found between the tibial articular surface and the supporting metal tibi tray. This residue could not be adequately removed to give accurate weig loss measurements. Six of the tibial components showed an increase weight, thus negating this part of the study.

SUMMARY

The knee simulator used in this study provides all of the normal degr of freedom and applies representative loading conditions. As a resul provides a means of evaluating performance characteristics and short wear behavior of prosthetic materials. This and previous studies indicate Poly Two tibial components "wear" significantly less than conventio polyethylene, however, carbon fiber associated damage with Poly-Two major wear mechanism. This break-up of the fibers is prompted by "rolling" action of the femoral component on the tibia. This behavior ma be observed in the typical pin-on-disk test.

Visual, stereoscopic, and SEM examination of the tibial compon showed that the original surfaces of Poly Two components contain tively large number of carbon fibers. In the contact region, these su fibers were gradually removed during the course of the test. Areas found on the tibial component tested for 500,000 steps where the was completely depleted of carbon fibers. The most common wear m nisms, found on all nine Poly Two tibial test specimens, were carbon associated damage and anteroposterior scratching. Three types of fiber damage was found: fibers removed from the wear surface, UHM removed from above the fibers, and fiber breakage. Fiber removal w served as troughs in the surface where carbon fibers had been. UH removal frequently appeared as an area where the polyethylene ha removed from the top of an intersection of several fibers. Anterop scratches were always found in areas of carbon fiber associated d possibly due to the abrasive action of broken carbon fibers. Surface mation was found on eight of the tibial components with none of t dences considered excessive. Pits were found on six tibial compone bottoms of the pits seemed to be lined with carbon fibers indicat the pit had formed when a piece of material had pulled away poor adhesion to the carbon fibers or fatigue cracks had propag coalesced until a large wear particle had been formed. A pit in th of forming was found where a particle, surrounded by an appare crack, was pulling away from three carbon fibers that were ju the surface. Two incidences of minor abrasion were found. No co could be found between tibial component wear mechanics and the femoral materials.

Visual examination of Ti-6Al-4V femoral components revealed no the abnormal or corrosive wear mechanisms that have been rep Rostoker and Galante.[1,4] There were, however, light surface scra were not present on the Co-Cr-Mo femoral components. From th

mental 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. No scratching was observed on the titanium nitride coated Ti-6Al-4V femoral components. The titanium nitride coated femoral component tested for 500,000 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 large number of carbon fibers. As the original surface layer was worn away, scratching and carbon fiber associated damage were major wear mechanisms. After the surface fibers were removed, the amount of carbon fiber associated wear was reduced, but scratching remained a major wear mechanism.

(2) Pitting of the tibial components was found as a major wear mechanism. The bottom and sides of the pits were lined with carbon fibers, probably due to poor fiber-UHMWPE adhesion and/or fatigue cracks initiating at carbon fibers.

(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 scoring or corrosive wear as seen by Galante and Rostoker[4] in their study using disk-on-flat wear screening device and distilled water as a lubricant.

(5) Ti-6Al-4V femoral components, tested with either Poly Two or UHMWPE tinbial components, had many light scratches of apparent abrasive wear that were not observed on the Co-Cr-Mo or TiN coated Ti-6Al-4V components.

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

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Designation: F 67 – 89

Standard Specification for Unalloyed Titanium for Surgical Implant Applications[1]

This standard is issued under the fixed designation F 67; 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 (ε) indicates an editorial change since the last revision or reapproval.

1. Scope

1.1 This specification covers the chemical, mechanical, and metallurgical requirements for four grades of unalloyed titanium used for the manufacture of surgical implants.

1.2 The values stated in inch-pound units are to be regarded as the standard.

2. Referenced Documents

2.1 *ASTM Standards:*

B 265 Specification for Titanium and Titanium Alloy Strip, Sheet, and Plate[2]

B 348 Specification for Titanium and Titanium Alloy Bars and Billets[2]

B 381 Specification for Titanium and Titanium Alloy Forgings[2]

E 8 Test Methods of Tension Testing of Metallic Materials[3]

E 16 Methods of Free Bend Test for Ductility of Welds[4]

E 120 Test Methods for Chemical Analysis of Titanium and Titanium Alloys[5]

E 190 Method for Guided Bend Test for Ductility of Welds[3]

E 290 Test Method for Semi-Guided Bend Test for Ductility of Metallic Materials[3]

F 981 Practice for Assessment of Compatibility of Biomaterials (Nonporous) for Surgical Implants with Respect to Effect of Materials on Muscle and Bone[6]

2.2 *Aerospace Material Specification:*

AMS 2249C Chemical Check Analysis Limits, Titanium and Titanium Alloys[7]

2.3 *American Society for Quality Control (ASQC) Standard:*

C1-1968 Specifications of General Requirements for a Quality Program[8]

3. General Requirements for Delivery

3.1 Material furnished to this specification shall conform to the requirements of the latest issue of B 265, B 348, and B 381.

3.2 In the case where a conflict exists between this specification and those listed in 3.1, this specification shall take precedence.

4. Ordering Information

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

4.1.1 Quantity (weight or number),

4.1.2 Grade (1, 2, 3, or 4),

4.1.3 ASTM designation,

4.1.4 Form (sheet, strip, plate, bar, billet, forging),

4.1.5 Condition (5.1),

4.1.6 Mechanical properties (if other than annealed conditions),

4.1.7 Finish (5.2),

4.1.8 Applicable dimensions including thickness, width, and length (exact, random, or multiple number),

4.1.9 Special tests, and

4.1.10 Special requirements.

5. Manufacture

5.1 *Condition*—Material shall be furnished by the manufacturer in the hot-rolled, hot-rolled and annealed, condition.

5.2 *Finish*—Unalloyed titanium shall be free of injurious external and internal imperfections that will interfere with the purpose for which it is intended. Annealed material may be furnished pickled, blasted, or as ground, or both ground and blasted, or as shipped as hot rolled, descaled, or pickled. The manufacturer shall be permitted to remove surface imperfections by spot grinding provided that this does not reduce the thickness of the material below the minimum permitted by the tolerance for that thickness.

6. Chemical Composition

6.1 The heat analysis shall conform to the requirements to chemical composition prescribed in Table 1. Check analysis may be used for reporting purposes and shall conform, except hydrogen, samples of which shall be taken from the finished product.

6.2 *Product Analysis*—Product analysis is provided to broaden the specified heat analysis limits to allow for variations between laboratories in the determination of chemical content. The manufacturer is not to ship material outside the limits specified in Table 1 for product analysis. Product analysis limits shall be as follows:

6.2.1 The product analysis

This specification is under the jurisdiction of ASTM Committee F-4 on Medical and Surgical Materials and Devices and is the direct responsibility of subcommittee F04.02 on Resources.

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[2] *Annual Book of ASTM Standards*, Vol 02.04.

[3] *Annual Book of ASTM Standards*, Vol 03.01.

[4] Discontinued—See 1977 *Annual Book of ASTM Standards*, Part 10.

[5] *Annual Book of ASTM Standards*, Vol 03.05.

[6] *Annual Book of ASTM Standards*, Vol 13.01.

[7] Available from Society of Automotive Engineers, 400 Commonwealth Drive, Warrendale, PA 15096.

[8] Available from American Society for Quality Control, 161 W. Wisconsin Ave., Milwaukee, WI 53203.

TABLE 1 Chemical Requirements

Element	Composition,[A] %							
	Grade 1		Grade 2		Grade 3		Grade 4	
	Flat Product	Bar and Billet	Flat Product	Bar and Billet	Flat Product	Bar and Billet	Flat Product	Bar and Billet
...gen, max	0.03	0.03	0.03	0.03	0.05	0.05	0.05	0.05
...on, max	0.10	0.10	0.10	0.10	0.10	0.10	0.10	0.10
...drogen, max	0.015	0.0125[B]	0.015	0.0125[B]	0.015	0.0125[B]	0.015	0.0125[B]
..., max	0.20	0.20	0.30	0.30	0.30	0.30	0.50	0.50
...gen, max	0.18	0.18	0.25	0.25	0.35	0.35	0.40	0.40
...inium	balance	balance	balance	balance	balance	balance	balance	balance

[A] Forgings are designated Grade F-1, F-2, F-3, or F-4 respectively. Forging compositions are identical to those specified for flat product.

[B] Bar only; max hydrogen content for billet is 0.0100 %.

TABLE 2 Product Analysis Tolerances[A]

Element	Limit or Maximum of Specified Range, %	Tolerance Under the Minimum or Over the Maximum Limit[B]
...gen	Up to 0.05	0.02
...on	0.10	0.02
...rogen	Up to 0.015	0.0020
	Up to 0.25	0.10
	Over 0.25	0.15
...gen	Up to 0.20	0.02
...gen	Over 0.20	0.03

[A] Refer to AMS 2249C.

[B] Under minimum limit not applicable for elements where only a maximum percentage is indicated.

...ifying the composition of a heat or lot or to determine ...ations in the composition within the heat.

...2.2 Acceptance or rejection of a heat or lot of material ...y be made by the purchaser on the basis of this check ...lysis.

...3 For referee purposes, Methods E 120 shall apply.

...3.1 Samples for chemical analysis shall be representative ...e material being tested. Extreme care must be taken in ...pling titanium for chemical analysis because of its ...ity for elements such as oxygen, nitrogen, and hydrogen. ...refore, when cutting samples for analysis, the operation ...uld be carried out in a dust-free atmosphere, if possible. ...ps should be collected from clean metal. Cutting tools ...uld be clean and sharp. Samples for analysis should be ...ed in suitable containers.

...Mechanical Requirements

...1 Bar, billet, and forging shall conform to the appro... requirements as to mechanical properties prescribed in ...3. Sheet, strip, and plate shall conform to the ...propriate requirements as to mechanical properties pre... in Table 4. Grades 3 and 4 may be ordered in the

TABLE 3 Mechanical Requirements—Bar, Billet, Forging[A]

Grade	Tensile Strength, min		Yield Strength, 0.2 % Offset, min		Elongation in 4D, min, %	Reduction of Area, min, %
	ksi	MPa	ksi	MPa		
1	35	240	25	170	24	30
2	50	345	40	275	20	30
3	65	450	55	380	18	30
4	80	550	70	483	15	25

[A] These properties apply to forgings having a maximum cross section not greater than 3 in.[2] (1935 mm[2]). Mechanical properties of forgings having greater cross sections shall be negotiated between the manufacturer and the purchaser.

cold worked condition to higher minimum tensile strength but a minimum 10 % elongation in 4*D* or 2 in. (50 mm) must be met.

7.2 For sheet and strip, the bend test specimen shall stand being bent cold through an angle of 105° without fracture on the outside of the bent portion. The bend shall be made on a diameter equal to that shown in Table 4 for the applicable grade.

7.2.1 Supplementary bend test requirements for sheet and plate are listed in S1.

7.3 Perform tension testing in accordance with Test Methods E 8. Determine tensile properties using a strain rate of 0.003 to 0.007 in./in. (mm/mm)·min through the specified yield strength, and then the cross-head speed shall be increased so as to produce fracture in approximately one additional minute.

7.4 Any other special requirements shall be specified on the implant manufacturer's purchase order.

8. Certification

8.1 The manufacturer's certification that the material was manufactured and tested in accordance with this specification together with a report of the test results shall be

TABLE 4 Mechanical Requirements—Sheet, Strip, Plate

Grade	Tensile Strength,[A] min		Yield Strength,[A] (0.2 % Offset)				Elongation in 2 in. or 50 mm, min, %	Bend Test[B]	
			min		max			Under 0.070 in. (1.8 mm) in Thickness	0.070 to 0.187 in. (1.8 to 4.75 mm) in Thickness
	ksi	MPa	ksi	MPa	ksi	MPa			
1	35	240	25	170	45	310	24	3T	4T
2	50	345	40	275	65	450	20	4T	5T
3	65	450	55	380	80	550	18	4T	5T
4	80	550	70	483	95	655	15	5T	6T

[A] Minimum and maximum limits apply to tests taken both longitudinal and transverse to the direction of rolling. Mechanical properties for conditions other than annealed or thickness over 1 in. (25 mm) may be established by agreement between the manufacturer and the purchaser.

[B] *T* equals the thickness of the bend test specimen. Bend tests are not applicable to material over 0.187 in. (4.75 mm) in thickness.

furnished to the implant manufacturer at the time of shipment. Minimum specimen fall

9. Quality Program Requirements

9.1 The producer shall maintain a quality program, such as, for example, is defined in ASQC C1-1968.

9.2 The manufacturer of surgical implants or medical appliances shall be assured of the producer's quality program for conformance to the intent of ASQC C1-1968, or other recognized program.

SUPPLEMENTARY REQUIREMENTS

These requirements shall apply only when specified in the purchase order, in which event the specified tests shall be made by the manufacturer before shipment of the plates.

S1. Surface Requirements Bend Tests

S1.1 The purpose of this test is to measure the cleanliness or ductility, or both, of the metal surface.

S1.2 Two guided- or free-bend tests of sheet or plate material limited to Grades 1, 2, and 3 shall be made. Each of these bends will place opposite surfaces of the sheet or plate material in tension.

S1.3 The bends are to be made in accordance with Method E 190 or Method E 16, except that the welds mentioned in these standards are not required. The bend specimen may be of less than full material thickness; however, the outer surface of the specimen must be representative of the product as supplied.

S1.4 The bend radius will be such to provide minimum elongation of the outer fibers of the bent specimen as follows:

Grade 1—20 % equivalent to 2T bend radius at 180° bend
Grade 2—20 % equivalent to 2T bend radius at 180° bend
Grade 3—16 % equivalent to 2½T bend radius at 180° bend

S1.5 Criteria for acceptance will be the absence of any cracking or surface separations (not originating at the edge of specimen).

APPENDIX

(Nonmandatory Information)

X1. RATIONALE

X1.1 The primary reason for this standard is to characterize composition and properties to assure consistency in the starting material used directly or as modified by forging in the manufacture of medical devices.

X1.2 The material compositions specified herein have been shown to produce a well-characterized level of local biological response following long term clinical use and has been used as control material in Practice F 981.

X1.3 The choice of composition and mechanical properties is dependent upon the design and application of the medical device.

X1.4 A maximum limit for 0.2 % offset yield strength has been added to the mechanical requirements for sheet and plate to coincide with Specification B 265.

X1.5 The bend test sample thickness limits previously specified were incorrect. Supplementary bend test requirements have been added in accordance with Specification B 265.

X1.6 Additional product analysis tolerance information has been included for clarification purposes.

Designation: F 136 – 84

Standard Specification for Wrought Titanium 6A1-4V ELI Alloy for Surgical Implant Applications[1]

This standard is issued under the fixed designation F 136; 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 (ε) indicates an editorial change since the last revision or reapproval.

1. Scope

1.1 This specification covers the chemical, mechanical, and metallurgical requirements for wrought annealed Ti-6A1-4V E.L.I. (extra low interstitial) titanium alloy to be used in the manufacture of surgical implants.

1.2 The material in this specification has been subjected to testing in laboratory animals.[2,3] The results of these studies and the clinical history indicate a well characterized level of local biological response.[4,5]

1.3 The values stated in inch-pound units are to be regarded as the standard. The metric equivalents in parentheses are provided for information only.

2. Referenced Documents

2.1 *ASTM Standards:*

B 265 Specification for Titanium and Titanium Alloy Strip, Sheet, and Plate[4]

B 348 Specification for Titanium and Titanium Alloy Bars and Billets[4]

B 381 Specification for Titanium and Titanium Alloy Forgings[4]

E 8 Test Methods of Tension Testing of Metallic Materials[5]

E 120 Test Methods for Chemical Analysis of Titanium and Titanium Alloys[6]

E 290 Test Method for Semi-Guided Bend Test for Ductility of Metallic Materials[7]

F 620 Specification for Titanium 6A1-4V ELI Alloy Forgings for Surgical Implants[8]

2.2 *CI-1968 Specifications of General Requirements for a Quality Control Program*[9]

3. Product Classification

3.1 *Strip*—Any product under 0.1875 in. (4.75 mm) in thickness and under 24 in. (610 mm) wide.

This specification is under the jurisdiction of ASTM Committee F-4 on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee F04.02 on Resources.

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[2] Laing, P. G., Ferguson, Jr., A. B., and Hodge, E. S., "Tissue Reaction in Rabbit Muscle Exposed to Metallic Implants," *J. Biomed. Materials Research*, Vol. 1967, pp. 135–149.

[3] Laing, P. G., "Compatibility of Biomaterials," Orthopedic Clinics of North America, Vol. 4, No. 2, April, 1973, pp. 249–273.

[4] *Annual Book of ASTM Standards*, Vol 02.04.

[5] *Annual Book of ASTM Standards*, Vol 03.01.

[6] *Annual Book of ASTM Standards*, Vol 03.05.

[7] *Annual Book of ASTM Standards*, Vol 03.01.

[8] *Annual Book of ASTM Standards*, Vol 13.01.

[9] Available from American Society for Quality Control, 161 W. Wisconsin Ave., Milwaukee, WI 53203.

3.2 *Sheet*—Any product under 0.1875 in. (4.75 mm) in thickness and 24 in. (610 mm) or more in width.

3.3 *Plate*—Any product 0.1875 in. (4.75 mm) thick and over and 10 in. (254 mm) wide and over, with widths greater than five times thickness. Plate up to 1.75 in. (44.45 mm), thick inclusive is covered by this specification.

3.4 *Bar*—Rounds from 3/16 in. (7.9 mm) to 1.75 in. (44.45 mm) in diameter. (Other sizes by special order.)

3.5 *Forging bar*—Bar as described in 3.4, used for production of forgings, may be furnished in the hot rolled condition.

3.6 *Wire*—Rounds less than 3/16 in. (4.8 mm) in diameter.

4. Ordering Information

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

4.1.1 Quantity (weight or number of pieces),

4.1.2 Applicable ASTM designation,

4.1.3 Form (sheet, strip, plate, wire, bar, or forging),

4.1.4 Condition (See 5.1),

4.1.5 Mechanical properties (if applicable, for special conditions),

4.1.6 Finish (see 5.2),

4.1.7 Applicable dimensions including size, thickness, width, or print number,

4.1.8 Special tests, and

4.1.9 Special requirements.

5. Materials and Manufacture

5.1 The various titanium mill products covered in this specification are normally formed with the conventional forging and rolling equipment found in primary ferrous and nonferrous plants. The ingot metal for such mill operations is usually melted in arc furnaces of a type conventionally used for reactive metals.

5.2 *Finish*—Annealed material may be furnished to the implant manufacturer as descaled or pickled, sandblasted, ground, or combinations of these operations.

6. Chemical Requirements

6.1 The heat analysis shall conform to the chemical composition of Table 1. Ingot analysis may be used for reporting all chemical requirements, except hydrogen. Samples for hydrogen shall be taken from the finished mill product.

6.2 The product analysis tolerances shall conform to the check tolerances of Table 2.

6.3 For referee purposes, Methods E 120 shall be used.

6.4 Samples for chemical analysis shall be representative of the material being tested. The utmost care must be used in

TABLE 1 Chemical Requirements

Element	Composition, %
Nitrogen, max	0.05
Carbon, max	0.08
Hydrogen, max	0.012[A]
Iron, max	0.25
Oxygen, max	0.13
Aluminum	5.5–6.50
Vanadium	3.5–4.5
Titanium[B]	balance

[A] Material 0.032 in. (0.813 mm) and under may have hydrogen content up to 0.0150 %.

[B] The percentage of titanium is determined by difference and need not be determined or certified.

TABLE 2 Permissible variation in product

Nitrogen	0.02
Carbon	0.02
Hydrogen	0.00
Iron	0.10
Oxygen	0.02
Aluminum	0.4
Vanadium	0.1

TABLE 3 Annealed Mechanical Properties[A]

Size	Tensile Strength min, psi (MPa)	Yield Strength (0.2 % offset), min psi (MPa)	Elongation in 4d or 4w min, %[B]
Under 0.167 in. (4.75 mm) thickness or diameter	130 000 (896)	120 000 (827)	10
0.167 (4.75 mm) to 1.75 in. (44.45 mm) incl	125 000 (860)	115 000 (795)	10
	Bend Test[C]		
Under 0.070 in. (1.778 mm) in thickness	9 T		
0.070 in. (1.778 mm) to 0.167 in. (4.750 mm) incl in thickness	10 T		

[A] Mechanical properties for conditions other than annealed may be established by agreement between the supplier and the implant manufa

[B] Elongation on material under 0.125 in. (0.813 mm) in thickness may be obtained by negotiation.

[C] Applies to bar, plate, and forgings only.

[D] Bend test applicable to sheet and strip products; *T* = thickness of bend specimen in reference to diameter of bend.

sampling titanium for chemical analysis because of its affinity for elements such as oxygen, nitrogen, and hydrogen. Therefore, in cutting samples for analysis, the operation should be carried out insofar as possible in a dust-free atmosphere. Chips should be clean and sharp. Samples for analysis should be stored in suitable containers.

7. Mechanical Requirements

7.1 Material supplied under this specification shall conform to the mechanical property requirements given in Table 3.

7.2 Specimens for tension tests shall be machined and tested in accordance with Test Methods E 8. Tensile properties shall be determined using a strain rate of 0.003 to 0.007 in./in. min (metric equivalent mm/mm/min) through the specified yield strength.

7.3 For sheet and strip, the bend test specimen shall withstand being bent cold through an angle of 105° without fracture in the outside surface of the bent portion. The bend shall be made on a diameter equal to that shown in Table 3.

Test conditions shall conform to Te

8. Special Requirements

8.1 The microstructure shall be a
alpha and beta phases resulting from
plus beta field. There shall be no co
at prior beta grain boundaries. The
elongated alpha platelets. There shall

8.2 The beta transus temperatur
suitable method and reported on th

9. Quality Program Requirements

9.1 The producer shall maintain
as, for example, is defined in Specifi

9.2 The manufacturer of surgi
applications shall be assured of and
quality program for conformance
tions C1-1968, or other recognize

10. Marking, Packing, Certificat

10.1 Marking, packing, certificat
be as specified in Specifications B2

APPENDIX

(Nonmandatory Information)

X1 RATIONALE

X1.1 The purpose of this specification is to characterize the chemical, physical, mechanical, and metallurgical properties of wrought annealed Ti-6Al-4V E.L.I. alloy to be used in the manufacture of surgical im

X1.2 The alloy composition co
been employed successfully in hum

characterized level of local biological response, for over
cade.

X1.3 The microstructural requirements contained in this
ndard represent the current general consensus of opinion
h respect to optimization of mechanical properties for
plant applications.

X1.4 The minimum mechanical properties specified assure a baseline of strength and ductility for the highly stressed devices for which this alloy is typically used.

Designation: F 648 – 84

Standard Specification for Ultra-High-Molecular-Weight Polyethylene Powder and Fabricated Form for Surgical Implants[1]

This standard is issued under the fixed designation F 648; 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 (ε) indicates an editorial change since the last revision or reapproval.

1. Scope

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

1.2 The requirements of this specification apply to UHMWPE in two forms. One is virgin polymer powder (Section 4). The second is any form fabricated from this powder from which a finished product is subsequently produced (Section 5). This specification addresses material characteristics and does not apply to the packaged and sterilized finished implant.

1.3 The provisions of Specification D 4020 apply. Special requirements detailed in this specification are added to describe material which will be used in surgical implants.

1.4 The biological response to polyethylene in soft tissue and bone has been well-characterized by a history of clinical use (1, 2, 3)[2] and by laboratory studies (4, 5, 6).

1.5 The following precautionary caveat pertains only to the test method portion, Section 7, of this specification: *This standard may involve hazardous materials, operations, and equipment. This standard does not purport to address all of the safety problems associated with its use. It is the responsibility of whoever uses this standard to consult and establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.*

2. Referenced Documents

2.1 *ASTM Standards:*

D 256 Test Methods for Impact Resistance of Plastics and Electrical Insulating Materials[3]

D 621 Test Methods for Deformation of Plastics Under Load[3]

D 638 Test Method for Tensile Properties of Plastics[3]

D 648 Test Method for Deflection Temperature of Plastics Under Flexural Load[3]

D 790 Test Methods for Flexural Properties of Unreinforced and Reinforced Plastics and Electrical Insulating Materials[3]

D 1505 Test Method for Density of Plastics by the Density-Gradient Technique[3]

D 1898 Practice for Sampling of Plastics[4]

D 1921 Test Method for Particle Size (Sieve Analysis) of Plastic Materials[4]

D 2240 Test Method for Rubber Property—Durometer Hardness[4]

D 4020 Specification for Ultra-High-Molecular-Weight Polyethylene Molding and Extrusion Materials

3. Description of Terms Specific To This Standard

3.1 *fabricated form*—any bulk shape or form machined from the virgin polymer powder by a process of fabricating surgical implants, packaging, and sterilization.

3.1.1 *Discussion*—This form results from the application of heat and pressure to the virgin polymer powder. The material characteristics of this form are evaluated by applicable requirements of this specification. Typically, this includes extruded bars or molded blocks from which the final product form is machined, or a near-net shape subsequently trimmed.

3.2 *generic property*—that property of a material defined solely by the chemical composition of the repeating unit of the virgin polymer.

3.3 *virgin polymer powder*—the polymer powder as obtained from the manufacturer and prior to consolidation into a bulk shape.

4. Virgin UHMWPE Powder Requirements

4.1 *Generic Properties:*

4.1.1 The virgin polymer shall be a homopolymer of ethylene, as described in Specification D 4020.

NOTE 1—Information on the degree of branching, comonomer concentration, and vinylidene content would be useful, but is not a suitable method to determine the polymer.

4.1.2 Molecular weight of the polymer shall be indicated by determining the relative solution viscosity, when tested with the method given in Specification D 4020, or greater. The accuracy of the test shall be determined by vendor-purchaser agreement.

NOTE 2—While the precise relationship between the impact and wear resistance of implants and the molecular weight of polyethylene used to fabricate them has not been established, it has been demonstrated that, for many such applications than are polyethylene.

The relative solution viscosity of UHMWPE powder may be used

[1] This specification is under the jurisdiction of ASTM Committee F-4 on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee F04.02 on Resources.

Current edition approved Sept. 28, 1984. Published February 1985.

[2] The boldface numbers in parentheses refer to the list of references at the end of this specification.

[3] *Annual Book of ASTM Standards*, Vol 08.01.

[4] *Annual Book of ASTM Standards*, Vol 08.02.

[5] *Annual Book of ASTM Standards*, Vol

ome minimum value of molecular weight is attained. At present, there is some uncertainty regarding the extension of e solution viscosity/molecular weight relationship to the MWPE range.

Information on the molecular weight distribution would permit control of the weight fraction of low-molecular weight material. Presently, there is not a suitable method to determine the distribution.

4.2 *Nongeneric Properties:*

4.2.1 The polymer powder shall contain as little extraneous matter (such as dirt, lint, silica, and discoloring material) as possible. The purchaser and vendor shall agree on which of the following test methods will be used.

4.2.1.1 When a 400 cm^2 sample prepared in accordance with 7.1.2.1 is viewed, there shall be no particle whose largest dimension is greater than 300 μm, and there shall be no more than 10 particles whose largest dimension is 300 μm or less.

4.2.1.2 When a 300-g sample prepared in accordance with 7.1.2.2 is viewed, there shall be no more than 25 particles present.

4.2.2 The polymer powder shall contain as few trace elements as possible, and the level of those trace elements shall be as small as possible. To promote uniformity between different lots of polymer powder, the following maximum concentration limits for trace elements have been established.

Element	ppm, max
Al	100
Ti	300
Ca	100
Cl	120

4.2.2.1 Analyses for these and other elements shall be conducted by vendor-vendee agreement.

NOTE 3—There is no evidence that the concentration of trace elements affects the physical properties or the biological response of UHMWPE fabricated forms.

4.2.3 All powder shall pass a No. 16 (1.18-mm) sieve.

NOTE 4—A limitation on particle size stems from the possibility that excessively large particles of UHMWPE may not flow enough in subsequent "sintering" or molding operations to yield a sufficiently uniform material. This could result in undesirable local inhomogeneity or a nonuniform structure.

5. UHMWPE Fabricated Form Requirements

5.1 *Compositional Requirements:*

5.1.1 No stabilizers or processing aids are to be added to the virgin polymer powder during manufacture of a fabricated form.

5.1.2 The surface of a fabricated form shall contain as few extraneous matter as possible. When a 400-cm^2 sample prepared in accordance with 7.2.2 is viewed, there shall be no particle whose largest dimension is greater than 300 μm, and there shall be no more than 10 particles whose largest dimension is 300 μm or less.

5.2 *Physical Requirements:*

5.2.1 The surface of a fabricated form shall contain as few light patches (which would indicate unfused areas) as possible. When a 400-cm^2 sample prepared in accordance with 7.2.1 is viewed, there shall be no light patch whose largest dimension is greater than 300 μm.

5.2.2 The density of the fabricated form shall be between 0.930 and 0.944 g/cm^3.

5.3 *Mechanical Requirements:*

NOTE 5—The relationship between these mechanical properties and the *in vivo* performance of a fabricated form has not been determined. While trends are apparent, specific property-polymer structure relationships are not well-understood. These mechanical tests are frequently used to evaluate the reproducibility of a fabrication procedure and are applicable as quality control tests to determine lot to lot repeatability for a process of converting virgin polymer powder to a fabricated form. The mechanical properties are subject to variation as the fabrication process variables (such as temperature, pressure, and time) are changed.

5.3.1 UHMWPE in fabricated form from which implants shall be made shall meet the requirements listed in Table 1.

NOTE 6—The following mechanical tests may be conducted based on agreement between the vendor and purchaser:

(1) Deflection temperature: Test Method D 648 (1.8 MPa 264 psi)

(2) Flexural modulus: Test Methods D 790 (secant, 2 % offset)

6. Sampling

6.1 Where applicable, the requirements of this specification shall be determined for each lot of powder and fabricated form by sampling sizes and procedures according to Recommended Practice D 1898, or as agreed upon between the purchaser and seller.

7. Test Methods

7.1 *UHMWPE Powder:*

7.1.1 Determine the relative solution viscosity in accordance with the method given in Specification D 4020.

7.1.2 Determine the amount of extraneous matter by the following procedures as agreed by the vendor and purchaser.

7.1.2.1 Using a polished steel mold, press UHMWPE powder into sheets with a minimum surface area of 12 cm^2 and a maximum thickness of 6.0 mm, at 205 ± 10°C (400 ± 18°F) for 10 min. Examine a total surface area of 400 cm^2. Count the particles using optical microscopy within the translucent sheets.

7.1.2.2 A 300-g sample is divided into four 75-g samples. Place a 75-g sample in each of four 1000 mL Erlenmeyer flasks, add 400 mL isopropyl alcohol, shake 5 min, and let settle for 5 min. Count the total number of particles of extraneous matter in the four flasks.

7.1.3 Determine the trace element concentration by the following methods or by methods agreed upon by the vendor and purchaser:

Ti Atomic absorption or emission spectroscopy
Al Atomic absorbtion or emission spectroscopy
Ca Atomic absorption or emission spectroscopy
Cl Potentiometric methods or titration methods

7.1.4 Ensure that the particle size of the powder is correct by passing it through a No. 16 (1.18-mm) sieve in accordance with Method B of Test Method D 1921.

7.2 *UHMWPE Fabricated Form:*

7.2.1 The requirement that there will be no addition of any stabilizer or processing aid during fabrication of the fabricated form shall be met by certification of the fabricator.

7.2.2 Use optical microscopy to determine the size of the particles of extraneous matter and the size of light patches at the surface of the fabricated form. Examine a surface area of 400 cm^2 taken from locations within the fabricated form agreed upon by the vendor and the purchaser.

TABLE 1 UHMWPE Fabricated Form Mechanical Requirements

Property	ASTM Test Method	Requirement minimum
Tensile Strength, 23°C	D 638 (Speed C)	
Ultimate		4000 psi (27 MPa)
Yield		2800 psi (19 MPa)
Elongation	D 638 (Speed C)	200 %
Izod Impact Strength	D 256 (15° notch A), double	1070 J/M (20 ft/lb)
Deformation under load	D 621 (A) (7 MPa (1000 psi) for 24 h)	2 % deformation after 90 min recovery
Hardness	D 2240 (Shore D)	60

7.2.3 Determine the density in accordance with Test Method D 1505.

7.2.4 Determine specific mechanical properties in accordance with the methods listed in Table 1. Mechanical specimens shall be produced by methods that represent those used to produce surgical implants.

REFERENCES

(1) Charnley, J., Cupic, A., "The Nine and Ten Year Results of the Low Friction Arthroplasty of the Hip," *Clinical Orthopaedics*, Vol 95, No. 9, 1973.

(2) Halley, D., Charnley, J., "Results of Low Friction Arthroplasty in Patients Thirty Years of Age or Younger," *Clinical Orthopaedics*, No. 112, October, 1975.

(3) Mirra, J., Amstutz, H., Matos, M., Gold, R., "The Pathology of the Joint Tissues and Its Clinical Relevance in Prosthesis Failure," *Clinical Orthopaedics*, No. 117, June, 1976.

(4) Turner, J., Lawrence, W., Autian, J., "Subacute Toxicity of Biomaterials Using Histopathologic Evaluation of Rat Tissue," *Journal of Biomedical Materials Research*, [illegible]

(5) Laing, P., "Compatibility of Biomaterials," *Orthopaedics North America*, Vol 4, No. 2, April, 1973.

(6) Escalas, F., Galante, J., Rostoker, W., Biocompatibility of Materials for Total Joint Replacement," *Journal of Biomedical Materials Research*, Vol 10, No. 2, 1976.

Designation: F 799 – 87

Standard Specification for Thermomechanically Processed Cobalt-Chromium-Molybdenum Alloy for Surgical Implants[1]

This standard is issued under the fixed designation F 799; 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 (ε) indicates an editorial change since the last revision or reapproval.

Scope

1.1 This specification covers the material requirements of high-strength, thermomechanically processed, cobalt-chromium-molybdenum alloys used for surgical implants. Material conforming to this specification has been evaluated for biocompatibility and corrosion resistance[2] and has been found to be comparable to material conforming to Specification F 75. The properties specified in this document specifically apply to finished or semifinished parts that receive no subsequent metallurgical processing.

1.2 The values stated in inch-pound units are to be regarded as the standard. The metric equivalents of the inch-pound units may be approximate.

Referenced Documents

2.1 *ASTM Standards:*

E 8 Methods of Tension Testing of Metallic Materials[3]

E 18 Test Methods for Rockwell Hardness and Rockwell Superficial Hardness of Metallic Materials[3]

E 112 Methods for Determining the Average Grain Size[3]

E 354 Methods for Chemical Analysis of High Temperature, Electrical, Magnetic and Other Similar Iron, Nickel and Cobalt Alloys[4]

F 75 Specification for Cast Cobalt-Chromium-Molybdenum Alloy for Surgical Implant Applications[5]

F 981 Practice for Assessment of Compatibility of Biomaterials (Non-porous) for Surgical Implants with Respect to Effect of Materials on Muscle and Bone[5]

2.2 *Aerospace Material Specifications:*[6]

AMS 2269C Chemical Check Analysis Limits, Wrought Nickel Alloy and Cobalt Alloys

AMS 2248B Chemical Check Analysis Limits, Wrought Heat, and Corrosion-Resistant Steels and Alloys

2.3 *American Society for Quality Control Standard:*[7]

ANSI/ASQC C1-1968 Specification of General Requirements for a Quality Program

Significance and Use

3.1 The purpose of this specification is to characterize the material properties of currently available cobalt-chromium-molybdenum implant parts manufactured by processes other than conventional casting techniques.

Ordering Information

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

4.1.1 Quantity,

4.1.2 ASTM designation and date of issue,

4.1.3 Mechanical properties,

4.1.4 Form (semifinished parts, part No.),

4.1.5 Applicable dimensions or print number,

4.1.6 Condition (as hipped, forged, heat treated, annealed),

4.1.7 Special tests, and

4.1.8 Other requirements.

Condition

5.1 Finished or semifinished parts conforming to this specification may be prepared by a variety of methods including powder consolidation and forging; and may be in a heat-treated, hot-worked or annealed condition.

Chemical Requirements

6.1 The cobalt-chromium-molybdenum alloy supplied to the manufacturer for the production of surgical implants shall conform to the chemical composition limits specified in Table 1. The product analysis tolerances shall conform to the requirements in Table 2.

Mechanical Requirements

7.1 *Tensile Properties:*

TABLE 1 Chemical Requirements

	Composition, %	
	min	max
Chromium	26.0	30.0
Molybdenum	5	7
Nickel	—	1.0
Iron	—	0.75
Carbon	—	0.35
Silicon	—	1.0
Manganese	—	1.0
Nitrogen	—	0.25[A]
Cobalt[B]	balance	

[A] If N < 0.10, content does not have to be reported.

[B] Approximately equal to the difference between 100 % and the sum percentage of the other specified elements. The percentage of cobalt by difference is not required to be reported.

This specification is under the jurisdiction of ASTM Committee F-4 on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee F04.02 on Resources.

Current edition approved Sept. 25, 1987. Published November 1987. Originally published as F 799 – 82. Last previous edition F 799 – 82.

Supporting data are available on loan from ASTM Headquarters, 1916 Race Street, Philadelphia, PA 19103. Request Research Report RR: F04 - 0000.

[3] *Annual Book of ASTM Standards*, Vol 03.01.

[4] *Annual Book of ASTM Standards*, Vol 03.05.

[5] *Annual Book of ASTM Standards*, Vol 13.01.

[6] Available from Society of Automotive Engineers, 400 Commonwealth Drive, Warrendale, PA 15096.

[7] Available from American Society for Quality Control, 161 W. Wisconsin Avenue, Milwaukee, WI 53203.

TABLE 2 Product Analysis Tolerances[A]

Element	Permissible Variation Under the Minimum Limit or Over the Maximum Limit, %[B]
Chromium	±0.30
Molybdenum	±0.15
Nickel	0.05
Iron	0.03
Carbon	0.02
Silicon	0.05
Manganese	0.03
Nitrogen[C]	0.02

[A] Refer to AMS Standard 2269C for Chemical Check Analysis Limits (except nitrogen).
[B] For elements where only a maximum percentage is indicated, the "under minimum limit" is not applicable.
[C] Refer to AMS 2248B.

TABLE 3 Mechanical Requirements

Ultimate Tensile Strength, min, psi, (MPa)	Yield Strength (0.2 % offset), min, psi (MPa)	Elongation,[A] min, %	Reduction in Area, min, %	Hardness, R_c, min
170 000 (1172)	120 000 (827)	12	12	35

[A] Gage length = 4 × diameter.

7.1.1 Tensile properties shall be determined in accordance with Methods E 8.

7.1.2 The mechanical properties of test specimens prepared from finished or semifinished parts shall conform to the requirements in Table 3.

7.1.3 Tension specimens shall be produced from finished or semifinished parts or from material having the same process history as that which exists in the final surgical implant device. Tension specimens may have [illegible] on the reduced section and may be taken [illegible] parallel to the long axis of the finished [illegible].

7.1.4 A minimum of two test specimens [illegible] one specimen falls below the specified [illegible] or breaks outside the gage limits, two additional [illegible] shall be tested and both must pass.

7.2 *Hardness*—Finished or semifinished parts [illegible] to this specification shall have a minimum hardness of 35 HRC. The hardness determination [illegible] formed in accordance with Methods E 18.

8. Special Tests

8.1 Finished or semifinished parts [illegible] specification shall have a homogeneous microstructure with a grain size of ASTM No. 5 or finer [illegible] accordance with Methods E 112.

9. Certification

9.1 A certification shall be provided [illegible] that the material meets the requirements [illegible]

10. Quality Program Requirements

10.1 The alloy producer and any [illegible] tain a quality program such as, for example, ASQC C1-1968.

10.2 The manufacturer of surgical [illegible] devices shall be assured of the producer's conformance to the intent of ASQC C1 or other recognized programs.

APPENDIX

(Nonmandatory Information)

X1. RATIONALE

X1.1 The purpose for this standard is to characterize composition and properties to assure consistency in thermomechanically processed cobalt-chromium-molybdenum finished or semifinished parts used in the manufacturing of medical devices that receive no subsequent metallurgical processing.

X1.2 Material conforming to this specification has been evaluated for biocompatibility and corrosion resistance and has been found to be identical to material conforming to Specification F 75. Materials conforming to Specification F 75 have been used as a control in Practice F 981.

X1.3 Published data[8,9] indicate [illegible] fine-grained homogeneous metallurgical [illegible] from thermomechanical processing [illegible] respect to tensile strength and fatigue [illegible] material conforming to Specification [illegible] requirements include fine-grained [illegible] tensile strength.

X1.4 The maximum iron content [illegible] coincide with compositions that are [illegible]

[8] Bardos, D. I., "High Strength Co-Cr-Mo [illegible]," *Concepts of Internal Fixation of Fractures*, edited [illegible] New York, NY, 1980, p 111.
[9] Weinman, S., "Vitallium FHS Forged [illegible] *of Internal Fixation of Fractures*, p 118.

Ion implantation of cobalt-chromium prosthetic components to reduce polyethylene wear

by Piran Sioshansi, PhD
an *Orthopedics Today* essay

The wear of ultra-high molecular weight polyethylene (UHMWPE) is a significant problem affecting the longevity and performance of prosthetic total joints.

With improved designs for cemented and cementless applications and recent progress in improving short and long term fixation of implants, it is becoming increasingly important to resolve the problems associated with polyethylene wear. Polyethylene wear debris is believed to cause macrophage response and granulomas, and other complications that promote loosening or interfere with prosthetic joint performance and longevity.

Polyethylene is currently the only suitable material for total joint articular applications. It combines many desirable inherent properties such as low friction, good biostability, and good formability and machinability.

However, polyethylene wear and associated debris remain a major problem. Recent reports indicate polyethylene's linear wear rate is on the order of 200 microns per year in a typical hip prosthesis, amounting to 2 mm of wear in ten years of operation.

Attempts to find an adequate substitute material for polyethylene have not been totally successful, and no new material is expected to become available in the near future. Therefore, finding a scientific method to address the polyethylene wear issue and overcome the problem of polyethylene wear debris is of great importance in total joint replacement applications.

The results of a recent study at Spire Corporation indicate that the ion implantation process, a technology already well established for treatment of titanium alloy orthopedic implants, is extremely effective when applied to cobalt-chromium (Co-Cr) orthopedic bearing components in minimizing the wear of UHMWPE. Spire markets the ion implantation process under the tradename Ionguard.® Ion implantation of Co-Cr to reduce polyethylene wear is specifically designated Ionguard-II.™

Initial funding for this research was provided by the National Institutes of Health through a grant from the National Institute of Arthritis and Musculoskeletal and Skin Diseases, awarded to Spire in 1990. Extensive research efforts in this area have now been productive in identifying the optimal process parameters for minimizing wear of polyethylene.

ION IMPLANTATION TECHNOLOGY

In the ion implantation process, the surface of a Co-Cr orthopedic component is exposed to energetic ion beams in a vacuum chamber. An active ion species such as nitrogen impinges on the surface of the Co-Cr alloy, interacting with the material to beneficially alter the physical and chemical structure of the surface.

Changes in the physical structure are generally due to interaction of incoming energetic particles with the alloy's crystalline structure. The solid state structure of the surface is altered, resulting in smaller grains with a pseudo- amorphous structure. The chemical structure is altered by the interaction of the incoming nitrogen with the host chromium atoms, forming small hard phase chromium nitride precipitates. These physical and chemical changes in the Co-Cr surface produce a lower coefficient of friction and a harder, more homogeneous surface structure.

An inherent and extremely important feature of the ion implantation process is the resulting change in surface energy of the treated material. Ion implanted surfaces typically exhibit a higher surface energy, as demonstrated by water contact angle measurements. This is extremely desirable for improving tribological performance of lubricated materials in relative motion. It is generally believed that a hydrophilic material with a high surface energy improves the ability of the surface to hold a liquid film between metal/polymer contact during motion. Thus, the wear is drastically reduced.

Ion implantation is the high technology approach for altering the surface properties of materials without adversely affecting the desirable bulk properties. Ion implantation is performed at room temperature in a high vacuum, clean environment. The process does not alter surface finish or dimensional integrity of the part, thus, it is readily applicable to finished delicate medical components.

The technology's great attribute is its excellent reliability, reproducibility, and built-in quality control, virtually guaranteeing 100% yield for batch processing of orthopedic components. The technology has already an established history in the processing of titanium orthopedic implants, where the ability to eliminate metallic wear debris that may occur during articulation with UHMWPE. Wear of polyethylene, mass, per se, is not a

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primary goal for pursuing ion implantation with Co-Cr components is to reduce wear in the opposing UHMWPE surface.

THE EXPERIMENT

A carefully designed and executed research program has been completed for comparing the wear of polyethylene in contact with control and ion implanted cobalt-chromium surfaces, as well as zirconia ceramic.

Pins of Co-Cr and zirconia with identical geometries were prepared for testing in a pin-on-disk tribosystem. The experimental set-up consisted of 3.2 mm radius hemispherical-tipped pins in contact with 6.4 mm thick, 28.6 mm radius UHMWPE disks. The pins were circulated on the disks at 90 revolutions per minute, wearing a 9.5 mm radius track. All disks were gamma sterilized prior to testing. The surface finish of both types of pins was approximately 2 μin RMS and that of the disks was approximately 0.5 μm.

The load on the pins was 10 N, which produced an initial peak Hertzian contact stress of approximately 59 MPa. However, the Hertzian stress was estimated to decrease to 15 MPa after a short time, due to compression in the polyethylene. This value is below the yield strength of UHMWPE.

The pin-on-disk tests were run for 123,000, 370,000, and 1 million cycles in bovine blood serum at room temperature. The bovine serum was replaced on a daily basis for the longer runs by stopping the experiments, suctioning the liquid out and replacing it with fresh serum.

Several additional tests were performed to characterize the changes effected by ion implantation in the cobalt chromium alloy. Coefficient of friction between the pin and disk was monitored throughout the wear testing, and surface energy determinations were made via water contact angle measurements. Microhardness measurements were made on a Buehler Microhardness Tester under a load of 2 g.

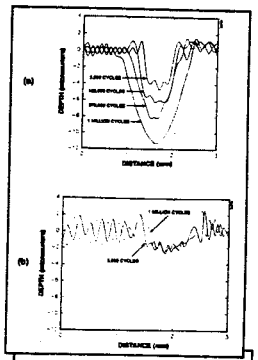

Fig. 1: Representative wear track profiles for UHMWPE in contact with control (a) and ion implanted Co-Cr (b) at 5,000, 123,000, 370,000, and 1 million cycles. Wear track profiles of disks opposite ion implanted pins at 123,000 and 370,000 cycles are omitted because they are essentially identical to those shown for 5,000 and 1 million cycles.

RESULTS

Wear results were obtained by disassembling the pin-on-disk couple and measuring the groove on the polyethylene disk. The volume of the groove was measured by a standard profilometer and was attributed to be a combination of cold flow (compression or creep) as well as wear. To separate the two factors, several experiments were run to only 5,000 cycles. Testing showed the groove at this point is due entirely to cold flow. All subsequent measurements, taken at periods of 123,000 cycles, 370,000 cycles and 1,000,000 cycles, were corrected for this cold flow measurement. That is, the difference in volume between the grooves measured in the longer tests and the grooves measured in the 5,000 cycle test is attributed to wear.

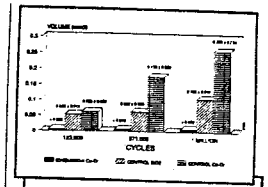

Fig. 2: Mean wear results of UHMWPE in contact with control Co-Cr, ion treated Co-Cr, and zirconia.

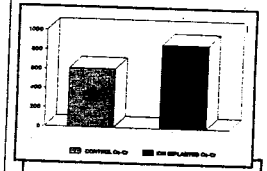

Fig. 3: Microhardness comparison of ion implanted and untreated Co-Cr. Measurements were taken with a Knoop hardness indenter at 2 g load.

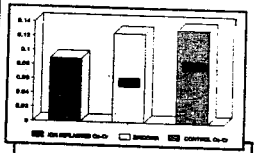

Fig. 4: Coefficient of friction values for ion implanted Co-Cr, control Co-Cr, and zirconia against UHMWPE in bovine serum.

Representative wear track profiles are shown in Figure 1 for each test length. The wear tracks for the control tests increase in size with test length. However, the wear tracks for the disks opposite the ion implanted

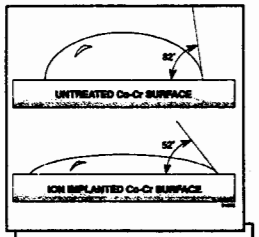

Fig. 5: Water contact angles of control (a) and ion treated Co-Cr (b) show increased surface energy induced by ion implantation.

Fig. 6: LFIT joint prostheses.

pins remain essentially constant. Here, a small groove, attributed entirely to compression, appears after 5,000 cycles, but as the test progresses the size of the groove does not increase, indicating that no appreciable polyethylene wear is occurring.

Mean corrected UHMWPE wear results are compared in Figure 2 for ion implanted and control cobalt-chromium. Results of the test conducted using the ceramic pin are also shown for comparison. These results show that the ion treatment of Co-Cr virtually eliminates wear in polyethylene, performing even better than the much more expensive ceramic parts.

Additional tests showed that ion implantation had several notable effects on the Co-Cr surface. Microhardness increased 42% at a 2 g load, from 611 to 867 (Fig. 3), and friction against UHMWPE decreased from 0.131 to 0.089 (Fig. 4). The water contact angle tests showed a substantial increase in surface energy. The contact angle changed from 82 to 52 with a lower angle indicating increased surface energy (Fig. 5).

DISCUSSION

Preliminary pin-on-disk results show that ion implantation significantly reduces the wear of the polyethylene in contact with cobalt-chromium components by approximately three orders of magnitude. Close examination shows the ion treated cobalt- chromium has a lower coefficient of friction, increased surface hardness, and much higher surface energy (hydrophilic), as measured by the water contact angle technique.

The increased wetability of the surface and lower coefficient of friction are significant factors in reducing UHMWPE wear. However, these properties cannot, by themselves, explain the negligibly small wear on the ion implanted Co-Cr surface measured in the current study. Zero wear can only be explained in the context of much higher surface energy induced on the Co-Cr components.

Increased surface energy improves the hydrophilicity of the surface and, thus, the ability of the surface to retain a liquid film. The liquid film, in turn, minimizes the contact between polyethylene and ion treated cobalt- chromium bearing surfaces, and thus limits the probability of asperity interlocking and plowing action on the UHMWPE that is responsible for creating wear debris.

CONCLUSIONS

Ion implantation of Co-Cr orthopedic joints appears to be effective for addressing the wear of ultra-high molecular weight polyethylene. Ion implantation increases surface wetability, reduces the coefficient of friction, and improves surface hardness on Co- Cr alloys.

Preliminary pin-on-disk experiments show that the wear of polyethylene in contact with ion treated Co-Cr components is negligibly small. The near zero polyethylene wear can be explained by the liquid film that ion treated cobalt-chromium surfaces can retain. Ion implantation increases the surface energy and, thus, the ability of cobalt chromium to retain a liquid film (bovine serum or synovial fluid), minimizing contact between polyethylene and cobalt-chromium surfaces.

Ion implantation technology offers great advantages as a reliable, reproducible process for treatment of sensitive orthopedic products.

PRODUCT AVAILABILITY

Spire Corporation has entered into an ion treatment production processing contract with Osteonics, a division of Stryker Corporation.

Under the terms of the contract, Osteonics has committed to treating an entire product line with the process. In return, Spire Corporation has offered Osteonics an exclusive arrangement for the duration of the contract. Ion implanted hip components have been in manufacturing since the beginning of May, and the product was launched on June 15, 1991. Ion implanted Co-Cr knee components (Fig. 6) are scheduled for availability in August.

Osteonics has named the ion treated cobalt-chromium hip and knees LFIT® (Low Friction Implant Treated).

Dr. Sioshansi is vice president, Surface Modification Division, Spire Corporation (Patriots Park, Bedford, MA 01730).

TMJ™ IMPLANTS INC.

June 2, 1992

Honorable Ted Weiss
Congress of the United States
House of Representatives
Human Resources and Intergovernmental
Relations Subcommittee
Rayburn House Office Building, Room B372
Washington, D.C. 20815-6148

Dear Congressman Weiss:

Thank you for your letter of May 28th. This letter provides an overview of the medical need for and use of the Fossa-Eminence and Condylar Prostheses currently manufactured and distributed by TMJ Implants, Inc. for the treatment of severe temporomandibular joint problems. These products were first introduced in the early 1960's and have been successfully used for over 30 years. The Fossa-Eminence Prosthesis is intended for replacement of the articular disc of the temporomandibular joint in cases of internal derangement, meniscal perforation, adhesions or ankylosis, and can be used individually or in conjunction with the Condylar Prosthesis. The Condylar Prosthesis is intended for use in conjunction with the Fossa-Eminence Prosthesis to form a total prosthesic temporomandibular joint where there is a loss of condylar height, loss of meniscus with fibrous adhesions, or bony ankylosis.

First, let me state that my background is that of a oral and maxillofacial surgeon who practiced from 1948-1988. For most of those years, much of my practice was devoted to surgery of the temporomandibular joint. I was an assistant clinical professor of surgery in the Department of Head and Neck Surgery at the Medical School of the University of California, Irvine, California, in the 1960's to 1970's. My ciricula vitae is provided as Attachment 1.

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Having performed scores of surgeries on the temporomandibular joints of patients, beginning in the early 1950's, I realized a more universal and dependable surgery was sorely needed. In 1960, I developed a method of plating the base of the skull with a highly polished metal fossa-eminence implant which would allow the disc and condyle to function smoothly against the nonchanging metal prosthesis.

In 1961, I placed my first Fossa-Eminence Prosthesis in the joint of a patient 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 31 years and is doing very well (See, Attachment 2). The year following my first surgery, she required a Fossa-Eminence Prosthesis in her opposite joint and it, too, has done well over all 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 Fossa-Eminence Prosthesis. Indeed, at that time I was able to re-examine the original Fossa-Eminence Prosthesis which appeared just as I had placed it over a quarter of a century earlier and continued to be fully functional. Both the original Fossa-Eminence and the subsequently implanted Condylar Prostheses have performed well together, relieving the patient's pain and disability.

Since 1961 over 3,000 patients from across the United States have been operated on and have received partial (Fossa-Eminence Prosthesis only) or total (Fossa-Eminence and Condylar Prostheses) joint replacement. Many of these were patients who had as many as 20 previous surgeries using other devices or alternative surgical procedures without success, and for whom the TMJ Implants, Inc. prostheses were able to provide relief.

Over 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 is now used successfully by several hundred surgeons and in several hundred hospitals across America. It is also used in numerous university teaching institutions. Patient and physician satisfaction of the products and clinical results have resulted in increased product demand.

(See, Attachment 3). 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 where a fracture of the Condylar Prosthesis required explantation. Subsequent investigation of the fractured condyle has led us to believe that the fracture was caused by the surgeon attempting to bend the implant prior to implantation, despite 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 surgical procedure itself. Except for these few incidents, I am aware of virtually no reported incidents of product failure or other occurrence which has in any way resulted in patient injury or other adverse consequences.

The usefulness of the Fossa-Eminence and Condylar Prostheses 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 (Attachment 4). A two year follow report of partial or total temporomandibular joint reconstruction on 57 cases concluded that joint reconstruction is 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 W. Christensen

Robert W. Christensen, D.D.S.
President

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

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

Report of a Case

Robert W. Christensen, D.D.S., Pasadena, Calif.

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.[1] Other factors which predispose the joint to ankylosis 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 maceration, 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 traction 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 plane of inclination which the condyle must travel. The resorptive phase may be followed by varying degrees of osteosclerosis of the articular surfaces.

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 fibro-osseous ankylosis develops, which will be followed by complete bony ankylosis.

Generally speaking, the fibrous or osseous ankylosis requires the same type of treatment with, perhaps, slight variations in technique. Surgical intervention is the only possible way of helping the patient with any type of ankylosis.[3]

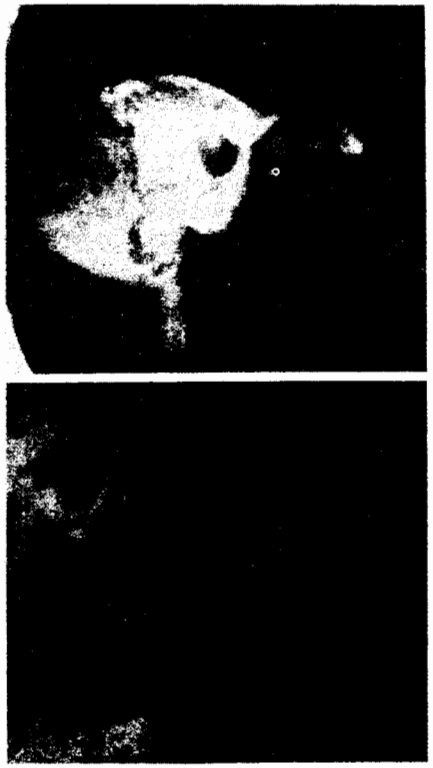

Fig. 2.

Fig. 1.—Laminagraph showing bone-to-bone contact through perforation of disc. Note erosion of cortical bone on posterior slope of articular eminence.

Fig. 2.—Roentgenogram of joint showing lipping of anterior rim of condyle and flattening of articular surfaces of condyle and articular eminence.

Over a period of many years, previous authors have advocated either no treatment or high condylectomy for fibrous ankylosis and osteoarthrotomy for osseous ankylosis.[3] A more uniform approach to both types of ankylosis would seem to be welcome. Every effort should be directed toward restoring a reasonably 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 fascia, 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.[4]

Ideally, 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 restore a lost condyle or to cover the condylar stump with a nonanatomic 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 pressures 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 glenoid fossa and articular eminence both radiographically and clinically, we should be able to cover this surface with a thin, anatomic cast-Vitallium prosthesis.

With this premise, I decided to make castings to cover the glenoid 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-Vitallium implant screws, which would be used for anchorage. The articular surface is highly polished, while other surfaces and margins are sandblasted. This thickness of Vitallium 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 photograph, to include the glenoid 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.

Osseous Ankylosis.—In cases of osseous 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 glenoid fossa and attempt to make it at the level of the articular eminence. In so doing, one can be sure not to perforate the cranial 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 some cases, when a large segment of bone has been removed the powerful elevator muscles have tended to close the bone gap, thus allowing a refusion to develop and at times permitting an open-bite to occur.

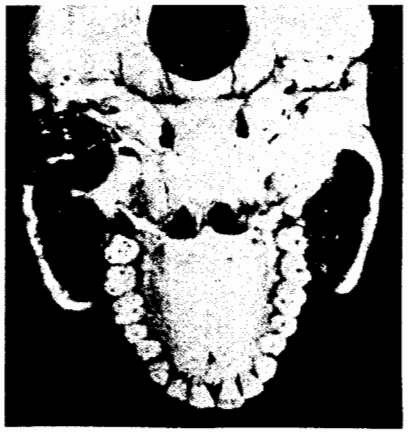

Fig. 3.

Fig. 4.

Fig. 3.—Inferior view of skull with joint prosthesis in place. (From Christensen, Robert W.: D. Radiog. & Photog. 37: 3, 1964, published by Eastman Kodak Company.)
Fig. 4.—Lateral view of skull showing condyle resting against joint prosthesis.

By using many skulls and filling the glenoid fossa with modeling compound or plasticene, one can make a pattern which will lie on the external surface 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 curvature of the osteotomy which will be most suitable. By making the final prosthesis like the previously mentioned glenoid fossa and articular eminence, but following the contour of the pattern, one can be sure that it will slide into place following the osteotomy. In this case, the condylar head can be left in the fossa and the prosthesis can be attached to it. This decreases the hazards attached to removal of the condyle. The thickness of the prosthesis can be from 0.014 to 0.022 inch, so that varying degrees of adaptability can be selected. For this purpose, these thicknesses give ample rigidity and act as a permanent barrier to a recurrence of the ankylosis of the joint. It is conceivable that tantalum, about 0.019 inch in thickness, could be fabricated at the time of surgery and would also be useful. I have preferred cast-Vitallium for its rigidness and also for the fact that the articular surface can be highly polished, thus giving it a smooth surface for the condyle to function against.

In all cases of ankylosis of one or both mandibular joints, it is wise to correct the disease surgically, since, over a period of time, a fibrosis may occur in the elevator muscles, thus causing an additional type of restriction which is difficult to relieve.

CASE REPORT

Sister L., a 35-year-old nun, was referred to my office on Dec. 5, 1960, for consultation regarding an intermittent, dull pain in the right mandibular joint, which had been present for 2 to 3 years. Pain to a lesser degree was noted in the left mandibular joint.

Past History.—The patient stated that when she was 7 years old she was struck in the left temporal area by the pedal of a bicycle. A scar was visible in the skin for many y[ears]

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 (1948) a surgeon she visited in another city performed a meniscectomy.

The patient stated that she had experienced joint pain, cracking, and periods of trismus prior to 1948 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 few 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 ankylosis.

This operation also was performed through a horizontal skin incision, and the mandible was immobilized by intermaxillary traction for 5 weeks postoperatively. The recovery again was uneventful, 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 to assist in closing an anterior open occlusion which had developed. The mandible became asymmetrical, and occlusal equilibration, followed by gold crown restoration on virtually all posterior teeth, was 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 very pleasant and calmly disposed, with a noticeable asymmetry of the face.

The left side of the mandible was elevated approximately ¾ inch above the right side. When the patient opened her mouth, the chin deviated to the left 12 mm. The vertical opening was less than ¾ inch. There was noticeable pain in the patient's facial expression as she attempted to open her jaws. The pain emanated more from the right mandibular joint area.

On palpation, the right condyle would move forward more than would have been expected with the degree of opening that the patient could accomplish. In contrast, the left joint could not be discerned during movements. There was tenderness over the right joint, and clicking was noted.

The intraoral examination showed marked attrition 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.

Roentgenographic Examination.—A centric profile roentgenogram disclosed a shortening of the condyle area on the left side, producing a ¾ inch variation between the right and left angles of the mandible.

Mandibular joint films showed a normal-appearing right joint (Fig. 5) with hypermobility of the right condyle, to the point of near dislocation when the mouth was opened ¾ inch.

The left joint showed severe degenerative changes. The condyle head was missing, and the neck of the condyle had an osteoarthritic contour with much lipping and spurring of its margins. Its position was opposite the crest of the articular eminence and showed fibro-osseous attachment to the poorly defined, flattened eminence (Fig. 6). There was no change in this position during open or closed occlusal position. The glenoid fossa was empty and appeared flattened, with areas of osteoporosis in its cortical margins.

A posteroanterior roentgenogram of the mandible showed an elevation of the left side of the mandible, which was due to the condylectomy and removal of molar teeth.

Treatment Plan.—From the history, clinical examination, and x-ray findings, it was apparent that the patient had a fibro-osseous ankylosis of the left joint as a result of the previous meniscectomy and condylectomy (Fig. 7). Because of the unilateral ankylosis, the patient's mandibular movements were accentuated in the right joint, causing a constant strain

Fig. 5.

Fig. 6.

Fig. 5.—Preoperative roentgenogram of patient's normal right mandibular joint.

Fig. 6.—Preoperative roentgenogram of patient's ankylosed left mandibular joint. (From Christensen, Robert W.: D. Radiog. & Photog. 37: 3, 1964, published by Eastman Kodak Company.)

on the capsule and ligaments, which was manifesting its state of overfunction by eliciting pain.

It was apparent that any attempt at restoring permanent pain-free function in the right mandibular joint would be useless unless normal function could be restored in the nonfunctioning left joint. Since the right joint appeared normal on roentgenographic exami

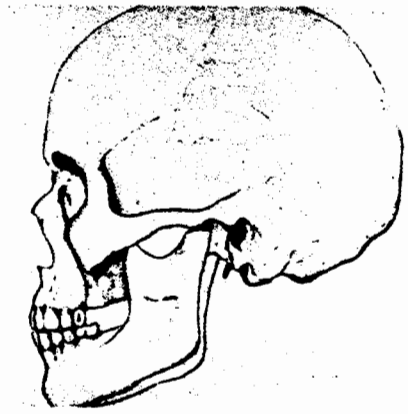

Fig. 7.

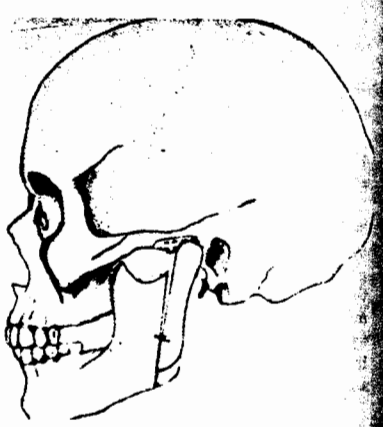

Fig. 8.

Fig. 7.—Drawing showing ankylosis of condyle neck to articular eminence. (From Christensen, Robert W.: D. Radiog. & Photog. 37: 3, 1964, published by Eastman Kodak Company.)

Fig. 8.—Drawing showing vertical osteotomy completed with condyle repositioned in glenoid fossa prosthesis. (From Christensen, Robert W.: D. Radiog. & Photog. 37: 3, 1964, published by Eastman Kodak Company.)

nation, no surgical intervention in this joint was advisable at this time. Restoration of function in the left joint would mean taking three major steps: (1) freeing of the ankylosis; (2) reconstruction of the condyle so that it would be in the glenoid fossa; and (3) creation of a metal barrier to prevent future fusion.

Restoration of the height and position of the condylar neck to its proper position could best be accomplished by means of a vertical osteotomy in the ramus of the mandible and repositioning of the proximal segment of bone so that its superior surface would be in the fossa and its inferior-anterior surface would rest against the cut surface of the ramus. The two segments of the ramus would be secured by a transosseous wire suture, and the mandible would be immobilized for 9 weeks. The fossa-articular eminence 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 taught school, it was decided that the surgical procedure should be postponed until summer vacation. Accordingly, on June 19, 1961, the patient was admitted to St. Luke Hospital, and the operation was performed on the following day.

The routine application of Winter arch fracture bars 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 previous 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 inch skin incision via the Risdon approach. The bone cut was made with a specially adapted bone saw (Christensen variation of the Joseph nasal saw)[5] and was directed parallel to the posterior surface of the ramus from the mandibular notch to just forward 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 sterile gauze dressing was placed over this wound, and the preauricular incision was made with a scalpel to facilitate the arthroplasty and freeing of the ankylosis. The skin incision ran vertically in the preauricular fold from the superior to the inferior attachment of the ear. A skin flap was elevated by sharp dissection and sutured forward with three silk sutures. The approach, to the level of the joint, was carried along the cartilage of the ear by sharp dissection. When the lateral rim of the glenoid fossa was exposed, we used sharp and blunt dissection to elevate the attachment of the capsule and masseter muscle until the posterior third of the zygoma and the lateral surface of the articular eminence was exposed.

The condyle stump was now fully exposed and found to be attached by very dense fibro-osseous tissue to the crest of the articular eminence. The glenoid fossa was filled with soft tissue which was reflected by blunt dissection with a periosteal elevator until the entire fossa was exposed.

The fibrous and partially bony attachment of the condyle neck to the eminence was severed by means of a scalpel and sharp chisel. When this had been dissected, the assisting surgeon used a Kelly forceps to grasp the inferior end of the proximal fragment, through the Risdon approach, and retracted this segment of bone inferiorly. This made it possible to free the condyle neck from the eminence and to totally expose the anterior, inferior, and posterior surfaces of the articular eminence and glenoid fossa, so that a suitable surface of bone would be available for the cast-Vitallium prosthesis.

At this point the various cast prostheses, twenty in number, were placed against the bone to check for accuracy of fit. One pattern fit all areas precisely and was now held in position while a hole was drilled for one of the 5 mm. cast-Vitallium implant screws. The hole was drilled slightly smaller in diameter than one of the screws, and the screw was inserted. This held the prosthesis in proper adaptation to all the surfaces of bone (Fig. 9). The second screw was then placed in a similar fashion.

The proximal segment of bone was now positioned so that the condylar surface was in the most posterior portion of the glenoid fossa of the prosthesis. The inferior margin of this segment of bone was now tilted forward to contact the posterior surface of the osteotomy of the ramus approximately 5/8 inch higher than the inferior margin of the mandible. Because the condyle was tilted posteriorly, there was a v-shaped space between the two fragments

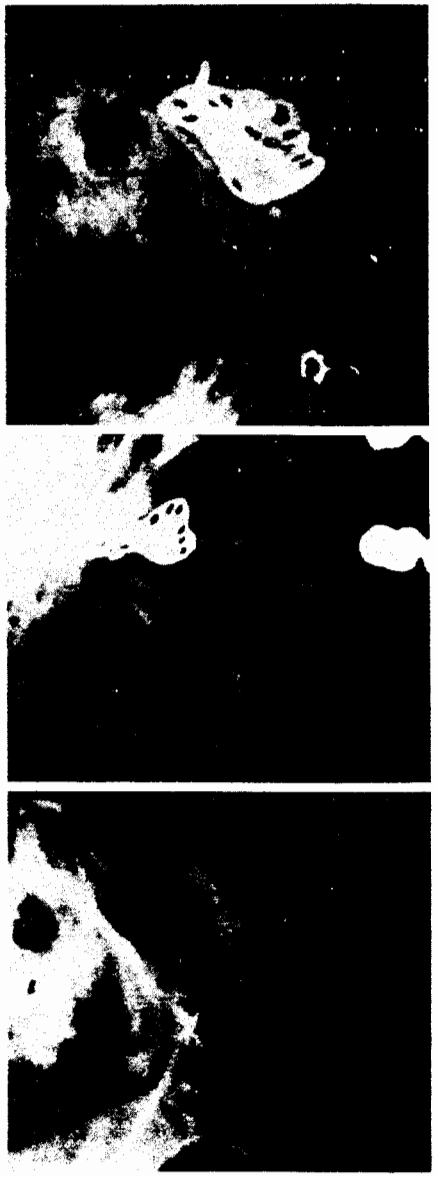

Fig. 9.—Roentgenogram of left mandibular joint with prosthesis in place. (From Christensen, Robert W.: D. Radiog. & Photog. 37: 3, 1964, published by Eastman Kodak Company.)

Fig. 10.—Roentgenogram of left ramus showing healed vertical osteotomy and transosseous wire in place. (From Christensen, Robert W.: D. Radiog. & Photog. 37: 3, 1964. published by Eastman Kodak Company.)

Fig. 11.—Roentgenogram of right mandibular joint, taken in May, 1962, showing [illegible] articular disc.

above the point of contact at the lower margin. A single transosseous steel wire was placed near the lower margin, where the two bones contacted each other (Fig. 10). This was found to immobilize the two fragments adequately, since the jaws were secured by intermaxillary traction.

The preauricular wound was now closed in layers; 3-0 catgut sutures were used on the deeper tissues and 5-0 Dermalon interrupted mattress sutures on the skin margins. The Risdon 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.

The patient's recovery was uneventful, and she was discharged on the fourth postoperative 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 9 weeks to allow the bone fragments to unite. At the end of that time the intermaxillary elastic and wire traction was removed. The patient was able to open the jaws ⅝ inch, and the occlusal splint was removed. One week later, under local anesthesia, the fracture arch bars and circumferential wire were removed.

Over the next few weeks the patient was able to open her jaws 1¼ inches. She could create left lateral excursions with ease and excursions to the right to a lesser degree.

The pain which she had noticed in the left mandibular joint subsided after the operation and has not returned. However, the pain in the right joint, which diminished for a few months, slowly increased to the point where further evaluation became necessary.

Pain and grating increased in the right mandibular joint until, in May, 1962, new roentgenograms were taken. These showed a much different picture than those taken in December, 1960. The right condyle head was 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 demineralization 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 its normal excursion. The subtotal return of function was probably due to the loss of the attachment, or function, of the external pterygoid muscle 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 forced open 1½ inches, severe pain in the right joint limited voluntary opening to less than 1 inch. It was decided that a cast-Vitallium glenoid

Fig. 12.

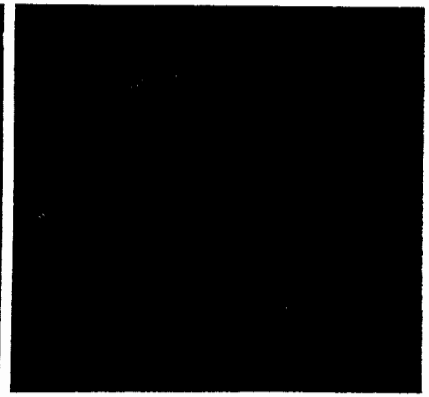

Fig. 13.

Fig. 12.—Centric profile roentgenogram of skull with jaw open and prosthesis in place.

Fig. 13.—Roentgenogram of right mandibular joint, in closed position, showing condyle in prosthesis.

Fig. 14.

Fig. 15.

Fig. 14.—Roentgenogram of right mandibular joint with jaw open 1 inch and condyle moved forward in prosthesis.

Fig. 15.—Posteroanterior roentgenogram of skull, showing position of right and left mandibular joint prostheses.

fossa prosthesis should be inserted in the right joint in an attempt to curtail the resorptive processes and to allow the right condyle to move free of pain.

The operation was performed at Huntington Memorial Hospital on Aug. 4, 1962. A few specific variations of technique and observations should be recorded briefly.

The operation was performed through a preauricular incision, and the upper joint space was exposed by careful dissection of the capsular attachments from bone. The erosion of the cortical surface which had been noted on the roentgenograms was now visualized clinically. Adjacent to this same area, the articular disc was seen to have an oval-shaped perforation. The articular surface of the condyle, as seen through the perforation, appeared normal. To facilitate exposure of the glenoid fossa and articular eminence, the capsule, disc, and condyle were retracted inferiorly with a special retractor. When the prosthesis was fully inserted, the mandible was moved with great ease, causing the condyle and disc to slide freely and smoothly over the highly polished surface of the prosthesis.

The patient's postoperative course was most interesting. On the first postoperative day she was able to open her jaws 1¼ inches and go into left lateral excursions with ease. There was no grating or limitation of function; nor was there joint pain. On the third postoperative day the patient was discharged from the hospital and was able to chew the hardest foods without pain. Less than one month after the surgical procedure the patient was able to open her jaws 1½ inches, and to date she is totally free of pain (Fig. 12).

Radiographs taken one month after the operation show the normal function of the right condyle against the glenoid fossa prosthesis (Figs. 13 and 14). The posteroanterior mandibular film shows the position of both the right and left joint prostheses in relation to skull and mandible (Fig. 15).

This patient is most grateful for the relief from pain and the restoration of mobility which this procedure has afforded her.

SUMMARY

This article describes a new technique for creating an anatomic, physiologic, prefabricated, well-tolerated mandibular joint prosthesis for the correction of early and late mandibular joint arthroses.

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 value to many persons suffering from various degrees of mandibular joint arthrosis.

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