B 291.

14. Tensile Properties

14.1 The tensile properties shall be determined according to the requirements of the latest revision of ASTM B 200, B 240, and B 291.

15. Heat Treatment

15.1 The heat treatment shall be determined according to the requirements of the latest revision of ASTM B 200, B 240, and B 291.

16.2 F-67 standard specification means the standard, nominal, and regulatory requirements for four grades of unalloyed titanium for use in the manufacture of surgical implants.

17.1 When used in both-patented units shall be to the requirements of the latest revision of ASTM B 200, B 240, and B 291.
TABLE 1

<table>
<thead>
<tr>
<th>Test Method</th>
<th>Sample Size</th>
<th>Pass/Fail</th>
</tr>
</thead>
<tbody>
<tr>
<td>Method A</td>
<td>3</td>
<td>Pass</td>
</tr>
<tr>
<td>Method B</td>
<td>4</td>
<td>Fail</td>
</tr>
</tbody>
</table>

TABLE 2

<table>
<thead>
<tr>
<th>Test Method</th>
<th>Sample Size</th>
<th>Pass/Fail</th>
</tr>
</thead>
<tbody>
<tr>
<td>Method C</td>
<td>5</td>
<td>Pass</td>
</tr>
<tr>
<td>Method D</td>
<td>6</td>
<td>Fail</td>
</tr>
</tbody>
</table>

When testing electrical equipment, it is crucial to ensure the safety of the components and systems. Therefore, in setting standards for analysis, the operation should be evaluated in terms of stability and efficiency. The methods outlined in this document are intended to guide manufacturers and suppliers for accurate and consistent results.

8. Mechanical Requirements

8.1. Materials utilized in this specification shall conform to the mechanical property requirements given in Table 4.

8.2. Inspections for water tests shall be conducted and results recorded in accordance with Test Method 3. Physical properties shall be determined by the test method specified in Section 6.2.1.

9. Quality Program Requirements

9.1. The production shall comply with the requirements of this specification. The manufacturer shall notify the purchaser in writing of any changes made to this specification.

9.2. The manufacturer shall provide the purchaser with a copy of the vendor's quality assurance manual and procedures.

10. Marking and Certification

10.1. The manufacturer shall stamped on the equipment a serial number and date of manufacture. The manufacturer shall also provide the purchaser with a certificate of conformance.

APPENDIX

[XI RATIONALE]

XI.1. The purpose of this specification is to characterize the equipment through statistical analysis and graphical representation of the results. The tests were developed with the intent to meet the requirements of the procurement contract.

XI.2. The data were analyzed using statistical methods and the results were used to make informed decisions regarding the equipment's performance.

The manufacturer is responsible for ensuring that the equipment meets the specifications outlined in this document.

The data presented in this document is subject to the accuracy of the equipment used and the conditions under which the tests were conducted. Any discrepancies or anomalies should be immediately brought to the attention of the relevant authorities.

The manufacturer is responsible for ensuring that the equipment meets the specifications outlined in this document.

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The manufacturer is responsible for ensuring that the equipment meets the specifications outlined in this document.

The data presented in this document is subject to the accuracy of the equipment used and the conditions under which the tests were conducted. Any discrepancies or anomalies should be immediately brought to the attention of the relevant authorities.
Standard Specification for
Ultra-High-Molecular-Weight Polyethylene Powder and
Fabricated Form for Surgical Implants

This standard is issued under the fixed designation F649; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (e) indicates an editorial change or deletion without substance change to the text version.

1. Scope
1.1 This specification covers ultra-high molecular weight polyethylene powder (UHMWPE) fabricated for use in surgical implants.

2. Referenced Documents
2.1 ASTM Standards:
D297 Test Method for Impact Strength of Plastics and Elastomers
D627 Test Method for Vickers Hardness of Plastics Under Load
D676 Test Method for Tensile Stress-Strain Properties of Plastics (Udraulic Testing Machine)
D695 Test Method for Tensile Stress-Strain Properties of Plastics (Electric Testing Machine)

3. Terminology

4. General Requirements

5. Specifications

6. Test Methods

7.Fabricated Form Requirements

8. Mechanical Properties

9.2 The minimum value of the ultimate tensile strength is determined at 23 ± 1°C (73.4 ± 1.8°F) for all specimens prepared in accordance with the procedure described in 8.4.1.1. The test specimen shall be at least 1 in. (25 mm) in length.

9.2.1 The minimum value of the ultimate tensile strength shall be determined according to the procedure described in 8.4.1.1. The test specimen shall be at least 1 in. (25 mm) in length.

9.2.2 The minimum value of the ultimate tensile strength shall be determined according to the procedure described in 8.4.1.1. The test specimen shall be at least 1 in. (25 mm) in length.

9.2.3 The minimum value of the ultimate tensile strength shall be determined according to the procedure described in 8.4.1.1. The test specimen shall be at least 1 in. (25 mm) in length.

9.2.4 The minimum value of the ultimate tensile strength shall be determined according to the procedure described in 8.4.1.1. The test specimen shall be at least 1 in. (25 mm) in length.

9.2.5 The minimum value of the ultimate tensile strength shall be determined according to the procedure described in 8.4.1.1. The test specimen shall be at least 1 in. (25 mm) in length.

9.2.6 The minimum value of the ultimate tensile strength shall be determined according to the procedure described in 8.4.1.1. The test specimen shall be at least 1 in. (25 mm) in length.

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9.2.8 The minimum value of the ultimate tensile strength shall be determined according to the procedure described in 8.4.1.1. The test specimen shall be at least 1 in. (25 mm) in length.

9.2.9 The minimum value of the ultimate tensile strength shall be determined according to the procedure described in 8.4.1.1. The test specimen shall be at least 1 in. (25 mm) in length.

9.2.10 The minimum value of the ultimate tensile strength shall be determined according to the procedure described in 8.4.1.1. The test specimen shall be at least 1 in. (25 mm) in length.

9.2.11 The minimum value of the ultimate tensile strength shall be determined according to the procedure described in 8.4.1.1. The test specimen shall be at least 1 in. (25 mm) in length.

9.2.12 The minimum value of the ultimate tensile strength shall be determined according to the procedure described in 8.4.1.1. The test specimen shall be at least 1 in. (25 mm) in length.

9.2.13 The minimum value of the ultimate tensile strength shall be determined according to the procedure described in 8.4.1.1. The test specimen shall be at least 1 in. (25 mm) in length.

9.2.14 The minimum value of the ultimate tensile strength shall be determined according to the procedure described in 8.4.1.1. The test specimen shall be at least 1 in. (25 mm) in length.

9.2.15 The minimum value of the ultimate tensile strength shall be determined according to the procedure described in 8.4.1.1. The test specimen shall be at least 1 in. (25 mm) in length.

9.2.16 The minimum value of the ultimate tensile strength shall be determined according to the procedure described in 8.4.1.1. The test specimen shall be at least 1 in. (25 mm) in length.

9.2.17 The minimum value of the ultimate tensile strength shall be determined according to the procedure described in 8.4.1.1. The test specimen shall be at least 1 in. (25 mm) in length.

9.2.18 The minimum value of the ultimate tensile strength shall be determined according to the procedure described in 8.4.1.1. The test specimen shall be at least 1 in. (25 mm) in length.

9.2.19 The minimum value of the ultimate tensile strength shall be determined according to the procedure described in 8.4.1.1. The test specimen shall be at least 1 in. (25 mm) in length.

9.2.20 The minimum value of the ultimate tensile strength shall be determined according to the procedure described in 8.4.1.1. The test specimen shall be at least 1 in. (25 mm) in length.
TABLE 1

<table>
<thead>
<tr>
<th>Property</th>
<th>Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tensile Strength</td>
<td>80K</td>
</tr>
<tr>
<td>Ultimate Strength</td>
<td>90K</td>
</tr>
<tr>
<td>Elongation</td>
<td>15%</td>
</tr>
<tr>
<td>Ductility</td>
<td>20%</td>
</tr>
</tbody>
</table>

**REFERENCES**

1. **Chemical Composition**: The composition of the alloy is critical, with specific elements contributing to its properties.
2. **Mechanical Testing**: The alloy undergoes rigorous testing to ensure it meets the specified requirements.
3. **Performance Criteria**: The alloy's performance is evaluated in various conditions to ensure reliability.

**Significance and Use**

1. The alloy is designed for applications requiring high strength and durability, such as in aerospace and automotive industries.
2. **Chemical Properties**: The alloy's chemical composition includes elements that enhance its mechanical properties.
3. **Environmental Resistance**: The alloy is resistant to corrosion and other environmental factors.

**Designation**: F 759 - 87

**Standard Specification for Thermomechanically Processed Cobalt-Chromium-Molybdenum Alloy for Surgical Implants**

This standard is intended for use in the fabrication of surgical implants. It specifies the requirements for the alloy to ensure its suitability for use in surgical implants.

**AATMA Standards**: The alloy must meet the standards set by AATMA for surgical implants.

**Chemical Requirements**: The alloy must meet specific chemical requirements to ensure its performance.

**Mechanical Properties**: The alloy's mechanical properties are critical for its use in surgical implants.

**Table 1**: Chemical Requirements

<table>
<thead>
<tr>
<th>Element</th>
<th>Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Co</td>
<td>60 - 62%</td>
</tr>
<tr>
<td>Cr</td>
<td>20 - 22%</td>
</tr>
<tr>
<td>Mo</td>
<td>2 - 3%</td>
</tr>
<tr>
<td>Nb</td>
<td>1 - 2%</td>
</tr>
<tr>
<td>Si</td>
<td>0.1 - 0.3%</td>
</tr>
<tr>
<td>Fe</td>
<td>0 - 3%</td>
</tr>
<tr>
<td>Mn</td>
<td>0 - 2%</td>
</tr>
<tr>
<td>Ni</td>
<td>0 - 1%</td>
</tr>
<tr>
<td>Others</td>
<td>0 - 0.5%</td>
</tr>
</tbody>
</table>

**Fabrication**

1. The alloy is produced through specific thermomechanical processes to ensure its quality.
2. **Quality Control**: Rigorous quality control measures are in place to ensure the alloy meets the specified requirements.

**Applications**

1. The alloy's use in surgical implants highlights its suitability for applications requiring high-strength and durability.
2. **Biocompatibility**: The alloy is biocompatible, ensuring it is safe for use in surgical implants.
3. **Economic Considerations**: The cost-effectiveness of the alloy makes it a viable option for various applications.

**References**

1. [Source 1](http://example.com)
2. [Source 2](http://example.com)
TABLE 3 Mechanical Requirements

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Tensile Stress (ksi)</th>
<th>Elongation</th>
<th>% Reduction</th>
<th>Impact Energy (ft-lb)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.41</td>
<td>90</td>
<td>22</td>
<td>45</td>
<td>25</td>
</tr>
<tr>
<td>1.42</td>
<td>100</td>
<td>25</td>
<td>50</td>
<td>30</td>
</tr>
</tbody>
</table>

Note: Tensile property shall be determined in accordance with ASTM A 370-82. Failure shall be determined in accordance with ASTM E 23-82. Impact test shall be determined in accordance with ASTM E 23-82.

9. Certifications

9.1 A certification shall be provided that the material meets the requirements of this standard.

10. Quality Program Requirements

10.1 The manufacturer and the material producer shall be subject to the requirements of the American Society for Quality Control (ASQC) C 1-1969.

APPENDIX

11. RATIONALE

11.1 The purpose of this standard is to ensure consistency in the production of materials that meet the specified requirements.

11.2 Materials produced under this standard shall be subject to the requirements of the American Society for Quality Control (ASQC) C 1-1969.

11.3 Published data indicates that materials produced under this standard have consistently met the specified requirements.
Ion implantation of cobalt-chromium prosthetic components to reduce polyethylene wear

by peas Skineland, PhD
an Orthopaedic Tissue engineer

The wear of ultra-high molecular weight polyethylene (UHMWPE) is a significant problem affecting the longevity of total joint replacement surgery. The wear of polyethylene, a semicrystalline thermoplastic, is a complex process involving the formation of lubricating films and the removal of particulates. The wear mechanism varies with different implant designs and material properties. Polyethylene is currently the only material used for total joint arthroplasty in joints that experience low to moderate levels of loading, due to its low cost, good wear performance, and good formability and weldability. However, polyethylene wear can cause several deleterious effects, such as bone resorption, polyethylene debris, and mechanical loosening. The use of implant designs with lower polyethylene wear rates has been studied extensively. In this paper, the authors discuss the use of ion implantation as a method to modify the surface of polyethylene components to reduce wear.

Initial studies of ion implantation were focused on the modification of the surface properties of various materials. However, ion implantation of polyethylene has been more recently studied as a method to reduce wear. The authors describe the process of ion implantation and its potential benefits in reducing polyethylene wear in total joint replacement implants.

The authors review several studies that have investigated the use of ion implantation to modify the surface properties of polyethylene. These studies have shown promise in reducing polyethylene wear in various joint replacement designs. The authors conclude by discussing the potential clinical implications of ion implantation and its role in improving the longevity of total joint replacements.

The use of ion implantation as a method to modify the surface properties of polyethylene components has shown promise in reducing wear in total joint replacement surgery. Future studies are needed to further investigate the effectiveness of this technique and to develop optimal implantation conditions for different implant designs.
Honorablc Ted Wall,  
Congress of the United States  
House of Representatives  

June 2, 1992  

Dear Congressman Wells:  

Thank you for your letter of May 28th. This letter provides an overview of the medical need for and use of the Posa-Enamine and Condylar Prostheses currently manufactured and distributed by TMJ implants, Inc. for the treatment of temporomandibular joint problems. These products were first introduced in the early 1960's and have been successfully used over 30 years. The Posa-Enamine Prosthesis is intended for replacement of the articular disc of the temporomandibular joint. The condylar prosthesis is a joint replacement type implant designed to replace the condylar head, loss of meniscal cartilage, and soft tissue coverings, and can be used individually or in conjunction with the Condylic Prosthesis. The Condylic Prosthesis is intended for use in conjunction with the Posa-Enamine Prosthesis to form a total prosthetic temporomandibular joint replacement system.  

First, let me state that my background is that of a oral and maxillofacial surgeon who practiced from 1942-1986. For most of those years, much of my practice was devoted to surgery of the temporomandibular joint. At present, I am an assistant clinical professor of surgery in the Department of Head and Neck Surgery at the Medical School of the University of California, Irvine, in the 1960's to 1970's. My clinical notes are provided as Attachment 1.

17301 West Colfax Avenue, Suite 817 - Golden, Colorado 80401 303-277-3326 - FAX 303-277-1421
Honorole Ted Weiss
June 2, 1972
Page 2

Having performed scores of surgeries on the temporomandibular joints of patients, beginning in the early 1960's, I have been acutely aware that dependable surgery was sorely needed. In 1961, I developed a method of placing the base of the skull with a highly polished titanium implant, which would allow the disc and condyle to function smoothly against the nonchafing metal prosthesis.

In 1961, I placed my first Prosthesis-Achilles Joint in the patient of a doctor who had had two previous joint surgeries performed by another surgeon a few years earlier. That particular patient has been followed by me for over 10 years and is doing very well (see Attachment 1). The year following my operation, the patient had surgery on the opposite joint and it, too, has done well over those years. Twenty-five years after placing her first implant, it was necessary to place a Condylar Prosthesis on the first side due to degeneration of the patient's mandibular condyle. The subsequent surgery was in no way related to the performance of the previously implanted Prosthesis-Achilles Joint. Indeed, at the time I was able to re-examine the original Prosthesis-Achilles Joint which appeared just as I had placed it over a quarter of a century ago...

Since 1961 over 3,000 patients from across the United States have been operated on and have received partial (Fossa-Replacement Prosthesis only) or total (Fossa-Replacement and Condylar Prosthesis) joint replacement. Many of these were patients who had their previous surgeries using other devices or alternative surgical procedures without success. For whom the TMJ Implants, Inc. prostheses were able to provide relief.

Since the nearly 30 years during which I used this technique to restore a degenerated temporomandibular joint, I never had to remove an implant due to its failure, looseness, infection, or any other related incidents. This technique was used successfully by several hundred surgeons in several hundred hospitals across America. It is also used in numerous institutions. Patient and physician satisfaction of the products and clinical results have resulted in increased product demand.

Honorable Ted Weiss
June 2, 1972
Page 3

(See, Attachment 2). Having had the opportunity of assisting many surgeons and teaching many more I have had first hand opportunity of seeing this technique help many patients.

Consistent with my own experience, other clinicians have had very few incidents of problems with this technique. I am aware of one patient with an allergy to the metal alloy and another patient whose fracture of the Condylar Prosthesis has been caused by the patient attempting to sand the implant with a sanding stick in his position, deep in the fact that product labeling clearly warns oral surgeons not to bend the prosthesis. There have also been one or two cases of post surgical infection which were not related to the implant, but due to the patient's resistance or to the particular procedure itself. Except for these few incidents, I am aware of virtually no reported incidents of product failure or other contra indications, to the point where it is difficult to in any way resulted in patient injury or other adverse consequences.

The usefulness of the Fossa-Achilles and Condylar Prosthesis for treatment of severe degenerative joint disease is further supported by the preliminary results of an ongoing clinical study conducted by the University of Pennsylvania. A two year follow report of partial or total temporomandibular joint reconstruction on 37 cases concluded that "the implants are an acceptable surgical technique."

Publication of detailed study results are expected late this summer.

We hope this information has been a help to the Committee.

Sincerely,

TMJ IMPLANTS, INC.

Robert M. Christman, M. D., B.S.
President

7/75
MANDIBULAR JOINT ARTHROSIS CORRECTED BY THE INSERTION OF A CAST-VITALLIUM GLENOID FOSSA PROSTHESIS: A NEW TECHNIQUE

ROBERT W. CHRISTENSEN, D.D.S.
Pasadena, Calif.

Reprinted from
ORAL SURGERY, ORAL MEDICINE AND ORAL PATHOLOGY
St. Louis
Vol. 17, No. 6, Pages 712-720, June, 1964
(Copyright © 1964 by The C. V. Mosby Company)
(Printed in the U. S. A.)

MANDIBULAR JOINT ARTHROSIS CORRECTED BY THE INSERTION OF A CAST-VITALLIUM GLENOID FOSSA PROSTHESIS: A NEW TECHNIQUE

Report of a Case


Degenerative mandibular joint conditions are of frequent occurrence and offer the dental profession a challenge in diagnosis and treatment. This article will not attempt to discuss the many factors which may contribute to the changes which occur in the joint. Instead, it will be limited to a brief presentation of mandibular joint arthrosis and will describe my technique for correction of the problems that were encountered in a particular case.

First, however, it is apparent that a neuromuscular imbalance is probably the greatest factor causing the derangement of the mandibular joint. Other factors which predispose the joint to arthrosis are birth trauma, hemarthrosis, infections, fractures of the condyle, tumors, rheumatoid arthritis or osteoarthritis, anatomic variations in the condyle or articular eminence, or surgical procedures on the mandibular joint (especially meniscectomy).

At times the patient may be unaware of the early stages of mandibular joint degeneration until perforation, or even erosion, of the articular disc has occurred and early changes in the bony articular surfaces of the joint have begun.

If the perforation of the disc is small, we see, radiographically, a limited point of contact between the anterior surface of the condyle and the posterior surface of the articular eminence. This contact, being pathologic, causes resorptive processes in the articular surface of the temporal bone (Fig. 1) and frequently, to a lesser degree, at the surface of the condyle. This causes the condyle to move with more difficulty, and usually with pain and grating, when sliding over the roughened surface of the articular eminence. More traction is required by the external pterygoid muscle whose fibers attach to the most anterior rim of the condyle. This tension produces the lipping which is seen in this area of the condyle (Fig. 2). Pressure resorption causes a flattening of the articular surfaces of both condyle and articular eminence in an attempt to minimize the places of inclination which the condyle must travel. The resorptive phase may be followed by varying degrees of osteoarthritis of the articular surfaces.
MANDIBULAR JOINT ARTHRITIS

During this period of degeneration the pain factor may assist in limiting condylar mobility, and fibrous attachment from condyle to fossa may develop. In time fibrous oseous ankylosis develops, which will be followed by complete bony ankylosis.

Generally speaking, the fibrous or oseous ankylosis requires the same type of treatment with, perhaps, slight variations in technique. Surgical inactivation is the only possible way of helping the patient with any type of ankylosis.\(^1\)

Christopher 03.30.40 P.
Dec. 1940

* * * * *

**Figure 1.** Lateral graph showing bone picture content through perforation of Masseter muscle. Note outline of ramus and condyle.

**Figure 2.** Photograph of left side showing spaces of anterior ramus of odontoid process and ankylosed condyle.

Over a period of many years, previous authors have advocated either treatment or high condylotomy for fibrous ankylosis and osteoarthrotomy for oseous ankylosis. A more uniform approach to both types of ankylosis would seem to be warranted. Every effort should be directed toward restoring a normal anatomic joint surface and to create the most nearly normal and pain-free joint function possible.

In the previously reported articles on osteoarthrotomy of the mandibular joint, various procedures have been recommended, ranging from placing nothing in the new joint space to the use of tarsia, muscle, cartilage, plastic, or metal. Good results have been reported with each variety of osteoarthrotomy. In a case that I reported in 1955 I placed no new material between the two bone surfaces, and the patient has done well for 9 years.\(^2\)

Essentially, it would seem that a rigid mechanical barrier of anatomic shape should be most valuable. For that reason, I have devised a metal prosthesis which is anatomic, creates a permanent barrier, and is well tolerated.

The problem that has faced oral surgeons who might have wished for an anatomic prosthesis is: How does one know the shape of the particular bone prior to surgery? Most attempts have been focused on attempting to remove a lost condyle or to cover the condylar stump with a nonsensitive barrier. The most promising procedure, from a strictly biomechanical point of view, would be to place the prosthesis against the base of the skull where unusual lateral pressure would not tend to loosen it.

Fibrous Ankylosis—It occurred to me that, in the case of a fibrous ankylosis where it is possible to define the gneidous fossa and articular eminence both radiographically and clinically, we should be able to cover this surface with a thin, anatomic cast-Vittallium prosthesis.

With this premise, I decided to make castings to cover the gneidous fossa, articular eminence, and adjacent zygomatic process on each of twenty skulls (Fig. 3). The castings were made 0.022 inch thick and were perforated on the surface covering the zygoma and lateral articular eminence with numerous holes for the 5 mm. cast-Vittallium implant screws, which would be used for anchorage. The articular surfaces are highly polished, while other surfaces and margins are sandblasted. This thickness of Vittallium has also some resiliency and can be formed slightly with pliers to allow for last-minute variations in contour.

The borders are extended, as shown in the photographs, to include the gneidous fossa, articular eminence, and lateral surfaces of both, on to the lateral aspect of the zygomatic process of the temporal bone (Fig. 4).

In the preparation of this type of prosthesis for any given case, it is important to have accurate roentgenograms of the joint in order to obtain as much information as possible concerning the anatomic shape of the joint.

Oseous Ankylosis—In cases of oseous ankylosis, the procedure needs to be varied slightly because of the loss of normal anatomic contour of the joint. In such cases it is necessary to perform an osteotomy below the normal gneidous fossa and attempt to make it at the level of the articular eminence. In so doing, one can be sure not to perforate the aurial cavity. In the past, it has been suggested that, if possible, the condylar head, or at least a 1 cm. segment of bone, be removed. This has been necessary when no mechanical barrier has been placed in the area. In one case, when a large segment of bone has been removed, the powerful elevator muscles have tended to close the bone gap, thus allowing a reduction to develop and at times permitting an open bite to occur.
Mandibular Joint Arthroscopy

Fig. 1. Lateral view of skull showing condyle removed against joint process. By using many skulls and filling the glomus fossa with modelling powd or plastomers, one can make a pattern which will lie on the external face of the condyle, fossa, and eminence and determine just how the cut should be made. If this small pattern is fixed with screws to the bone, then one can follow the exact contour of the scaphoid which will be most suitable, making the final prosthesis like the previously mentioned glomus fossa. After the arthroscopy, but following the contour of the pattern, one can be sure that it will slide into place following the scaphoid. In this case, the condyle can be left in the fossa and the prosthesis can be attached to it. This eases the hazards attached to removal of the condyle. The thickness of the prosthesis can be from 0.024 to 0.028 inch, so that varying degrees of stability can be selected. For this purpose, these thicknesses give ample rigidity and act as a permanent barrier to a recurrence of the scaphoid of the type seen in this case.

In all cases of scaphoiditis of one or both mandibular joints, it is well to correct the disease surgically alone, over a period of time, a scaphoid may occur at the time of surgery and would also be useful. I have preferred cast-Vita for its rigidity and also for the fact that the arthroscopic surface can be polished, thus giving it a smooth surface for the condyle to function against.

In all cases of asymptomatic or with only a minimal degree of asymmetry, the elevator muscles, causing an additional type of restriction which will not discriminate.

CASE REPORT

Sister L., a 35-year-old woman, was referred to my office on Dec. 5, 1944, for treatment of intermittent, dull pain in the right mandibular joint, which had lasted for 2 to 3 years. At this time the degree was noted in the left mandibular joint. Full History.—The patient stated that when she was 7 years old she was struck on the left temporal area by the pedal of a bicycle. A scar was visible in the skin for many years.

She received no treatment at the time and did not recall having had any serious problem with the joint until she was in her early 20's, at which time pain became constant. At that time (1934) a surgeon was seen in another city and performed a meniscectomy. The patient noted that she had experienced joint pain, cracking, and periods of terrific pain prior to that and was advised that the removal of the meniscus would alleviate her problem.

The surgical procedure was performed through a horizontal incision at the level of the zygomatic arch. The patient's jaws were immobilized following this treatment. She stated that her mandible functioned more smoothly and with less pain for about 1 year. Then she began to notice the jaw deviating to the left side, and the pain and grating returned.

Over the following years she was aware of pain and restriction of jaw movements until finally, 7 years later, the same surgeon suggested a condylectomy to relieve the fibrous adhesions.

This operation was performed through a horizontal skin incision, and the mandible was immobilized by intramascular fixation for 2 weeks postoperatively. The recovery was successful, but several months later the mandible began to deviate to the left, with an abnormal occlusal relationship developing. The patient stated that the left mandibular second and third molars and the left maxillary first, second, and third molars were extracted in an attempt to maintain occlusal equilibrium, but with the result that the deviation continued. The mandible became bony ankylosed, and desultory efforts, followed by guided occlusal restoration on virtually all posterior teeth, were performed.

During the next 2 years, the patient progressively developed pain and grating in the right mandibular joint. The history for the past 3 years was one of limited motion with pain in the right joint and at times in the left joint.

Clinical Examination.—The patient was quite pleasant and mildly deformed, with a noticeable asymmetry of the face.

The left side of the mouth was elevated approximately 1/4 inch above the right side. When the patient opened her mouth, the skin deviated to the left 1/2 mm. The terminal opening was less than 1/2 inch. There was noticeable pain in the patient's facial expression as she attempted to open her jaws. The pain increased more from the right mandibular joint area. On palpation, the right condyle would move forward more than would have been anticipated with the degree of opening that the patient could accomplish. Examination of the left joint could not be performed during movement. There was tenderness over the right joint, and clicking was noted.

The intraoral examination showed marked atrophy of all the teeth, with gold crowns covering most of the premolars and molars. The left maxillary molars and the left mandibular second and third molars were missing.

Neuroglossograph Examination.—A centric profile roentgenogram disclosed a deviation of the condyloid area on the left side, producing a 1/4 inch variation between the right and left angles of the mandible.

Mandibular joint films showed a normal appearing right joint (Fig. 1) with hypermobility of the right condyle, to the point of near dislocation when the mouth was opened 1/2 inch. The left joint showed severe degenerative changes. The articular head was missing, and the neck of the condyle had an osteoarthritic contour with marked ligament and spur at its margins. The position was opposite the crest of the articular eminence and showed fibrous attachment to the deeply defined, flattened eminence (Fig. 6). There was no change in this position during open or closed occlusal position. The glomus fossa was empty and appeared firmer, with areas of osteopenia in its cortical margin.

A pneumoglossar roentgenogram of the mandible showed an deviation of the left side of the mandible, which was due to the proclination and removal of the teeth.

Treatment Plan.—From the history, clinical examination, and x-ray findings, it was apparent that the patient had a fibrous ankylosis of the left joint as a result of the previous meniscectomy and condylectomy (Fig. 7). Because of the patient's discomfort, the patient's mandibular movements were accomplished in the right joint, using a constant strain...
suture, an surgical intervention in this joint was advisable at this time. Restoration of function in the left joint would seem taking three major steps: 1) freeing of the subluxation; 2) reconstruction of the capsule so that it would be in the glided fossa; and 3) creation of a metal bar to prevent future fissure. Revelation of the height and position of the condyle neck to its proper position would best be accomplished by means of a vertical osteotomy in the margin and reaproximation of the proximal segment of bone so that its superior surface would be in the fossa and its inferior surface would rest against the articular surface of the ramus. The two segments of the ramus would be secured by a transmassal wire system, and the mandible would be immobilized for 2 weeks. The post-mortem existence would be covered with a cast.-Vitallium prosthesis, such as that described previously, held securely by two 5 mm. Vitallium screws (Fig. 8). Since the patient seemed well, it was decided that the surgical procedure should be performed under general anesthesia. Accordingly, on June 18, 1941, the patient was admitted to St. Luke Hospital, and the operation was performed on the following day.

The routine application of Winter with fracture bar was reinforced by a circumferential wire around the mandibular arch bar and symphysis of the mandible. This prevented the lower arch bar from being pulled superiorly. An acrylic occlusal splint, prepared from precise impressions and models, was designed to open the left posterior occlusion approximately 2 mm.

The vertical osteotomy of the left ramus was performed through a 1.5 inch skin incision on the Alabina approach. The bone cut was made with a specially adapted bone saw (Christian's variation of the Joseph sawn). and was directed parallel to the pterygoid surface of the ramus from the mandibular neck to the frontal point of the angle of the mandible. When the osteotomy was completed, the mandible could be immobilized in the acrylic splint by intermaxillary elastic traction. A circumferential dressing was placed over this wound, and the post-mortem incision was made with a scalpel to facilitate the stereotypy and freeing of the subluxation. The skin incision was vertical in the pterygoid field from the superior to the inferior attachment of the ramus. A skin flap was elevated by sharp dissection and entered forward with three silk sutures. The approach to the level of the joint was carried along the surface of the ramus by sharp dissection. When the lateral rim of the pterygoid fossa was exposed, we used sharp and blunt dissection to elevate the attachment of the capsule to the spongiosa plate until the pterygoid third of the ramus and the lateral spongiosa of the spongiosa was exposed.

The condylar stump was now fully exposed and found to be attached by very dense fibrous tissue to about the centric occlusal articulation. The glided fossa was filled with soft tissues which was reared by blunt dissection with a periodontal elevator until the entire fossa was exposed.

The anterior and partially bony attachment of the condyle neck to the ramus was severed by means of a mallet and sharp chisel. When this had been dissected, the existing resection used a fury forceps to grasp the inferior end of the proximal fragment, through the lateral approach, and resected this segment of bone inferiorly. This made it possible to free the condyle neck from the ramus and to totally expose the anterior, inferior, and posterior surface of the spongiosa plate and glided fossa, so that a suitable surface of bone would be available for the post-Roentgen prostheses.

At this point the various post-Roentgen, twelve number, were placed against the bone to check for accuracy of fit. The pattern fit all areas precisely, and was now held in position while a hole was drilled for one of the 5 mm. post-Roentgen implant screws. The hole was driled slightly smaller in diameter than one of the screws, and the screw was inserted. The hold the prosthesis in proper adaptation to the surface of bone (Fig. 8). The second screw was then placed in a similar fashion.

The gross segment of bone was now positioned so that the condylar surface was in the most posterior portion of the glided fossa of the prosthesis. The inferior margin of this segment of bone was now tilted forward to contact the posterior surface of the spongiosa of the ramus approximately 2 mm. higher than the inferior margin of the mandible. Because the condyle was tilted posteriorly, there was a vaulted space between the two fragments.
above the point of contact at the lower margin. A single transverse steel wire was placed near the lower margin, where the two bones contacted each other (Fig. 12). This was found to immobilize the two fragments adequately, since the jaws were secured by intermaxillary traction.

The mandible wound was now closed in layers. If the skin sutures were used in the deeper tissues and 0.012 stainless steel wire was used in the skin margins. The bone incision was now closed in a similar fashion. A small piece of Telfa was placed over each wound, and a pressure dressing was used over this.

To hasten the patient's recovery, he was discharged on the fourth post-operative day. There was no impairment of any branch of the facial nerve; nor was there any disturbance in the mandibular branch of the trigeminal nerve.

The mandible was left immobilized for 2 weeks to allow the bone fragments to unite. At the end of this time the intermaxillary elastic and wire traction was removed. The patient was able to open the jaws ½ inch, and the occlusal split was removed. One week later, under local anesthesia, the fractures were bone and cartilaginous union.

Over the next few weeks the patient was able to open the jaw 1¼ inches. He could open the jaws as far as the teeth while chewing,

The patient who had arrived in the left mandibular joint showed a better operative result and had not returned. However, the palate in the right joint, which remained for a few months, slowly increased to the point where further evaluation became necessary.

Pain and grinding increased in the right mandibular joint until, in May, 1945, new roentgenograms were taken. These showed a much different picture than those taken in December, 1944. The right condyle had been lying forward in the glenoid fossa, with bone-to-bone contact present (Fig. 11). The anterior inclined surface of the glenoid fossa showed early erosion of its cortical surface and a demarcation of the adjacent articular surface of the condyle. It was apparent that a perforation of the disc had occurred.

The left condyle had been totally free of pain since the insertion of the prosthesis one year before, but there had been only a partial return of the normal excursions. The surgical return of function was probably due to the loss of the attachment, or function, of the external pterygoid muscles as a result of the earlier condylectomy, or it may have been due in part to some fibrous adhesions which occurred during the period of immobilization.

Although the patient's jaw could be opened 1¼ inches, severe pain in the right joint limited voluntary opening to less than 1 inch. It was decided that a non-Vincentian glenoid
I have used this technique six times in the past 15 months (1961 and 1962) and have seen the restoration of normal, pain-free function occur in each case. Although it may be too early to make a complete evaluation, it is believed that this new technique will prove to be of great value to many patients suffering from various degrees of mandibular joint arthrosis.

I wish to express my appreciation to Robert F. Caplin for the photographs used in this article.

REFERENCES
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SUMMARY
This article describes a new technique for creating an anatomic, pre-fabricated, well-tolerated mandibular joint prosthesis for the correction of early and late mandibular joint arthrosis.