

**SECTION IX**

**REGULATORY CONTROL OF RISKS**

## SECTION IX.

### REGULATORY CONTROL OF RISKS

Preceding sections of this petition have shown that total hip arthroplasty incorporating the use of a metal/metal articulation as part of a total hip system is equivalent to the class II, semi-constrained, metal/polymer total hip prosthesis. Neither it nor any other surgical procedure is free of complications, but this petition demonstrates that the risks to health have been identified and the controls to minimize those risks are in place. The risks inherent in the metal-on-metal hip replacement procedure are similar to those for total hip replacement surgery utilizing a class II device.

Complications can be distinguished between those related to surgery in general, and those that are specific to the device. Broken components requiring revision surgery would be considered a failure of the device. Loosening may involve device design, but it also depends on surgical technique, as well as uncontrollable patient factors. The complications specific to the metal-on-metal device are similar to those specific to class II hip joint replacement prostheses. Complications such as infection, pulmonary embolism, gastrointestinal and genitourinary problems are not generally device specific, but are risks associated with most major surgical procedures.

The primary difference between the metal-on-metal total hip prosthesis (class III) and the metal/polymer total hip prosthesis is the wear of articulating surfaces. The metal-on-metal articulating surfaces wear on both the metal ball and the acetabular cup, but at a much slower rate than metal/polymer articulating surfaces. The metal/polymer hip generally wears primarily in the polymer acetabular cup. The surfaces of the prosthetic components that are in apposition to bone (fixation surfaces) are the same in both the metal-on-metal and the metal/polymer devices. Moreover, the fixation methods to bone are the same for both devices.

Based upon the above considerations, this petition recommends that the approach to regulatory control of risks should be the same for a metal-on-metal hip prosthesis as for a metal/polymer hip prosthesis. Regulatory control of the device can be simple and straightforward. Device risks can be handled through material standards, with substantial equivalence determinations serving to control device design. Patient and surgical risks can be minimized through device labeling, and device quality through Good Manufacturing Practices (GMP) Quality System Regulation (QSR). FDA has authority through the 510(k) process, as well as its general authority over misbranding and adulteration, to impose controls along these lines. FDA guidance documents are available to provide specific guidance regarding materials, testing, and labeling. The risks defined by clinical experience are well suited to controls of these types, and this petition's specific recommendation of the appropriate controls follows in this section.

<b>RISKS AND CONTROLS FOR METAL ON METAL HIP ARTHROPLASTY</b>	
<b>Risks/Complications Identified in this Petition</b>	<b>Means to Control/Minimize risks</b>
<b>Loosening/Migration of Components</b>	510(k) Requirement – Sterility Adulteration Authority – GMP,QSR Sterility Misbranding Authority – Labeling Indications/contraindications/warnings/precautions
<b>Revision of Components Dislocation of the Hip prosthesis</b>	510(k) Requirement – Substantially Equivalent Design 510(k) Requirement – Laboratory Testing Wear/fatigue/liner torque-out/liner push-out/lever-out 510(k) Requirement – Conformance to Material Stds. Misbranding Authority – Labeling Indications/contraindications/warnings/precautions
<b>Implant Failure Fracture/Wear Osteolysis Sensitivity to Materials</b>	510(k) Requirement – Substantially Equivalent Design 510(k) Requirement – Conformance to Material Stds. 510(k) Requirement – Conformance to FDA guidance for acetabular & hip femoral components GMP/QSR – Design Controls/Quality Systems Misbranding Authority – Labeling Indications/contraindications/warnings/precautions
<b>Infection</b>	510(k) Requirement – Sterility Adulteration Authority – GMP/QSR Sterility Misbranding Authority – Labeling Indications/contraindications/warnings/precautions
<b>Nerve Impingement/ Damage Pain Vascular Disorders Pulmonary Embolism Gastrointestinal/Genito- urinary Complications</b>	Misbranding Authority – Labeling Warnings/precautions/potential adverse effects

Device related risks associated with metal on metal hips are similar to those reported in the reclassification petition for constrained hip prostheses, which the Panel recommended be classified into class II. Those risks, as these, are grouped into three major categories, as follows.

## **RISKS TO HEALTH IDENTIFIED BY THE PETITIONER**

(grouped into three major categories)

### **1. LOSS OR REDUCTION OF JOINT FUNCTION**

Loosening, Revision of Components, Implant Failure/Fracture/Wear/Dislocation

#### **Special Controls to Minimize Risks**

**ASTM Material Standards** - F67, F75, F136, F1377, F1580

**ASTM Test Methods** – F1044, F1147, F1612, F1714, F1814, F1820, F1875,  
F1978

#### **FDA Guidance Documents**

Guidance Document for Testing Orthopedic Implants with Modified Metallic Surfaces Apposing Bone or Bone Cement. (Facts-on-Demand #827)

Guidance Document for Femoral Stem Prostheses (Facts-on-Demand #187)

Guidance Document for Testing Acetabular Cup Prostheses (Facts-on-Demand #453)

Guidance Document for Testing Non-Articulating, “Mechanically Locked” Modular Implant Components (Facts-on-Demand #916)

Draft Guidance Document for the Preparation of Premarket Notification 510(k) Applications for Orthopedic Devices – The Basic Elements (Facts-on-Demand #832)

Guidance for Industry on the Testing of Metallic Plasma Sprayed Coatings on Orthopedic Implants to Support Reconsideration of Postmarket Surveillance Requirements (Facts-on-Demand #946)

### **2. ADVERSE TISSUE REACTION**

Osteolysis, Sensitivity to Metal Implants

#### **Special Controls to Minimize Risks**

**ASTM Material Standards** - F67, F75, F136, F1377, F1580

#### **FDA Guidance Documents**

Use of International Standard ISO-10993, Biological Evaluation of Medical Devices Part I: Evaluation and Testing

### **3. INFECTION**

#### **Special Controls to Minimize Risk**

510(k) Sterility Review Guidance

#### **Additional Risks**

Nerve Impingement/Damage, Pain, Vascular Disorders, Pulmonary Embolism,  
Gastrointestinal/Genitourinary Complications

These additional identified risks are associated with orthopedic surgery in general, and are not unique to constrained hip surgery.

### **LIST OF SPECIAL CONTROLS**

Following is a listing of special controls available to minimize the risks to health identified by the petitioner and confirmed by a previous panel. These special controls are in addition to the general controls applicable to all orthopedic implants. These special controls include 18 ASTM standards for materials and test methods, and 8 FDA Guidance Documents. In addition, the FDA may require certain mechanical testing as part of a 510(k) premarket notification. These tests could include wear testing of the articulating surfaces as described in this petition.

The ASTM standards define implant material specifications and testing methods applicable to the metal-on-metal hip prosthesis. Adherence to these standards and comparison of the results from these standard tests can control the risks to health of adverse tissue reaction, pain and/or loss of function, and revision by having the manufacturer use surgical implant quality materials, prudent design assurance and good manufacturing practices.

The ASTM standards are FDA recognized consensus standards. ASTM standards may be obtained from ASTM Customer Services, 100 Barr Harbor Dr., West Conshohocken, PA 19428 (Telephone 610-832-9585). ASTM has a site on the World Wide Web at <http://www.astm.org/>.

#### **ASTM Standards**

1. ***ASTM F67-95 Standard Specification for Unalloyed Titanium for Surgical Implant Applications.*** This specification covers the chemical, mechanical, and metallurgical requirements for four grades of unalloyed titanium used for the manufacture of surgical implants.
2. ***ASTM F75-98 Standard Specification for Cobalt-28 Chromium-6 Molybdenum Casting Alloy and Cast Products for Surgical Implants (UNS R30075).*** This specification covers the requirements for Cast cobalt-chromium molybdenum alloy, shot, bar, or ingot for surgical implant applications.
3. ***ASTM F86-91 Standard Practice for Surface Preparation and Marking of Metallic***

### ***Surgical Implants***

4. ***ASTM F136-98 Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy (R56401) for Surgical Implant Applications.*** This specification covers the chemical, mechanical, and metallurgical requirements for wrought annealed Titanium-6 Aluminum-4 Vanadium ELI (extra low interstitial alloy (R56401) to be used in the manufacture of surgical implants.
5. ***ASTM F648-98 Standard Specification for Ultra-High-Molecular-Weight Polyethylene Powder and Fabricated Form for Surgical Implants.*** This specification covers ultra-high-molecular-weight polyethylene powder (UHMWPE) intended for use in surgical implants.
6. ***ASTM F983-86 Standard Practice for Permanent Marking of Orthopaedic Implant Components.*** The purpose of this standard is to (1) recommend that orthopedic implants be permanently marked, and (2) recommend practical amounts of information that should be included in the marking.
7. ***ASTM F1044-99 Standard Test Method for Shear Testing of Calcium Phosphate and Metal Coatings.*** This test method covers "lap shear" testing of porous and non-porous coatings adhering to dense metal substrates.
8. ***ASTM F1147-99 Standard Test Method for Tension Testing of Calcium Phosphate Porous Metal Coatings.*** This test method covers tension testing of porous and nonporous metal coatings adhering to dense metal substrates at ambient temperatures and determination of the degree of adhesion of coatings to substrates, or the internal cohesion of a coating in tension normal to the surface plane.
9. ***ASTM F1377-98a Standard Specification for Cobalt-28 Chromium-6 Molybdenum Powder for Coating of Orthopedic Implants (UNS-R30075).*** This specification covers requirements for cobalt-chromium-molybdenum alloy powders for use in fabricating coatings on cobalt-chromium-molybdenum alloy orthopedic implants.
10. ***ASTM F1472-99 Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium Alloy for Surgical Implant Applications (UNS R56400).***
11. ***ASTM F1612-95 Standard Practice for Cyclic Fatigue Testing of Metallic Stemmed Hip Arthroplasty Femoral Components with Torsion.*** This practice covers a method for the fatigue testing for evaluation in comparisons of various designs and materials used for stemmed femoral components.
12. ***ASTM F1636-95e1 Standard Specification for Bores and Cones for Modular Femoral Heads.*** This specification covers the functional dimensions and tolerances for tapered cones of proximal femoral stems and the bores of mating ceramic and metal heads.
13. ***ASTM F1714-96 Standard Guide for Gravimetric Wear Assessment of Prosthetic Hip-Designs in Simulator Devices.*** This guide describes a laboratory method using weight-loss technique for evaluating the wear properties of materials or devices, or both, which are being considered for use as bearing surfaces of human-hip-joint replacement prostheses. The hip prostheses are evaluated in a device intended to simulate the tribological conditions encountered in the human hip joint, for example, use of a fluid such as bovine serum, or equivalent pseudosynovial fluid shown to simulate wear mechanisms and debris generation as found in vivo, and test frequencies of 1 Hz or less.

14. ***ASTM F1814-97a Standard Guide for Evaluating Modular Hip and Knee Joint Components.*** This guide covers a procedure to assist the developer of a modular joint replacement implant in the choice of appropriate tests and evaluations to determine device safety.
15. ***ASTM F1820-97 Standard Test Method for Determining the Axial Disassembly force of a Modular Acetabular Device.*** This test method covers a standard methodology by which to measure the attachment strength between the modular acetabular shell and liner. Although the methodology described does not replicate physiological loading conditions, it has been described as means of comparing integrity of various locking mechanisms.
16. ***ASTM F1875-98 Standard Practice for Fretting Corrosion Testing of Modular Implant Interfaces: Hip Femoral Head-Bore and Cone Taper Interface.*** This practice describes the testing, analytical, and characterization methods for evaluating the mechanical stability of the bore and cone interface of the head and stem junction of modular hip implants subjected to cyclic loading by measurements of fretting corrosion.
17. ***ASTM F1978-99 Standard Test Method for Measuring Abrasion Resistance of Metallic Thermal Spray Coatings by Using the Taber™ Abraser.*** This test method quantifies the abrasion resistance of metallic coatings produced by thermal spray processes on flat metallic surfaces. It is intended as a means of characterizing coatings used on surgical implants.
18. ***ASTM F1978-99 Standard Test Method for Measuring Abrasion Resistance of Metallic Thermal Spray Coatings by Using the Taber™ Abraser.*** This test method quantifies the abrasion resistance of metallic coatings produced by thermal spray processes on flat metallic surfaces. It is intended as a means of characterizing coatings used on surgical implants.

#### **FDA Guidance Documents**

1. Guidance Document for Testing Orthopedic Implants with Modified Metallic Surfaces Apposing Bone or Bone Cement. (Facts-on-Demand #827)
2. Guidance Document for Femoral Stem Prostheses (Facts-on-Demand #187)
3. Guidance Document for Testing Acetabular Cup Prostheses (Facts-on-Demand #453)
4. Guidance Document for Testing Non-Articulating, "Mechanically Locked" Modular Implant Components (Facts-on-Demand #916)
5. Draft Guidance Document for the Preparation of Premarket Notification 510(k) Applications for Orthopedic Devices – The Basic Elements (Facts-on-Demand #832)
6. Guidance for Industry on the Testing of Metallic Plasma Sprayed Coatings on Orthopedic Implants to Support Reconsideration of Postmarket Surveillance Requirements (Facts-on-Demand #946)
7. Use of International Standard ISO-10993, Biological Evaluation of Medical Devices Part I: Evaluation and Testing (Facts-on-Demand #361)
8. 510(k) Sterility Review Guidance...and Revisions of 11/18/94 and ORDB 7/3/97 (K90-1) (Facts-on-Demand #361)

FDA guidance documents provide guidance on how to meet general orthopedic device premarket notification (510(k)) requirements, including biocompatibility testing, sterility testing, mechanical testing, and physician and patient labeling. Use of the preclinical section of the FDA guidance documents can control the risks to health of adverse tissue

reaction, infection, pain, and/or loss of function, and revision by having manufacturers use surgical quality implant materials, adequately test and sterilize their devices, and provide adequate directions for use, including recommended surgical techniques and patient information.

Guidance documents can be received via fax machine by telephoning the Center for Devices and Radiological Health's (CDRH) CDRH Facts-on-Demand system at 800-399-0381, or 301-827-0111 from a touch tone telephone. At the first voice prompt, press 1 to access the Division of Small Manufacturers Assistance FAX, at the second voice prompt, press 2, and then enter the document number followed by the pound sign (#). Then follow the remaining voice prompts to complete the request. The guidance documents are also available from CDRH World Wide Web address at <http://www.fda.gov/cdrh>.

## **LABELING**

The following indications for use, relative contraindications, warnings, and precautions were identified by a previous panel for the devices to be reclassified.

### **Indications For Use**

The metal on metal total hip replacement prosthesis is indicated for use in patients requiring hip replacement due to the following conditions:

- a) Non-inflammatory, degenerative joint disease including avascular necrosis, diastrophic variant, fracture of the pelvis, fused hip, Legg-Calve-Perthes disease, osteoarthritis, slipped capital epiphysis, subcapital fractures, and traumatic arthritis.
- b) Rheumatoid arthritis
- c) Correction of functional deformity
- d) Treatment of non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques.
- e) Failed previous surgery including: Joint reconstruction, internal fixation, arthrodesis, surface replacement arthroplasty, hemi-arthroplasty or previous total hip replacement.

### **Relative Contraindications**

1. Bone or musculature compromised by disease, infection, or prior implantation that cannot provide adequate support or fixation for the prosthesis.

2. Any active or suspected infection in or about the hip
3. Skeletal immaturity

#### Warnings

1. Patients should be warned on the impact of excessive loading that can result if the patient is involved in an occupation or activity that includes substantial walking, running, lifting, or excessive muscle loading due to patient weight causing extreme demands on the hip that can result in the failure of the device. Extreme demands on the device may also cause loosening of the prosthetic components.
2. Bending, contouring, or modifying the device may adversely affect the implant potentially leading to early implant failure.
3. Do not combine components from different manufacturers. This may lead to premature wear or failure of the device.

#### Potential Adverse Effects

1. Infection
2. Pain
3. Loosening, wear, or mechanical failure of prosthetic components
4. Dislocation of the hip prosthesis requiring additional surgery
5. Localized progressive bone resorption (osteolysis)
6. Nerve impingement or damage, vascular disorders (including thrombus)
7. Heterotopic bone formation
8. Sensitivity to implant materials
9. Gastrointestinal and/or genitourinary complications
10. Pulmonary embolism
11. Death
12. Myocardial infarction

## **SUGGESTED LABELING FORMAT FOR TOTAL HIP REPLACEMENT PROSTHESIS**

### **INFORMATION FOR PRESCRIBERS**

#### **DEVICE DESCRIPTION**

The metal/metal total hip replacement prosthesis is intended for use as a permanent replacement of the hip joint to restore hip function in patients suffering from certain pathologies of their hip joint. (See **INDICATIONS FOR USE** section)

<insert compatible cup shells and liners>

<insert compatible femoral head sizes/neck lengths>

Material: <insert applicable ASTM standard for metal>

<insert a description of the components and how they function>

#### **INDICATIONS FOR USE**

The metal/metal total hip prosthesis is intended for the replacement of the severely painful and/or disabled hip joint resulting from inflammatory arthritis, noninflammatory degenerative joint disease, acute traumatic fracture of the femoral head or neck, traumatic arthritis, diastrophic variant and failed previous surgery including: Joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthroplasty, or previous total hip replacement.

#### **CONTRAINDICATIONS, WARNINGS, PRECAUTIONS, and POTENTIAL ADVERSE EFFECTS**

##### **CONTRAINDICATIONS**

###### **Absolute Contraindications Include:**

1. overt infection;
2. distant foci of infections (which may cause hematogenous spread to the implant site);
3. rapid disease progression as manifested by joint destruction or bone absorption apparent on roentgenogram;
4. skeletally immature patients;
5. cases where there is inadequate neuromuscular status (e.g., prior paralysis, fusion and/or inadequate abductor strength), poor bone stock, poor skin coverage around hip joint which would make the procedure unjustifiable;

**Conditions presenting increased risk of failure include:**

1. uncooperative patient or patient with neurologic disorders, incapable of following instructions;
2. marked bone loss or severe osteoporosis;
3. metabolic disorders which may impair bone formation;
4. osteomalacia; and
5. poor prognosis for good wound healing (e.g., decubitus ulcer, end-stage diabetes, severe protein deficiency and/or malnutrition).

**Warnings**

1. Use of the metal/metal total hip prosthesis is a technically demanding surgical procedure. Familiarity with and attention to the surgical technique utilized with this device is imperative for optimal results.
2. It is essential to obtain correct vertical alignment and version alignment and of the device components. Incorrect alignment may result in suboptimal contact between the femoral head and acetabular prosthesis articulating surfaces resulting in the potential for increased wear.
3. The success of the hip joint reconstruction is heavily dependent upon the conformity of the articulating surfaces of the femoral and acetabular components, therefore it is imperative that the acetabular components not be interchanged between manufacturers.
4. Patients should be warned on the impact of excessive loading that can result if the patient is involved in an occupation or activity that includes substantial walking, running, lifting, or excessive muscle loading due patient weight causing extreme demands on the prosthesis that can result in its failure.
5. Bending, contouring, or modifying the device may adversely affect the implant potentially leading to early implant failure.

Proper surgical procedures and techniques are the responsibility of the medical professional. Each surgeon must evaluate the appropriateness of the procedure used based on personal medical training and experience. A detailed surgical technique is available for surgeon reference. Medical procedures for optimal utilization of the prosthesis should be determined by the physician. However, the physician is advised that there is recent evidence that the potential for deep sepsis following total hip arthroplasty may be reduced by:

1. Consistent use of prophylactic antibiotics.
2. Utilizing a laminar flow clean air system.
3. Having all operating room personnel, including observers, properly attired.
4. Protecting instruments from airborne contamination.

## 5. Impermeable draping.

**Metal Components.** Some of the alloys used to produce orthopedic prostheses may contain some elements that may be carcinogenic in tissue cultures or intact organisms. Questions have been raised in the scientific literature as to whether or not these alloys may be carcinogenic to actual prosthetic recipients. Studies conducted to date to evaluate these questions have not produced convincing evidence of such phenomenon.

**Cemented Application.** Care is to be taken to assure complete support of all parts of the device imbedded in bone cement to prevent stress concentrations which may lead to failure of the procedure. Complete cleaning prior to closure (complete removal of bone chips, bone cement fragments, and metallic debris) of the implant site is critical to prevent accelerated wear of the articular surfaces of the implant.

## PRECAUTIONS

1. Careful selection of components and familiarity with all aspects of the surgical technique are important to the success of the surgery.
2. An implant should be handled carefully to avoid damage that could compromise the mechanical integrity of the device and cause failure of the implant.
3. Inspect implants for nicks, scratches, or other defects that may cause failure of the implant.
4. To prevent contamination of the prosthesis, keep free of lint and powders. Do not open the package until surgery. Do not place the implant in contact with prepared bone surfaces before the final decision to implant has been made.
5. An implant should never be reused. Any implant once assembled and disassembled should be discarded. Even though it appears undamaged, it may have small defects and internal stress patterns that may lead to failure.
6. The wear rate of prosthetic surfaces is greatly accelerated if loose fragments of bone cement become detached and act as an abrasive in the bearing surfaces. When using bone cement, care should be taken to remove all excess from the periphery of the implant.

## POTENTIAL ADVERSE EFFECTS

1. Early and/or long term increased serum, urine, and tissue levels of metal ions.
2. Inadequate or lack of physiological lubrication of the prosthesis articulating surfaces.
3. Infection

4. Pain
5. Loosening, wear, or mechanical failure of prosthetic components
6. Dislocation of the hip prosthesis requiring additional surgery
7. Localized progressive bone resorption (osteolysis)
8. Nerve impingement or damage, vascular disorders (including thrombus)
9. Heterotopic bone formation
10. Sensitivity to implant materials
11. Gastrointestinal and/or genitourinary complications
12. Pulmonary embolism
13. Death
14. Myocardial infarction

**Important Physician Information.**

Bone resorption is a natural consequence of total joint arthroplasty due to changes in bone remodeling patterns. Bone remodeling is mediated by the changes in stress distribution caused by implantation. Extensive resorption around the prosthesis may lead to implant loosening and failure. It is generally agreed that osteolysis is the result of localized foreign-body reaction to particulate debris generated by cement, metal, and ultra-high molecular-weight polyethylene (UHMWPE). Regarding the etiology, it has been hypothesized that particulate debris generated by the components of a prosthesis migrate into the synovial cavity and the bone-implant interface, where they recruit macrophages and stimulate phagocytic action. The degree of recruitment is determined by the size, distribution, and amount of particulate debris (rate of debris generation). The phagocytic action results in the release of cytokines and intercellular mediators (IL-1, 2, PE2) which encourage osteoclastic bone resorption. Clinical and basic research is continuing in order to provide scientific basis for the causes of this phenomenon and potential ways to reduce its occurrence.

Osteolysis can be asymptomatic and therefore routine periodic radiographic examination is vital to prevent any serious future complication. Presence of focal lesions which are progressive may necessitate replacement of the prosthetic component(s).

**ANALYSIS OF PERTINENT CLINICAL STUDIES**

<insert bibliography>

## **PATIENT COUNSELING INFORMATION**

In addition to the patient related information contained in the Warnings and Potential Adverse Effects sections, the following information should be conveyed to the patient.

1. Joint prostheses will not restore function to the level expected with a normal healthy joint, and the patient should be instructed as to the limitations of the device.
2. Wear of the components can occur and potentially lead to future complications, including bone resorption and loosening, necessitating the removal and replacement of the prosthetic components.
3. The patient should be advised that the expected life of the joint replacement components is difficult to estimate, and that many factors may contribute to the longevity of the prosthesis. The patient can expect a restoration of mobility and reduction of pain, however device components cannot be expected to indefinitely withstand the activity level and loads of normal healthy bone.
4. Adverse effects may necessitate reoperation, revision, or fusion of the involved joint.

### **Products are Supplied Sterile**

<insert sterilization method>

Do not resterilize. Do not use any component from an opened or damaged package.

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

**FOLLOWING ARE TEST AND TEST METHODS  
RECOMMENDED FOR USE  
TO ESTABLISH SUBSTANTIAL EQUIVALANCE**

Following are specific tests that may be requested by the FDA to establish substantial equivalence in premarket notifications under Section 510(k). These are the specific tests recommended from the list of special controls that are important to establish substantial equivalence to the metal-on-metal hip devices to be reclassified by this petition. Of course, the FDA has the authority to specify other tests as deemed necessary by the Agency on a case by case basis. Copies of the applicable standards and publications describing these tests are provided at the end of this section.

## 1. KINEMATICS

The range of motion of the ball-acetabular cup combination should be evaluated and reported.

## 2. PUSH-OUT AND LEVER-OUT TESTING

The purpose of this testing is to evaluate the locking integrity of the metal/metal shell system. Push-out and lever-out integrity of the lock detail is considered to be important for *in vivo* longevity of an acetabular system.

Applicable documents include:

Tradonsky, S., Postak, P.D., Froimson, A.I. and Greenwald, A.S., A comparison of the disassociation strength of modular acetabular components. *Clinical Orthopaedics and Related Research*, 296: 14-160 (1993)

## 3. CYCLIC WEAR, DEGRADATION, AND CORROSION

Specimens should be cyclically loaded on a joint simulator or other appropriate instrumentation. This testing may be performed in accordance with ASTM F1714-96 Standard Guide for Gravimetric Wear Assessment of Prosthetic Hip Designs in Simulator Devices, and in accordance to the FDA Guidance Document for Testing Acetabular Cup Prostheses.

## 4. HIP SIMULATOR TESTS

Metal-on-metal hip bearings should be subjected to hip simulator wear tests in order to evaluate their wear performance in a more physiologically realistic scenario. Of additional value would be comparative wear assessments of candidate materials against similarly-classified and 510(k)-cleared implants for which similar hip simulator data have been generated. Commercially-available hip wear simulators are viable tools for evaluating wear performance because they have been shown to reliably produce the same wear rates and wear particle morphology for both standard metal-on-polyethylene and metal-on-metal bearings. Although there is currently no formal (ASTM or ISO) standard for the wear assessment of bearings for prosthetic hip designs using simulator devices, a substantial amount of relevant and published simulator data have been generated for modern metal-on-metal hip bearings by multiple institutions (academic and industrial) using similar methods.<sup>83,89,90,100,107,115,122,129,130,133</sup>

Applicable documents include:

Chan, Frank, W., J. Dennis Bobyn, John B. Medley, Jan Krygier and Michael Tanzier, Wear and Lubrication of Metal-on-Metal Hip Implants. *Clinical Orthopaedics and Related Research*, 369: 10-24, Dec. 1999.

## **5. OTHER TESTS**

**The FDA may require other tests to establish substantial equivalence deemed necessary by the Agency on a case by case basis.**

## A Comparison of the Disassociation Strength of Modular Acetabular Components

STEVEN TRADONSKY, M.D., PAUL D. POSTAK, B.Sc., AVRUM I. FROIMSON, M.D.,  
AND A. SETH GREENWALD, D. PHIL.(OXON.)

Five short-term *in vivo* disassembly of two-piece acetabular cup designs have been reported. This study evaluates the liner retention strengths of eight contemporary cup systems. Both push-out ( $663 \pm 65.5$  pounds force to  $29 \pm 1.4$  pounds force) and lever-out ( $684 \pm 114$  inch-pounds to  $43 \pm 1.5$  inch-pounds) test modes show a wide variation in retention strength. Repeat liner separation testing demonstrates a 26% and 32% respective decrease in locking mechanism integrity. These findings indicate that reseating modular liners at the time of surgery or reassembling a previously separated liner should be avoided.

Two-piece acetabular components have gained a wide degree of clinical popularity in total hip arthroplasties (THAs) and have been advocated for cementless and hybrid applications. Their advantages include an ability to maximize stability between the cup and pelvic bony bed, through the adjunctive use of screw fixation. The enhanced stability provided by these constructs serves to facilitate biologic fixation. Additionally, metal backing has been shown to improve stress distribution in the pelvic bed when used in conjunction with cement.<sup>3,9</sup> Secondly, modular polyethylene liners offer variable

head coverage as well as the potential for replacement in situations of clinical difficulty or material failure.

These modular constructs are not without short-term problems. There are numerous case reports in the literature as well as manufacturer citations to the FDA Medical Devices Register, documenting the early *in vivo* disassembly of modular acetabular components.<sup>1,2,4-6,10-12</sup> These cases are typified by the following one-year retrieval from The Mt. Sinai Medical Center, Cleveland, Ohio. The initial postoperative (Fig. 1A) and ten-month radiographs (Fig. 1B) of a 50-year-old woman who experienced left hip pain four months after THA for degenerative joint disease are shown. At revision, liner separation was confirmed. The retrieved components demonstrated polyethylene fracture, and significant galling of the cup interface attributed to six months of continued ambulation after the onset of hip pain (Fig. 2). Similar problems have led to the recall of one system<sup>7</sup> and a more careful scrutiny of two-piece cup performance.

This study investigates the disassociation strength of eight contemporary two-piece acetabular systems and addresses the practice of liner reinsertion after cup-liner separation.

### MATERIALS AND METHODS

Eight contemporary two-piece acetabular cup designs were evaluated in a controlled laboratory investigation at The Mt. Sinai Medical Center, Cleveland, Ohio. These systems included the Dur-

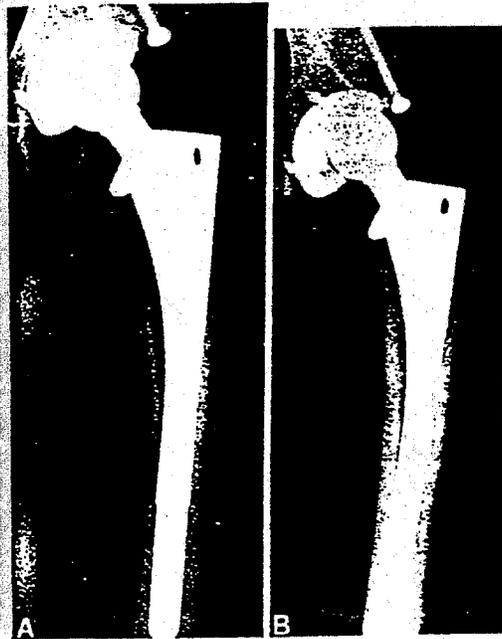
From the Department of Orthopaedic Surgery and the Orthopaedic Research Laboratory, The Mt. Sinai Center, Cleveland, Ohio.

Reprint requests to A. Seth Greenwald, D. Phil. (Oxon), The Orthopaedic Research Laboratory, The Mt. Sinai Medical Center, One Mt. Sinai Dr., Cleveland, OH 44106.

Received: August 4, 1992.

Revised: November 13, 1992.

Accepted: March 25, 1993.



FIGS. 1A AND 1B. (A) The initial postoperative and (B) ten-month radiographs of a 50-year-old woman who experienced left hip pain four months after THA for degenerative joint disease are shown. Liner separation is suggested from the proximal-lateral apposition of the head and cup surfaces.

aloc (DePuy, Warsaw, Indiana), Triloc (DePuy, Warsaw, Indiana), Omnifit (Osteonics Corp., Allendale, New Jersey), S-ROM (Joint Medical Products Corp., Stamford, Connecticut), PCA (Howmedica, Inc., Rutherford, New Jersey), Optifix

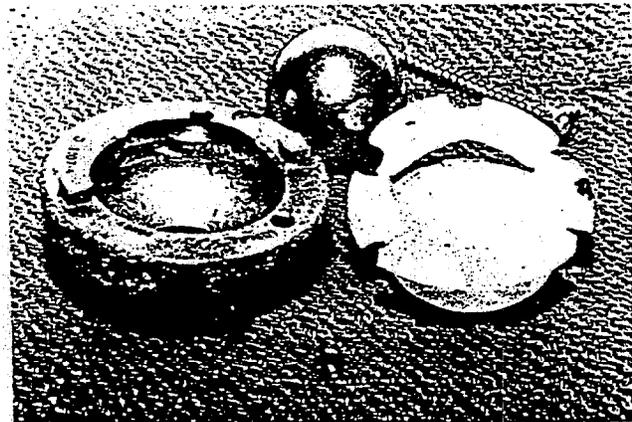
(Richards, Memphis, Tennessee), APR (Intermedics Orthopedics, Austin, Texas), and HGP II (Zimmer, Inc., Warsaw, Indiana). Two tests designed to measure the integrity of the locking mechanism were performed on each system. These tests consisted of polyethylene liner separation by push out and lever out. Three components from each system were evaluated for each test mode.

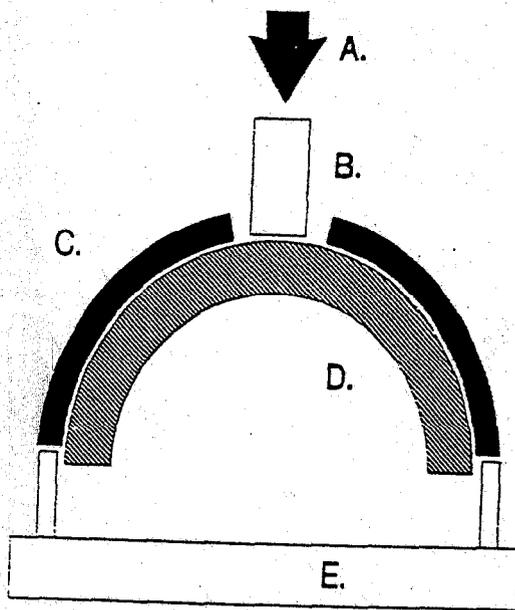
All tests were performed using a customized apparatus mounted on an Instron Testing Machine (Model 1115, Instron Corp., Canton, Massachusetts). Cups and liners were of implantable quality and equivalent size, (~52 mm cup outer diameter and 32 mm liner inner diameter).

A diagrammatic representation of the push-out test apparatus is shown in Figure 3. Once the liner was fully seated, a 0.25-inch diameter metal pin was advanced through the apical hole of the metal cup. A loading rate of 0.2 inches per minute was employed to fully dislodge the liner from the cup.

The lever-out test was designed to model the potential physiologic loading conditions present in the extremes of hip flexion and extension as well as situations of variable head coverage. *In vivo*, the kinematics of these disassociations are assumed to be a rotation of the liner about some point on the lip of the cup. The lever-out test assembly is shown in Figure 4. A 0.25-inch diameter metal rod, serving as a lever, was inserted into a hole drilled into the side wall of the polyethylene liner 0.375 inches below the lip. For each system, the fulcrum was positioned directly adjacent to the metal cup. The rod was loaded until liner separation, at 1.33 radians per minute about the fulcrum. The lever arm length was defined as the distance from the fixed fulcrum to the midpoint of the liner thickness. In this model, liner thickness is a contributing factor to lever-out strength. For the eight de-

FIG. 2. At revision, liner separation was confirmed. The retrieved components describe polyethylene fracture with significant galling of the cup interface attributed to six months of continued ambulation after the onset of hip pain.





FIGS. 3A-3E. Push-out test apparatus: (A) the direction of applied displacement and location of the load measuring device. (B) 0.25-inch cylindrical metal loading pin. (C) sectioned view of ~52-mm outer diameter metal acetabular cup. (D) sectioned view of 32-mm inner diameter polyethylene liner. (E) rigid, circumferential support for metal cup.

signs tested, the lever arm length varied from 2.1 to 2.3 inches.

For the push-out tests, the maximum force required to fully dislodge the liner from its cup was obtained from the force/displacement plot recorded on the Instron strip chart. The dislocation torque in the lever-out test was calculated as the product of the applied maximum force and the length of the lever arm. The average strength of three identical components for each design in both test modes were reported to assess the consistency of the locking mechanism.

To evaluate the reduction in the effectiveness of the locking mechanism after separation, the polyethylene liners were reinserted and the tests repeated.

Failure analysis was conducted on all systems after initial and repeat testing to determine the type and extent of the damage to the locking mechanism.

## RESULTS

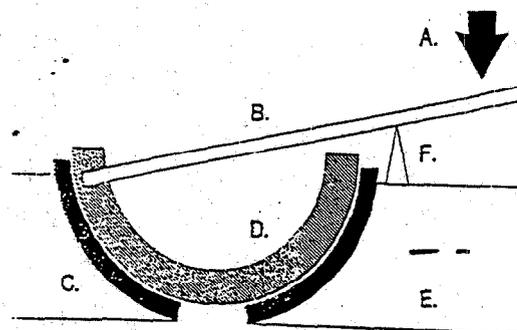
For both push-out and lever-out tests, all cup-liner assemblies failed by disassociation

of the liner from the cup, reflecting a failure of the liner retention mechanism.

The results demonstrate a wide variation in the push-out strength measurements between systems (Fig. 5). The force required to dislodge the liners varied from  $663 \pm 65.5$  pounds force in the Duraloc to  $29 \pm 1.4$  pounds force in the Triloc (Table 1).

For the repeat testing, the forces required for liner separation were consistently lower than those measured in the initial tests. The average reduction in repeat push-out force for all systems combined was 26%. This was found to be significantly different from zero at an alpha level of  $p = 0.0005$  using a two-tailed Student's *t*-distribution analysis. In two systems, damage to the locking mechanism during initial separation was so extensive that repeat testing was not possible. These systems are excluded from the average.

The results of the initial and repeat lever-out tests are presented in Figure 6. Considerable variation in the locking mechanism strength of the different systems was noted. The torque required to dislodge a liner varied from  $684 \pm 114$  inch-pounds in the Duraloc



FIGS. 4A-4F. Lever-out test assembly: (A) the direction of applied displacement and location of the load measuring device. (B) 0.25-inch cylindrical metal loading rod inserted into a hole in the liner 0.375 inch below the cup lip. (C) sectioned view of ~52-mm outer diameter metal acetabular cup. (D) sectioned view of 32-mm inner diameter polyethylene liner modified with a 0.25-inch hole in the side wall. (E) rigid mounting for the metal cup. (F) fixed fulcrum located directly adjacent to the metal cup.

### PUSH OUT TESTS

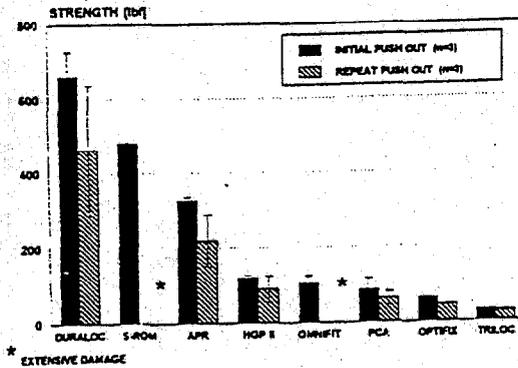


FIG. 5. The bar graph demonstrates the variation in push-out strengths between acetabular cup designs. For six systems, the combined mean repeat push-out strength was significantly less than the initial strength, ( $p = 0.0005$ ). In two designs, repeat testing was not possible because of extensive damage during initial testing. Error bars represent plus or minus one standard deviation.

to  $43 \pm 1.5$  inch-pounds in the Triloc (Table 2). Lever-out strength was only minimally influenced by the variations in liner thickness that contributed no more than 8% to the lever arm length.

For the repeat testing, the torques required for liner separation were consistently lower

than those measured in the initial tests. The average reduction in repeat torque-out strength for all systems combined was 32%. This was found to be significantly different from zero at an alpha-level of  $p = 0.017$  using a two-tailed Student's  $t$ -distribution analysis. In three systems, damage to the locking mechanism during initial separation was so extensive that repeat testing was not possible. These systems were excluded from the average.

To determine the extent to which the results evaluate the locking mechanism, the test methods were compared for each design. Using linear regression analysis, a significant correlation was found between the initial push-out and lever-out test method,  $r^2 = 0.889$  ( $n = 8$ ).

Visual inspection of the systems suggests five general types of locking mechanism. Three systems, the PCA, the Optifix, and the APR, employ a circumferential polyethylene flange on the liner that locks into a circumferential retaining slot in the cup. During liner insertion, the flange initially compresses and then expands into the retaining slot. The retention strength of this method is directly related to the geometry of the flange and its engagement in the slot. After initial testing,

TABLE 1. Retention Strengths of Two Piece Acetabular Cups: Initial and Repeat Push Out Test

	Push Out [lbf]	Repeat Push Out [lbf]	Percent Reduction of Initial Strength	Failure Analysis
	Mean SD	Mean SD		
Duraloc	663 ± 65.5	463 ± 174.6	30%	Cup retaining wire bent and liner damaged
S-ROM	482 ± 4.7	*		Extensive damage to liner flange
APR	325 ± 10.8	219 ± 69.3	33%	Liner flange deformed
HGP II	119 ± 6.2	89 ± 34.7	25%	Cup retention prongs bent and liner damage
Omnifit	103 ± 19.8	*		Extensive damage to liner and liner retaining wire
PCA	85 ± 29.6	61 ± 17.2	28%	Liner flange tip deformed
Optifix	61 ± 2.6	44 ± 2.2	27%	Liner flange deformed
Triloc	29 ± 1.4	26 ± 3.3	9%	Material loss from liner cutouts
$n = 3$ for all tests			mean 26%	$p = 0.0005$

lbf, pounds force; SD, standard deviation.  
\* Initial damage precluded repeat testing.

## LEVER OUT TESTS

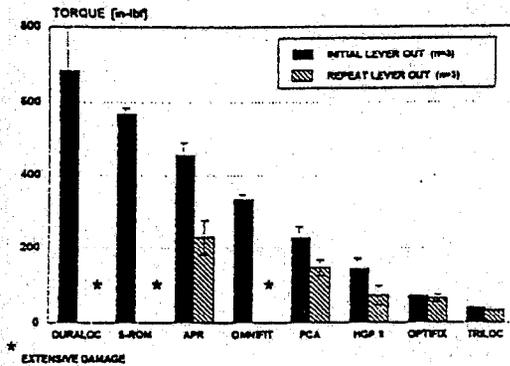


FIG. 6. The bar graph demonstrates the variation in lever-out strengths between acetabular cup designs. For five systems, the combined mean repeat lever-out strength was significantly less than the initial strength. ( $p = 0.017$ ). In three designs, repeat testing was not possible because of extensive damage during initial testing. Error bars represent plus or minus one standard deviation.

these flanges were markedly deformed, accounting for the observed strength reduction in subsequent separation. No deformation of the cups for these designs occurred.

A second locking mechanism, seen in the S-ROM design, is similar to the first. The

liner flange is interrupted, however, facilitating its insertion into intermittent gaps in the retaining slot of the cup. The liner then is rotated so that the flanges are completely engaged within the slot. Further rotation is limited by secondary, peripheral pins or screws. The S-ROM has the advantage that no damage is done to the liner or cup during assembly, thus allowing multiple liners to be inserted without concern. The damage to the liner after forcible separation was considerable, however, and prohibited subsequent testing of that liner.

A third locking mechanism is present in the Triloc design. Two protrusions on the rim of the cup engage two of six undersized cutouts in the lip of the liner at their mid-thickness. After separation, the liners exhibited evidence of material shaving in the cutouts caused by the sharp locking edges of the protrusions. A reduction in retention strength for this device was demonstrated when the same two slots were reused.

A fourth locking mechanism, used in the HGP II design, employs five pairs of spring-loaded prongs on the rim of the cup that lock into a circumferential slot in the liner. After separation, scoring of the liner in the region

TABLE 2. Retention Strengths of Two Piece Acetabular Cups: Initial and Repeat Lever Out Test

	Initial Lever Out [in-lb]	Repeat Lever Out [in-lb]	Percent Reduction of Initial Strength	Failure Analysis
	Mean SD	Mean SD		
Duraloc	684 ± 113.9	*		Extensive damage to cup retaining wire and liner
S-ROM	569 ± 15.3	*		Extensive damage to liner flange
APR	456 ± 34.0	229 ± 46.5	50%	Liner flange deformed
Omnifit	332 ± 13.0	*		Extensive damage to liner and liner retaining wire
PCA	228 ± 29.2	148 ± 20.6	35%	Liner flange tip deformed
HGP II	145 ± 26.0	75 ± 10.9	48%	Cup retention prongs bent with liner damage
Optifix	73 ± 2.6	67 ± 10.0	8%	Liner flange deformed
Triloc	43 ± 1.5	35 ± 1.5	17%	Material loss from liner cutouts
$n = 3$ for all tests		mean 32%		$p = 0.017$

in-lb, inch-pounds; SD, standard deviation.

\* Initial damage precluded repeat testing.

of the prongs was observed. Repeat testing of new liners in the same cup resulted in continually decreasing retention strengths. This can only be explained by the permanent deformation of the metal prongs. The results reported represent the initial and repeat retention strengths for six new cup-liner assemblies, three for each test mode.

A fifth locking mechanism, employed in the Duraloc and Omnifit designs, is characterized by the use of a metal wire retaining ring. In the case of the Duraloc, this wire is configured into a multiple series of bends and inserted into a slot in the cup. During assembly, the wire expands into a circumferential slot in the liner. After separation, the liners exhibited considerable deformation in the region of the slot. Deformation of the metal retaining ring was also observed, requiring a new wire ring for each test. In the case of the Omnifit, the metal wire ring is integral to the liner and engages four hooks located on the interior edge of the cup. After separation, deformation of the wire prohibited subsequent testing.

#### DISCUSSION

This study addresses the short-term disassociation of two-piece acetabular cups whose failure mechanism is attributed to design and material deficiency. Although it is reasonable that polyethylene creep and wear may increase the occurrence of liner disassociation over time, this mode of failure has not, as yet, been reported clinically nor demonstrated experimentally. Because the *in vivo* failure of these systems is complex and the mechanism of liner separation is not completely understood, the results do not infer the clinical superiority of one system over another. These results do provide a basis for comparison of liner locking mechanisms. It is not known how much force a cup-liner assembly should be able to withstand *in vivo*. It is reasonable, however, that those designs with a stronger locking mechanism, if appropriately assembled, are less likely to disassociate.

Although it is unlikely that pure push-out forces represent a component of *in vivo* hip loading, they do by comparison provide a measure of system integrity. By contrast, the lever-out test does simulate the torque acting on the liner during the extremes of hip flexion and extension. These orientations as well as liners that offer variable head coverage have been implicated as possible causes of liner disassociation.<sup>8</sup> The significant correlation between the push-out and lever-out tests in the current study supports the contention that both tests in fact measure the integrity of the retention mechanism.

The repeat push-out and lever-out tests for all systems evaluated indicate a significant reduction in retention strength. This is indicative of permanent material degradation of the cup-liner locking mechanism. In two designs, specifically the HGP II and Duraloc, failures in retention structures integral to the metal cup were observed. For the Duraloc, deformation of the retention wire necessitated its replacement in subsequent testing. This requires routine wire exchange in clinical situations where liner replacement is necessary and suggests that additional wires be available in the operating theater. For the HGP II, deformation of the retention prongs in successive testing resulted in continually decreasing retention strengths. This necessitated that new cups be used for all initial testing. Although it is possible in the clinical setting to forcibly bend the prongs in an attempt to improve the retention strength, this practice is neither recommended nor proven effective, and is potentially dangerous because of the risk of long-term prong fracture caused by metal fatigue. In clinical practice, the potential for subsequent liner disassociation arising from damage to the prongs must be weighed against the difficulty of cup replacement.

Given the significant decrease in retention strength in both push-out and lever-out tests, the practice of reseating modular liners at the time of surgery or reassembling a previously separated liner is strongly discouraged.

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# F1714-96 Standard Guide for Gravimetric Wear Assessment of Prosthetic Hip-Designs in Simulator Devices

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## 1. Scope

1.1 This guide describes a laboratory method using a weight-loss technique for evaluating the wear properties of materials or devices, or both, which are being considered for use as bearing surfaces of human-hip-joint replacement prostheses. The hip prostheses are evaluated in a device intended to simulate the tribological conditions encountered in the human hip joint, for example, use of a fluid such as bovine serum, or equivalent pseudosynovial fluid shown to simulate wear mechanisms and debris generation as found in vivo, and test frequencies of 1 Hz or less.

1.2 since the hip simulator method permits the use of actual implant designs, materials, and physiological load/motion combinations, it can represent a more physiological simulation than basic wear-screening tests, such as pinion-disk (see Practice F 732) or ring-on-disk (see ISO-6474).

1.3 It is the intent of this guide to rank the combination of implant designs and materials with regard to material wear-rates under simulated physiological conditions. It must be recognized, however, that there are many possible variations in the in vivo conditions, a single laboratory simulation with a fixed set of parameters may not be universally representative.

1.4 The reference materials for the comparative evaluation of candidate materials, new devices, or components, or a combination thereof, shall be the wear rate of extruded or Compression-molded, ultra-high molecular weight (UHMW) polyethylene (see Specification F 648) bearing against standard counter faces Stainless Steel (see Specification F 138); cobalt-chromium-molybdenum alloy (see Specification F 75); thermomechanically processed cobalt chrome (see Specification F 799); alumina ceramic (see Specification F 603), having typical prosthetic quality, surface finish, and geometry similar to those with established clinical history. These reference materials will be tested under the same wear conditions as the candidate materials.

**Adopted by:**

**Developed by ASTM Subcommittee:** F04.22

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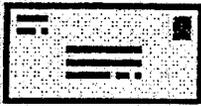
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**Subject Index**

hip designs; prosthetic

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**Support Desk**

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# Guidance Document For Testing Acetabular Cup Prostheses

~~Popular Items~~ ~~Interacting w/CDRH~~ ~~Special Interest~~ ~~Premarket~~ ~~Postmarket~~ ~~Rad. Health~~ ~~Topic Index~~

DRAFT

May 1, 1995

PLEASE FORWARD YOUR COMMENTS TO:

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**CONTENTS AND SUMMARY OF TEST METHODS AND REPORTING**

PREFACE

MATERIALS AND DESIGN DESCRIPTION

list each part of each component of the total hip system including:

1. the name of the component and each its parts
2. a description of the function of each major design feature

<http://www.fda.gov/cdrh/ode/453.html>

3/22/00

3. other components and tissues contacting the component
4. the material composition of each component to include:
  - a. previous submission to FDA or other references
  - b. voluntary standards and any deviations
  - c. any trade names for the materials
  - d. establishments which process the material
5. major processing methods
6. details about the design
  - a. diameters and head-cup clearance
  - b. sphericity
  - c. roughness
  - d. waviness
  - e. thinnest part of the articulating insert

### EVALUATION OF SURFACE TREATMENTS

### EVALUATION OF CALCIUM PHOSPHATE (Ca-P) COATINGS

### KINEMATICS (range of motion)

### STRESS ANALYSIS

### ATTACHMENT LOADS

1. assembly by the surgeon (minimum and maximum recommended loads)
2. disassembly by the surgeon
3. inadvertent disassembly (before and after cyclic loading)
4. any possible relationship between loosening and assembly loads

### FATIGUE PROPERTIES

fatigue, corrosion and articulating and non-articulating wear should be examined in any test performed, where possible

### CYCLIC WEAR, DEGRADATION AND CORROSION

#### DEVICE CHARACTERIZATION

worst case cup dimensions and tolerances  
final product  
composition and microstructure  
    number of physically and/or chemically distinct layers  
    thickness of each layer  
    the locations of the modified surfaces on the implant  
    variation in the modified surface thickness  
    roughness of all surfaces

#### TEST METHODS FOR ALL INTERFACES

at least three identical test and control specimens  
polymer samples should be presoaked  
three controls to correct for ongoing fluid sorption  
volume and concentration of the medium  
other test parameters

METHODS FOR TESTING FRETTING AND/OR CORROSION/DEGRADATION  
BETWEEN NON-ARTICULATING, "MECHANICALLY LOCKED," MODULAR  
IMPLANT COMPONENTS"

cyclic loading in a joint simulator  
device orientation and loading profile simulate worst case  
maintain 37 +/- 1 C, aerated test solution at a pH of 7.3 +/- 0.5  
surfaces exposed to solution should be the same  
specimens electrically insulated from the test apparatus

METHODS FOR TESTING ARTICULATING SURFACES

specimens must be cyclically loaded in a joint simulator  
lubricant composition and temperature  
specimen clamping  
dynamic load profile  
average rate of loading 1 Hz  
three body wear

contamination control and measurement  
characteristic wear markings  
location of particles lying on or embedded in surfaces  
the cup articulating surface should face up  
lubricant replacement  
non-filtering of the lubricant during the testing

MEASUREMENTS FOR ALL INTERFACE

wear particles, wear markings, material transfer and corrosion  
roughness and appropriate dimensions  
weight measurement  
    cleaning method  
    adjust for the change in weight of the soak controls  
    room temperature and humidity during weight measurement  
    volume of mass loss  
in vivo vs in vitro wear rates, wear particles and surfaces

MEASUREMENTS AT NON-ARTICULATING, "MECHANICALLY LOCKED,"  
MODULAR IMPLANT COMPONENTS"

metal ion concentration measured by AAS  
complimentary methods of monitoring fretting corrosion

fretting corrosion currents measured during cyclic loading

crack formation and fatigue strength

## MEASUREMENTS AT ARTICULATING SURFACES

articulating wear

frictional torque

## REPORTING

## APPENDICES

1. PARTS/COMPONENTS AND DESIGN FEATURES
  2. TEST REPORT CONTEN
- 

## **PREFACE**

The purpose of this document is to recommend to the device manufacturer or sponsor of premarket notifications (510(k)), Investigational Device Exemption (IDE), Premarket Approval (PMA), reclassification petition, or master file important information that should be submitted to FDA in order for FDA to determine the substantial equivalence and/or safety and effectiveness of acetabular cup prostheses. This information includes important issues and concerns, properties that should be evaluated, summaries of possible test methods, rationale/purpose of each test, pass/fail criteria or typical results for each test, literature citations, and a format for organizing data for submission to FDA.

The development of this guidance document is based on an evaluation of the literature and on the experience of the Orthopedic and Rehabilitation Devices Branch (ORDB) and is primarily intended to be a scientific position paper. Therefore, it suggests some important evaluation criteria, test procedures, and end points that FDA feels are necessary to provide reasonable assurance of substantial equivalence and/or safety and effectiveness of acetabular cup prostheses. Although this guidance document contains certain administrative requirements, it does not replace the requirements of the 21 CFR 801 or 807 or the statute.

FDA may require information in addition to what is contained in this document if circumstances require it. In other instances, the sponsor may be able to sufficiently justify the omission of some tests. Suggestions and recommendations presented in this document are not mandatory requirements, but reflect data and methodologies which ORDB has determined to be acceptable. Therefore, the words "should", "must" and "shall" are not used in a regulatory sense and should not be construed as such. They express FDA's current feeling as to what constitutes good scientific decision making.

The guidance document should be viewed as a living document. As scientific knowledge changes and scientific techniques are improved, FDA will revise the document. Nonetheless, the basic objectives will remain the same.

## **MATERIALS AND DESIGN DESCRIPTION**

Each part of each component of the total hip system should be listed along with the following information:

1. the name of the component and each its parts;
2. a description of the function of each major design feature (examples are given in APPENDIX 1: PARTS/COMPONENTS AND THEIR MAJOR DESIGN FEATURES);
3. the names of all other components and tissues that are expected to contact the component and the type of interface (i.e., articulating, fixed mating part, coating, tissue fixation);
4. the material composition of each component to include:
  - a. the document number of any previous submission to FDA or other reference which fully characterized the material (e.g., a master file, 510k, literature article);
  - b. a brief description of the material or the name and number of the voluntary standards that applies to the material (any difference in the final product and the requirements in the referenced standard must be itemized and justified);
  - c. any trade names for the materials; and
  - d. the names of establishments which process the material.
5. the major processing methods which determine the material microstructure and hence, its properties; and
6. details about the design (e.g., engineering drawings, model numbers, sizes, photographs) which should include the ball and liner design tolerances and manufacturing variability for interfaces. For example, this might include the following for the articulating interface:
  - a. diameters and head-cup clearance;
  - b. sphericity;
  - c. roughness; and
  - d. waviness.

The thinnest part of any UHMWPE articulating insert must be greater than 4 mm if attached to a metal or ceramic backing (conforming insert) and greater than 6 mm if there is no backing (nonconforming insert) (Bartel, D.L.; Burstein, A.H.; Toda, M.D.; Edwards, D.L.: 'The Effect of Conformity and Plastic Thickness on Contact Stresses in Metal-Backed Plastic Implants'. J. Biomech. Engr., 107, pp. 193-9, Aug., 1985).

#### **EVALUATION OF SURFACE TREATMENTS/COATINGS**

See the "Guidance Document for Testing Orthopedic Implants with Modified Metallic Surfaces  
<http://www.fda.gov/cdrh/ode/453.html>

3/22/00

Apposing Bone or Bone Cement".

## **EVALUATION OF CALCIUM PHOSPHATE (Ca-P) COATINGS**

See the "Calcium Phosphate (Ca-P) Coatings Draft Guidance for Preparation of FDA Submissions for Orthopedic and Dental Endosseous Implants".

### **KINEMATICS**

The range of motion of the ball-acetabular cup combination and of the metal shell and polymer insert (bipolar device) should be reported.

### **STRESS ANALYSIS**

High stresses leading to deformation, fracture or increased wear of the components may be due to:

1. poor tolerances (e.g., too large or too small a ball-cup clearance or a too tight press fit connection);
2. inadequate instructions for attachment (e.g., excessive use of force);
3. local stress risers (e.g., corners);
4. thermal expansion of parts during sterilization; and
5. thin cross-sections.

These parameters may be evaluated in a stress analysis with mechanical testing to justify assumptions made in the analysis.

### **ATTACHMENT LOADS**

The following loads should be determined:

1. assembly by the surgeon (minimum and maximum recommended loads),
2. disassembly by the surgeon,
3. inadvertent disassembly in the patient,
4. any possible relationship between loosening and assembly loads.

Inadvertent disassembly may be evaluated by tensile, torsional or cantilever loading before and after cyclic testing (see below). Tensile loading is simple and the results easy to interpret. For example, an insert is either pulled or pushed along the axis of the cup till failure of the locking mechanism, a load exceeding a safety factor is reached, the disengagement force becomes negligible or assembly becomes difficult (see ASTM draft Standard Test Method for Static Evaluation of Liner Locking Mechanism - Push Out Test).

Torsional loading is the most clinically relevant loading configuration at cup interfaces. The torque due to friction at the ball-liner interface is about 2.4 N-meters. The locking mechanism should exceed this by some safety factor (e.g., 12 N-meter (105 in-lb) for a safety factor of five (Semlitsch, M.; et al. 1977)).

Loosening may also be determined by measuring relative displacement between parts every 10,000 cycles of cyclic loading. An LVDT can measure the displacement while an axial compression load of 50 lbf and a torsional fatigue of +/- 22 in-lbf are applied.

## FATIGUE PROPERTIES

Cyclic fatigue testing should be considered for an acetabular cup which has the same design as a predicate cup except for differences in features which may affect the fatigue life. Whether evaluated separately or in a single test, the corrosion and fatigue properties of the device assembly and wear properties of both the articulating and non-articulating (mechanically locked) interfaces should be examined in any test performed, where possible.

## CYCLIC WEAR, DEGRADATION AND CORROSION

Cyclic testing should be considered for an acetabular cup which has the same design as a predicate cup except for differences in features which may affect loosening, cracking, deformation, corrosion, degradation and wear at interfaces. To simulate actual clinical wear mechanisms for both articulating and non-articulating (mechanically locked) interfaces as much as possible, the following test method and measurement parameters should be considered:

### DEVICE CHARACTERIZATION

The cup dimensions and tolerances that would be expected to result in the highest stresses (i.e., worst case) must be tested.

Test samples must be the final product to be shipped for clinical use.

In addition to the information listed in the MATERIALS AND DESIGN DESCRIPTION section of this documents, the exact composition and microstructure of the substrate and any modified surface present must be fully characterized quantitatively from a representative sample of the test specimens. The tolerances for the analyses must be reported. Surfaces exposed to wear must also include the following:

total number of physically and/or chemically distinct surface layers;

thickness of each layer;

drawing or photographs showing the locations of the modified surfaces on the implant and any variation in the modified surface thickness; and

roughness.

### TEST METHODS FOR ALL INTERFACES

<http://www.fda.gov/cdrh/ode/453.html>

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At least three identical test specimens and three identical controls must be tested. The number of samples depends on the standard deviation and the desired levels of statistical significance and difference in results between test and control specimens.

Polymer samples should be presoaked until a steady state fluid absorption (determined by weighing) is approached (about 30 days for UHMWPE). Samples must be stored and tested in isolation within a noncorrosive chamber.

Three polymer controls which are soaked as are the wear specimens but not wear tested, should be weighed to correct for ongoing fluid sorption by the wear tested components during the wear test. The soak controls should be agitated and cyclically loaded (except for tangential wear motions) as are the wear test specimens.

The volume and concentration of surrounding fluids shall be maintained during testing by avoiding evaporation or by replacing water loss.

Other test parameters should also be included in the methods if the in vitro results will more closely duplicate the in vivo results.

#### METHODS FOR TESTING FRETTING AND/OR CORROSION/DEGRADATION BETWEEN NON-ARTICULATING, "MECHANICALLY LOCKED," MODULAR IMPLANT COMPONENTS"

Specimens must be cyclically loaded in a joint simulator or other appropriate instrumentation. The device orientation and loading profile must simulate worst case fretting motions, cyclic stresses, three body wear and corrosion/degradation environment which could occur during clinical use.

Interpretation of the results may be simpler using a 37 +/- 1 C, aerated saline test solution having a pH of 7.3 +/- 0.5 (carbonate buffered). This is because saline leaves no deposits and the solution composition does not change with time. Ringer's or Hanks solutions may better simulate physiologic conditions and may be appropriate if corrosion is not an issue, but control of the composition, measurements of surface deposits and interpretation of the results must be more stringent than if saline is used. A 0.2% sodium azide or other suitable antibiotic may also be used. A 37 C temperature is preferred, though room temperature may be used if this has no effect on mechanisms (e.g., polymer deformation or creep). Solution temperature and pH must be monitored throughout the test. Accelerated testing (e.g., change in temperature, pH, P<sub>O2</sub>, electric potential) must be validated with a real time control.

The surfaces exposed to solution should be the same for all specimens and simulate corrosion as it might occur clinically. Corrosion testing of modular devices requires that corrosion is induced at appropriate interfaces and not at the outer surface. It is not enough to merely pit the outer surface of the material because this does not represent the corrosion that occurs as a result of the geometry and wear occurring at the crevice (Buckley, C.A.; et al. 1992).

Corrosion test specimens should be electrically insulated from the test apparatus to avoid galvanic corrosion effects (Higo, Y.; Tomita, Y. 1994, page 152).

## METHODS FOR TESTING ARTICULATING SURFACES

Specimens must be cyclically fatigue loaded in a joint simulator.

The lubricant shall consist of the following (or an equivalent pseudosynovial fluid used):

filter-sterilized blood serum,

0.2% sodium azide (or other suitable antibiotic),

20 mM EDTA (ethylene-diaminetetraacetic acid) to bind calcium and minimize its precipitation, and

$37 \pm 1$  C temperature.

Specimens shall be clamped for testing as outlined in McKellop, H.A.; Clarke, I.C.: 'Degradation and Wear of Ultra-High-Molecular-Weight Polyethylene'. ASTM (editor): Special Technical Publication 859, 1985. Any potting medium composition and processing methods used to fix test samples must be reported.

The dynamic load profile should be representative of the human hip joint forces during walking with peak loads of 2 kN (see Davy, D.T.; Kotzar, G.M.; Brown, R.H.; Heiple, K.G.; et al.: 'Telemetric Force Measurements Across the Hip After Total Arthroplasty'; and Paul, J.P.: 'Forces Transmitted by Joints in the Human Body'. Proc. Instn. Mech. Engrs., 181, pp. 8, 1966. JBJS, 70A, pp. 45, 1988).

The average rate of loading during the entire test must be 1 Hz.

Testing which includes three body wear may be necessary to adequately test the wear resistance of surfaces to obtain a clinically meaningful result. At a minimum, the presence of three body wear should be controlled and characterized as much as possible. For example:

contamination control and measurement

characteristic wear markings

location of particles lying on or embedded in surfaces

the cup articulating surface should face up

lubricant replacement

non-filtering of the lubricant during the testing

## MEASUREMENTS FOR ALL INTERFACES

Wear particles, wear markings, material transfer and corrosion (e.g., pitting, etched dendritic surface structure, discoloration) should be quantified after components are disassembled, and

<http://www.fda.gov/cdrh/ode/453.html>

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before and after cleaning if necessary. Material transfer that may occur while assembling or disassembling parts, prior to fretting, should be taken into account (Bhambri, S.K.; Gilbertson, L.N., page 123).

Roughness and appropriate dimensions of each test specimen must be measured before and after testing to assess the effects of wear and deformation. For the ball-cup interface this might include: diameters; head-cup clearance; sphericity; roughness; and waviness.

Weight changes of device components should be made if the test samples are small enough compared to the losses due to wear and corrosion. Samples shall be cleaned prior to weighing as outlined in McKellop, H.A.; Lu, B.; Benya, P.: 'Friction, Lubrication and Wear of Cobalt-Chromium, Alumina and Zirconia Hip Prostheses Compared on a Joint Simulator'. Trans. Orthop. Res. Soc., pp. 401, 1992. The weight loss of each wear component shall be adjusted for the change in weight of the soak controls. The room temperature and humidity during weight measurement shall be reported. The volume of wear debris shall be calculated by dividing by the density of the material.

Test methods should be validated by comparing *in vitro* results to *in vivo* results to determine if *in vitro* test methods are realistically simulating what occurs in patients (e.g., three body wear). This may be determined by comparing wear particles of *in vitro* test samples to those of explanted devices of similar design as well as *in vivo* and *in vitro* wear and corrosion rates.

#### MEASUREMENTS AT NON-ARTICULATING, "MECHANICALLY LOCKED," MODULAR IMPLANT COMPONENTS"

After noting their location on all surfaces, wear particles should be washed off implant surfaces into the test solution. A sample of the wear particles should be characterized, then all metal particles in solution dissolved with an acid (e.g., HCl), and the total metal content in the solution, including particles, measured by AAS (atomic absorption spectroscopy) (Kovacs, P.; et al. 1992). Care should be taken to remove all particles from the test specimen surface and to completely dissolve particulate or oxidized metal (Margevicius, R.W.; et al. 1989).

Complimentary methods of monitoring fretting corrosion may be used in addition to those listed above. For example: fretting corrosion currents measured during cyclic loading or crack formation and fatigue strength before and after fretting.

#### MEASUREMENTS AT ARTICULATING SURFACES

Wear per million cycles based on the change in component mass and frictional torque must be evaluated before testing and at intervals of no greater than a third of the total number of cycles. The same countersurfaces must be assembled after each wear measurement prior to continuing the test.

#### REPORTING

Test reports which omit information, or are not organized the same way by each investigator, makes FDA's review more difficult and delays determinations of substantial equivalence and/or safety and effectiveness. To facilitate FDA's review, detailed reports should include the information which is

organized and subdivided into separate sections (some sections may be combined to enhance clarification) as outlined in Appendix 2.

## **APPENDIX 1: PARTS/COMPONENTS AND THEIR MAJOR DESIGN FEATURES**

### **MODULAR PARTS/COMPONENTS**

### **MAJOR DESIGN FEATURES**

BACKING

ACETABULAR CUP

ARTICULATING INSERT

SCREW HOLE  
DOME HOLE

SUBLUXATION LIP (DEGREES)  
BC FLANGE  
ECCENTRICITY (OFFSET)  
CONSTRAINT

CAPTURED BALL  
FULLY-CONSTRAINED  
NONCONSTRAINED  
SEMI-CONSTRAINED

LINER

LOCKING RING

RADIOPAQUE MARKER

CEMENT SPACER

BALL (HEAD) PARTS

BORE INSERT

BIPOLAR INSERT

FEMORAL COMPONENT

STEM

CENTRALIZER  
BONE CEMENT PLUG  
EXTENDER  
SHAFT

GENERAL:

CROSS-SECTION: ROUND/OVAL  
HANDEDNESS: LEFT/RIGHT  
STRAIGHT OR CURVED  
TAPERED

DISTAL:  
COLLAR

COLLAR

FLUTED  
SLOT (CLOTHS PIN)

PROXIMAL:

EXTRACTION HOLE  
FENESTRATION

SLEEVE  
CEMENT SPACER  
OTHER

SPECIFIC STYLE (SEE ASTM F 370)

FIXATION MECHANISMS:  
COMPONENT-TO-TISSUE & COMPONENT-  
TO-COMPONENT

ADHESIVE  
BOLT OR SET SCREW  
BONE SCREW  
CORTICAL  
CANCELLOUS

CALCIUM PHOSPHATE CERAMIC  
METAL

COATING

PLASMA SPRAYED  
POROUS SINTERED

NORMALIZED  
ROUGHENED  
SMOOTH  
TEXTURED  
MORSE TAPER

SURFACE

OTHER

BONE CEMENT

PEG OR PIN

**APPENDIX 2: TEST REPORT CONTENT**

Detailed reports should be organized and subdivided into separate sections (some sections may be combined to enhance clarification) having the following headings (if applicable):

1. Report title
2. Investigators' names
3. Facility Performing the test
  - Name
  - Address
  - Phone Number
4. Dates
  - Test initiation
  - Test completion
  - Final report completion
5. Objectives/Hypothesis
6. Test and control samples
  - Sample selection criterion
  - Design
  - Materials
  - Processing methods
  - Differences between test samples, control samples and marketed device
7. Methods and Materials
  - Test setup schematic or photograph
  - Description of grips or potting medium interfacing with samples
  - Test equipment calibration schedule, methods and data
  - Discussion of dependent, independent and uncontrolled variables, e.g.:
    - Test and control sample parameters
    - Environment composition, pH, volume, flow, temperature, replacement
    - Electromagnetic fields, applied charge, irradiation
    - Load directions, points of application and magnitudes
    - Times (e.g. rates, frequencies, number of cycles)
    - Other
    - Rationale for choices of parameters, values, etc.
  - Methods of specimen examination (e.g., failure analysis)
  - Statistical justification for the number of samples
  - Chronological description of the test procedures
  - Deviations from referenced protocols and standards
8. Results
  - Time from manufacturing till testing commences
  - Discussion of the data and possible mechanisms

List of conclusions  
Discussion of the objective/hypothesis  
Simplifications and assumptions and their clinical implications

9. Appendices

Experimental data  
Calculations  
Bibliography of all references pertinent to the report

ASTM draft Standard Test Method for Static Evaluation of Liner Locking Mechanism - Push Out Test

## ION MEASUREMENTS

AAS (atomic absorption spectroscopy) is a method used to record the total metal content in a solution containing particles obtained from wear testing. However Margevicius, R.W.; et al. 1989 reported that in vitro corrosion is better measured by weight loss with a microbalance rather than by AAS. Weight loss records 1.5 to 3 times more than by AAS because:

1. particles remaining attached to the test specimen surface when removed from the solution, and
2. AAS is unable to detect particulate or oxidized metal which are not dissolved by acid.

On the other hand, Kovacs, P.; et al. 1992 found a correlation between solution metal ion concentration and weight loss due to controlled fretting of various metals against themselves. The metals included Ti-6Al-4V, CoCrMo and SS. Despite various parameters which affect fretting volume, simply monitoring ion concentration was a better way of measuring fretting volume than weight loss. Weight loss underestimated fretting, it was not sensitive enough for assessing implant fretting and the test must be interrupted to make measurements.

## FRETTING

Crevice corrosion requires diffusion so motion of the environment due to shaking or stirring may delay crevice corrosion (Kruger, J. 1979).

Attia, M.H. 1989 reviewed fretting fatigue test methods.

Fretting results in greater wear because wear debris are retained within the contact zone (Merklenberg, K.R.; Benzing, R.J. 1976).

Merritt, M.; Brown, S.A. 1988 Fretting corrosion of SS is lowered by the addition of protein to the solution due to its lubricating effect. Under static conditions, protein has been reported to cause both an increase. R.L.; Brown, et al. and a decrease in corrosion. Williams, R.L.; Brown, S.A.; Merritt, M. Protein had no effect on Ti-6Al-4V corrosion under static or fretting conditions.

Bundy, K.; et al. 1993 Disinfectants are more corrosive than Ringers solution, though not enough to cause artifacts in the assessment of corrosion attack.

Montague, A.C.; Merritt, K.; Brown, S.A.; Payer, J.H. Because Ca increases fretting corrosion of Ti-6Al-4V, the test solution Ca concentration should be specified. This effect varies with solution

composition due to its effects on solubility and dissociation of Ca compounds. The fretting corrosion of Ti-6Al-4V near a site of inflammation may be significantly increased due to the presence of H<sub>2</sub>O<sub>2</sub> there.

Buckley, C.A.; Gilbert, J.L. 1994 cyclically loaded CoCrMo (F75) balls on trunions made of either the same material or Ti-6Al-4V. The open circuit potential (OCP), fretting currents and pH of the saline solution within the crevice were measured. The fretting current decreased with the number of cycles until leveling out at around 300,000 cycles. The OCP recovered toward its resting potential even during loading. The pH at the interface was inconsistent.

Gilbert, J.L. reported that fretting currents began at load levels of about 200-300 N. This current could affect the oxide coating by affecting the potential. Chlorine increased 200% which caused a decrease in pH in the head-neck region. Scratching the surface caused a huge increase in current density. The fretting current decreased with time, possibly due to seating of the head on the neck.

Flemming, C.A.C.; et al. 1993 evaluated the effect of bore-neck angle mismatches of 6'25" and 3'8" on corrosion current during cyclic loading in 0.9% saline. A Ti-6Al-4V stem and F 799 CoCr head were used. The rest current for both samples was 20 nA. The minimum or critical load necessary to begin fretting for large and small mismatches was 100 and 250 N respectively. The current caused by the stick-slip fretting action depended on the load (in the 25-125 range) applied to the bore-cone with a large mismatch. (e.g., 31 nA at 25 N and 142 nA at 125 N). The current was a constant 50 nA for all loads between 25 and 125 N for the small mismatched bore-cone. During high cycle loading, the current for both types of mismatched specimens was about the same (13-14 uA).

Smith, B.J.; Ducheyne, P. 1994 after an initial anodic drop due to fretting-induced damage, the potential remains steady reflecting continuing damage to the surface. After about 10,000 cycles, a transition in the potential versus cycles plot occurs in which the potential decreases to smaller values, reflected a much lower rate of surface damage. The less severe wear, which prevailed for the rest of the experiment, may be caused by the accumulation of wear debris between the opposing surfaces. The flow properties of the fluid and particles protect the surfaces by thick film lubrication. The particles accumulate into a film because the:

- .fretting motion resulted in little exposure to the rest of the solution.
- .specimen geometry prevented particles from escaping. Smith, B.J.; Ducheyne, P. 1994
- .fretting motion was slow and so imparted little momentum to wear debris.

Crevice corrosion requires diffusion so motion of the environment due to shaking or stirring may delay crevice corrosion (Kruger, J. 1979).

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# THE AWARD PAPERS

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## The Otto Aufranc Award

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### Wear and Lubrication of Metal-on-Metal Hip Implants

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The implication of polyethylene wear particles as the dominant cause of periprosthetic osteolysis has created a resurgence of interest in metal-on-metal implants for total hip arthroplasty because of their potential for improved wear performance. Twenty-two cobalt chromium molybdenum metal-on-metal implants were custom-manufactured and tested in a hip simulator. Accelerated wear occurred within the first million cycles followed by a marked decrease in wear rate to low steady-state values. The volumetric wear at 3 million cycles was very small, ranging from 0.15 to 2.56 mm<sup>3</sup> for all implants tested. Larger head-cup clearance and increased surface roughness were associated with increased wear. Independent effects on wear of

material processing (wrought, cast) and carbon content were not identified. Implant wear decreased with increasing lambda ratio, a parameter used to relate lubricant film thickness to surface roughness, suggesting some degree of fluid film lubrication during testing. This study provided important insight into the design and engineering parameters that affect the wear behavior of metal-on-metal hip implants and indicated that high quality manufacturing can reproducibly lead to very low wear.

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The recent consensus that polyethylene wear particles are the primary cause of periprosthetic osteolysis in total hip arthroplasty has resulted in revived interest in alternative bearing technologies such as metal-on-metal head-cup articulations. Many of the first generation metal-on-metal hip implants from the 1960s and 1970s had high aseptic loosening rates secondary to excessive frictional torque and component seizing.<sup>2,13,32</sup> The failure of these early metal-on-metal hip implants generally has been attributed to poor engineering design and manufacture rather than to problems inherent to metal-on-metal articulations.<sup>13,32</sup> A large number of these early metal-on-metal

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implants, however, have functioned successfully for long periods.<sup>13,32</sup> Studies of retrieved first generation metal-on-metal implants have indicated the near retention of the original mirrorlike surface finish,<sup>2,12,14,18,25,26,31,33</sup> minimal periprosthetic osteolysis,<sup>2,10,33,34</sup> and very low volumetric wear rates up to two orders of magnitude lower than those of conventional metal-on-polyethylene articulations.<sup>2,4,10,14,17,18,21,25-30,33</sup>

In view of the problems associated with polyethylene wear particles, metal-on-metal implants may represent a more favorable bearing combination because of the potential for reductions in volumetric wear, particle numbers, and osteolysis.<sup>22</sup> For metal-on-metal bearings to represent an advance in technology, the wear performance must be substantially and reproducibly better than conventional metal-polyethylene articulations. Although wear particle-induced osteolysis may depend on multiple factors, including particle shape, size, and composition, it generally is regarded as being dose-dependent. Therefore, a major reduction in volumetric wear may be of tremendous potential clinical benefit. Despite the resurgence of interest in metal-on-metal hip implants, however, little information on the engineering issues and fundamental design parameters that affect wear performance of metal-on-metal implants has been published.

Much of the recent published work on hip simulator wear testing of metal-on-metal components consisted of preliminary studies of approximately 20 implants manufactured from three grades of CoCrMo alloys with two component diameters and a wide range of diametral clearances.<sup>7,9,19,21</sup> The results of these earlier studies suggested that material processing (wrought or cast) and head-cup clearance influenced wear performance. Surface roughness and sphericity were not well-controlled in these early studies but a general indication of the influence of these parameters on implant wear was provided. The need for additional study was suggested in which higher quality implants would be manufactured with more carefully controlled parametric changes so

that the effect on wear performance of each variable could be ascertained more precisely.

Before modern metal-on-metal hip implants can be considered for widespread clinical use, a greater scientific understanding of variables that control wear and influence implant design must be gained. It is hypothesized that wear can be controlled by one or more engineering and manufacturing variables, and that strict control over these parameters can optimize wear performance. The current study evaluated the wear performance of new experimental CoCrMo metal-on-metal implants using a hip simulator and determined specifically the effect on wear and lubrication of design factors such as material processing (wrought, cast), C content, head-cup clearance, and surface roughness.

## MATERIALS AND METHODS

The new experimental femoral heads and acetabular cups were custom-manufactured from two medical grades of CoCrMo alloy classified by the American Society for Testing and Materials. Twenty-two implants were evaluated, 14 implants from American Society for Testing and Materials F1537-94 wrought CoCrMo alloy and eight from F75-92 cast CoCrMo alloy (Table 1). The wrought implants had either a low C content ( $< 0.05\%$  C) (eight implants) or high C content ( $> 0.20\%$  C) (six implants), whereas the eight cast components had a high C content ( $> 0.20\%$  C). Grain sizes for both wrought alloys averaged less than  $10\ \mu\text{m}$ , whereas the grain sizes for the cast material ranged from 30 to  $1000\ \mu\text{m}$ . Carbide size also was smaller proportionally for the high C wrought material.<sup>7</sup> Implants were manufactured in one diameter of 28 mm to represent a common femoral head size used in total hip arthroplasty.

The implants examined in this study were manufactured with high precision machining and grinding with which stringent dimensional tolerance, high sphericity, and high quality surface finish were achieved. Each component was finished with a final stage su-

TABLE 1. Cobalt Chromium Molybdenum Hip Implants Tested

Material	Carbon Content (%)	Process	Grain Size ( $\mu\text{m}$ )	Number of Implants
F1537-94	Low (< 0.05)	Wrought	< 10	8
F1537-94	High (> 0.20)	Wrought	< 10	6
F75-92	High (> 0.20)	Cast	30 to 1000	8

TABLE 2. Specifications of CoCrMo Hip Implants

Test Number*	Material	Diametral Clearance ( $\mu\text{m}$ )	Average CLA Surface Roughness (Head) (nm)
1	F1537-94 low carbon	101.6	5.3
2		101.6	6.0
3		101.6	8.0
4		101.6	7.8
5		106.7	9.4
6		106.7	9.2
7		86.4	13.5
8		96.5	5.7
Mean $\pm$ SD		100.3 $\pm$ 6.5	8.1 $\pm$ 2.7
9	F1537-94 high carbon	71.3	19.8
10		66.0	10.0
11		76.2	6.0
12		76.2	4.6
13		66.0	2.1
14		35.6	3.0
Mean $\pm$ SD		65.2 $\pm$ 15.2	7.6 $\pm$ 6.6
15	F75-92 high carbon	30.5	7.2
16		45.7	5.8
17		71.1	7.3
18		81.3	6.4
19		10.2	12.7
20		40.6	6.8
21		86.4	5.0
22		86.4	7.6
Mean $\pm$ SD		56.5 $\pm$ 28.8	7.4 $\pm$ 2.3

CLA = centerline average; SD = standard deviation.

\*Test numbers correspond to those from Chan.<sup>5</sup>

perfinishing grinding process commonly used in the manufacture of precision components for the automotive and aerospace industries. This process resulted in a maximum deviation on sphericity of  $3\ \mu\text{m}$  and centerline-average surface roughness values within approximately  $20\ \text{nm}$ . Average surface roughness values (from measurements in five locations) of the femoral heads ranged from  $2$  to  $20\ \text{nm}$  with an overall average value of  $8\ \text{nm}$  (Table 2). Parts were designed for manufacture with  $45$  and  $90\ \mu\text{m}$  nominal diametral clearances between head and cup. These values were at the lower end of the approximate range used in original and recent generation clinical metal-on-metal prostheses.<sup>22,26</sup> Because of the range of dimensional tolerances that existed in the manufactured parts, the actual clearances between tested implant pairs ranged from approximately  $10$  to  $66\ \mu\text{m}$  for the smaller clearance implants and  $71$  to  $107\ \mu\text{m}$  for the higher clearance implants (Table 2). These parameters were superior to those obtained with the previous experimental implants<sup>7,19</sup> in which the clearance ranged from  $10$  to  $630\ \mu\text{m}$ , surface finish ranged from  $25$  to  $51\ \text{nm}$ , and sphericity deviation was as much as  $10\ \mu\text{m}$ . In the final step of the manufacture, all components were subjected to the cleaning and passivation processes used for clinical implants.

Wear testing was performed using a model EW08 MMED hip simulator (Matco, La Canada, CA) (Fig 1) that has been used extensively for the testing of metal-on-polyethylene implants and verified to produce wear particles and wear rates that compare favorably with those *in vivo*.<sup>15-17</sup> Furthermore, the kinematics of the simulator have been examined by Medley et al<sup>20</sup> who reported that although the simulator was a simple approximation of *in vivo* hip motion, it did include appropriate load angle and magnitude and a multidirectional sliding action that has been shown to be important for realistic hip simulation with polyethylene cups.<sup>3</sup> The hip simulator involved mounting the components in an anatomic configuration (cups below the heads) in chambers oriented at  $23^\circ$  to the hor-

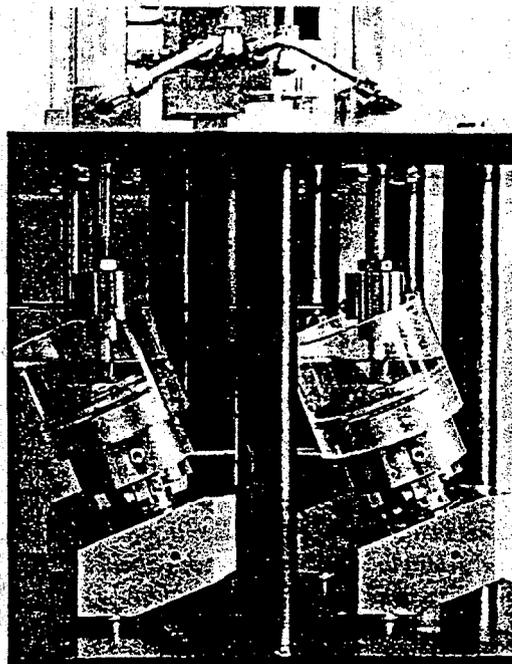


Fig 1. Photograph of two wear test stations of EW08 MMED hip simulator.

izontal plane and subjecting the implants to a biaxial rocking motion at a frequency of  $1.13\ \text{Hz}$ . A load simulating normal gait<sup>23</sup> with a peak of approximately  $2100\ \text{N}$  (three times body weight) was applied vertically to the femoral head. These conditions also were similar to what commonly has been applied in metal-on-polyethylene testing.<sup>15-17</sup>

Filter-sterilized bovine calf serum (HyClone Laboratories, Inc, Logon, UT) was used as the lubricating medium for all implant testing. Each implant was tested in approximately  $125\ \text{mL}$  of serum, up to two orders of magnitude greater than the typical adult synovial fluid volume ( $0.5$  to  $2\ \text{mL}$ ). The larger volume was necessary to fully immerse the articulating surfaces and to act as a heat sink in view of the absence of temperature control and fluid exchange while testing was in progress. Streptomycin at  $0.6\%$  volume (Life Technologies, Inc, Grand Island, NY) and Fungizone at  $1\%$  volume (Life Technologies, Inc) were added to the serum to provide antibacterial and antifungal activity, re-

spectively. An initial experiment with the eight low C wrought implants was run to determine the effectiveness of ethylenediaminetetraacetic acid on the inhibition of surface deposits (Ca and probably P rich). If present, these deposits may act as a protective barrier against direct contact of the articulating surfaces, thus preventing accurate assessment of the wear performance of the materials themselves. Deposits also may prevent accurate quantification of wear by the gravimetric method used in this study. Four of the implants were tested in serum with ethylenediaminetetraacetic acid (20 mmol/L), whereas the remaining four were tested without. If successful inhibition of surface deposits was achieved, all remaining implants in the study would be tested in lubricant with ethylenediaminetetraacetic acid.

The implants were tested to 3 million cycles (1 million cycles generally is considered the average activity in a year for a patient with a joint replacement<sup>24</sup>) with tests interrupted approximately every 300,000 cycles so that the progressive wear of each component could be evaluated. Wear was determined by documenting a change in weight (gravimetric wear) of the tested implants using a model AB-300 high precision analytical balance (Denver Instrument Company, Arvada, CO) with a resolution of 0.1 mg and a reproducibility of  $\pm 0.2$  mg. Tests were restarted each time with a fresh supply of bovine serum to ensure consistency in lubricant chemistry from one test segment to another.

The progressive gravimetric data were converted to volumetric wear using a value of 8.3 mg/mm<sup>3</sup> for the density of CoCrMo. Statistical analyses were performed using SPSS version 7.5 (SPSS Inc, Chicago, IL). Each group of data used in comparisons was analyzed for normality using the Kolmogorov-Smirnov test and equality of variances using Levene's test. Based on the normality and equality of variances of the data, the appropriate test of comparison was used. For parametric data with either equal or unequal variances, the independent samples two-tailed Student's *t* test was used, whereas the two-tailed Mann-Whitney test for independent

samples was used for nonparametric data. The significance of differences in average wear for implants tested in bovine serum with and without ethylenediaminetetraacetic acid and for implants of different material processing (wrought and cast) and C content (low and high) was determined. Univariate one-way analysis of variance (ANOVA) or the Kruskal-Wallis test (non-parametric) was used to determine the significance of differences in volumetric wear and wear rates between the three groups of CoCrMo (low C wrought, high C wrought, cast). The Bonferroni method (equal variances) or the Tamhane test (unequal variances) was the post hoc procedure used to identify specifically the differences that were significant. To determine steady-state wear rates, linear regression analysis using a least squares fit was performed on the data. For all statistical comparisons in this study,  $\alpha = 0.05$  was used as the level of significance.

Various analyses were performed to determine the independent effect on wear of each parameter with other parameters held constant. To determine the effect of material processing, the total volumetric wear of the high C wrought and cast implants was compared. These data were obtained by grouping the implants within the narrow ranges of 66 to 87  $\mu\text{m}$  for clearance and 5 to 10 nm for surface roughness. The effect of C content was evaluated by comparing results for wrought implants with clearance and roughness values of 75 to 105  $\mu\text{m}$  and 5 to 10 nm, respectively. To show any independent effect on wear of clearance and roughness, the total wear was plotted against clearance for a subset of implants with similar surface roughness values and against roughness for implants with similar diametral clearances, respectively. For the clearance and wear analysis, implants with average surface roughness values of 5 to 10 nm were selected. Implants with diametral clearance values ranging from 81 to 107  $\mu\text{m}$  were selected for the roughness and wear analysis. Regression analysis was used in each case to assess the individual relationships between wear and clearance and wear and roughness. The clearance and roughness

limits for these analyses were chosen because they represented a sufficiently narrow range within the overall values.

An alternative analysis was implemented in which the wear data at 3 million cycles were analyzed by a univariate one-way analysis of covariance (ANCOVA) performed using a general linear model procedure. The effect of material processing and C content on volumetric wear was evaluated while accounting for changes in diametral clearance and surface roughness.

The wear data also were linked to theoretical predictions of the type of lubrication that occurred with each implant. Following an approach initiated by Medley et al.,<sup>20</sup> a numerical analysis was developed by Chan<sup>5</sup> and Chan et al.<sup>8</sup> that estimated the time-varying thickness (during the gait cycle) of the lubricant film at the center of the head-cup contact area for the simulator-tested hip implants. The ratio between this theoretical lubricant film thickness, typically in the 20 to 70 nm range, and the measured surface roughness (head and cup combined) is known as the parameter lambda that quantified the extent of direct surface interaction in the contact area.<sup>5,8</sup> In general terms, lambda values less than approximately one suggest direct surface contact at the asperity tips, whereas lambda values greater than approximately three suggest surface separation by a

continuous lubricant film.<sup>11,35</sup> Lambda values between one and three indicate a combination of direct contact and continuous film lubrication (Fig 2). Chan<sup>5</sup> and Chan et al.<sup>8</sup> showed that a remarkably good estimation of the minimum film thickness during the gait cycle was provided by a steady-state formula (for film thickness) using the average applied load. This approach was used to obtain a unique minimum lambda value for each implant tested. The minimum lambda value was plotted against total volumetric wear to examine the influence of lubrication on simulator wear of the metal-on-metal hip implants. Regression analysis was used to quantify the correlation between wear and lambda, and a univariate one-way ANOVA or the Kruskal-Wallis test was used to determine the significance of differences between wear for lambda values less than one, between one and three, and greater than three.

## RESULTS

Throughout the 3 million cycles of testing for all 22 implants, discoloration of the lubricant from the accumulation of wear particles was not visually apparent, and temperature rises of the bulk lubricating fluid were less than 4° C. The plots of volumetric wear against the number of cycles (Figs 3-5) indicated that all im-

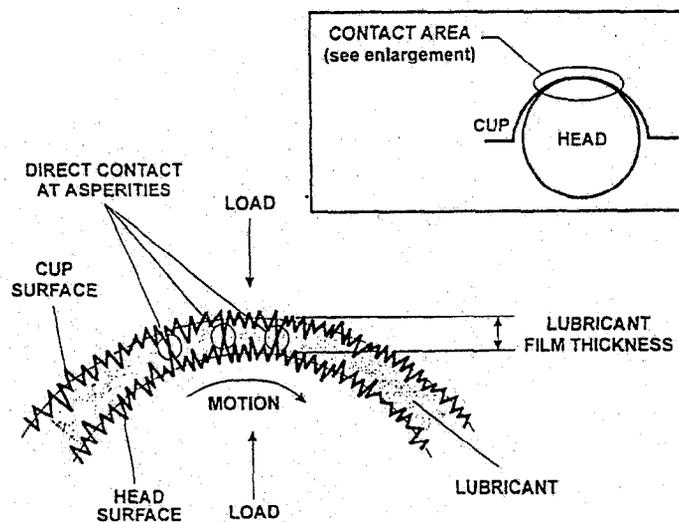


Fig 2. Schematic indicating the head-cup contact area with combination of direct surface interaction and separation by a continuous lubricant film (lambda values between one and three).

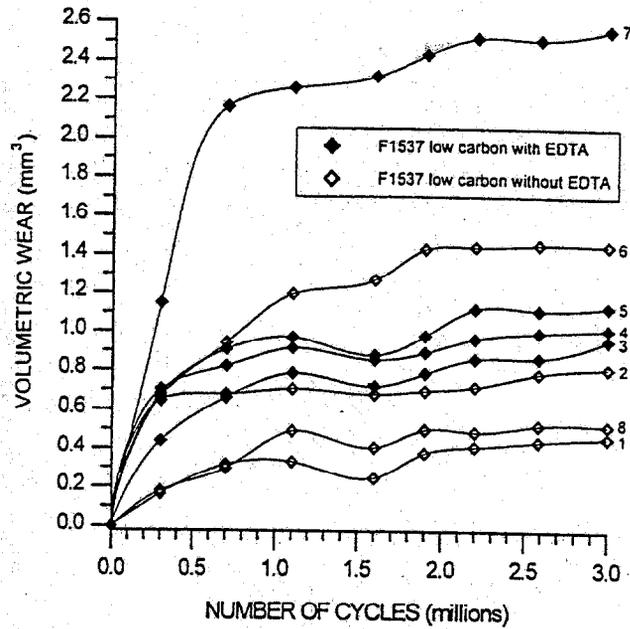


Fig 3. Total volumetric wear of low C wrought F1537-94 implants plotted against the number of cycles. Numbers in the graphs represent implant labels in Tables 2 and 3. EDTA = ethylenediaminetetraacetic acid.

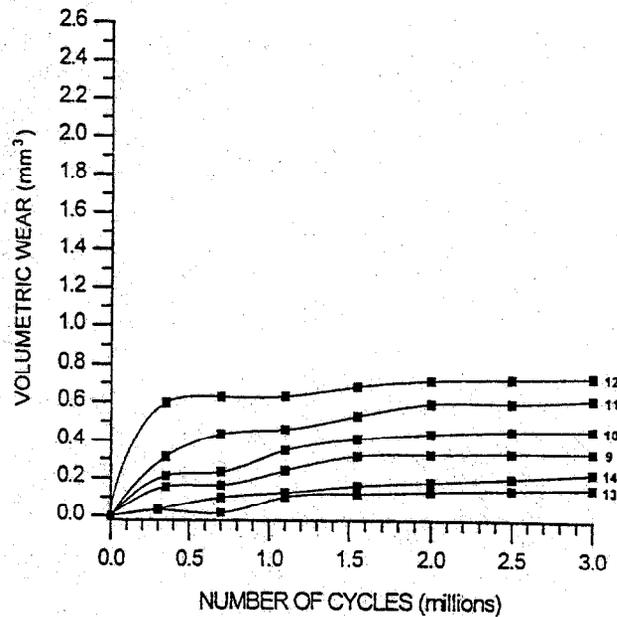


Fig 4. Total volumetric wear of high C wrought F1537-94 implants plotted against the number of cycles. Numbers in the graphs represent implant labels in Tables 2 and 3.

plants experienced a characteristic period of accelerated run-in wear within the first 1 million cycles. This was followed by a substantial decrease in wear rate tending toward low, steady-state values. In the following analyses, initial and total wear were defined as the wear

at 1 million and 3 million cycles, respectively, and steady-state wear rate was defined by the best-fit regression line from 1 to 3 million cycles.

The effect of using ethylenediaminetetraacetic acid as an additive to the bovine

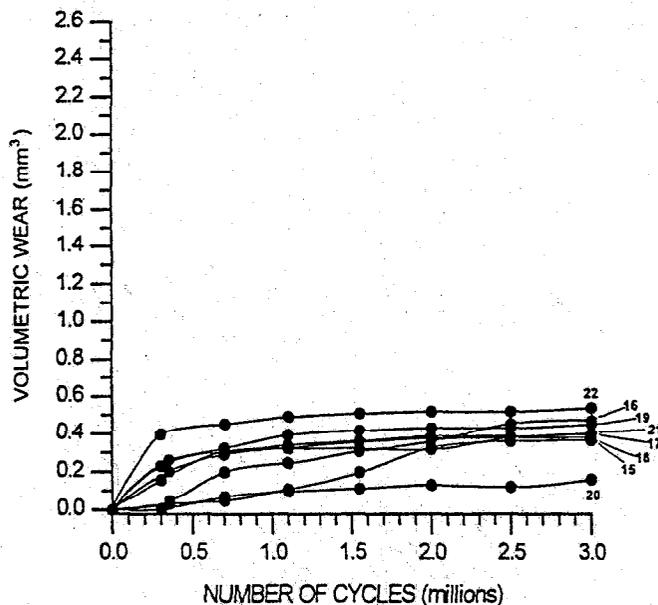


Fig 5. Total volumetric wear of high C cast F75-92 implants plotted against the number of cycles. Numbers in the graphs represent implant labels in Tables 2 and 3.

...m lubricant was evaluated in the low C wrought series (Fig 3). Descriptive statistics of these implants identified implant Number 7 as an outlier because of its disproportionately large surface roughness (Table 2) and large total wear (Table 3). Excluding results for implant Number 7, the average total wear was  $1.04 \pm 0.086 \text{ mm}^3$  for implants tested with ethylenediaminetetraacetic acid and  $0.81 \pm 0.45 \text{ mm}^3$  for those tested without ethylenediaminetetraacetic acid, a difference that was not statistically significant ( $p = 0.400$ , two-tailed Mann-Whitney test). The differences in average initial wear and steady-state wear rate with and without ethylenediaminetetraacetic acid (Table 3) were not significant either ( $p = 0.400$ , two-tailed Mann-Whitney test).

An inspection of the surface of the components by a high-powered stereomicroscope indicated that those tested within serum containing ethylenediaminetetraacetic acid either possessed minute traces of deposits or generally were free of deposits and maintained the same mirror surface finish as the original untested surfaces. Those tested in lubricant without ethylenediaminetetraacetic acid had varying degrees of deposit development from moderate to

severe in the form of circular regions about the centers of the heads and cups. To minimize the possible influence on implant wear of these strongly adherent deposits and to facilitate accurate wear measurements, ethylenediaminetetraacetic acid was used for all other tests.

An initial comparison of overall wear results was made between the low and high C wrought and cast materials (neglecting for the moment differences in other design parameters within each group). The average initial wear at 1 million cycles of the low C wrought implants was  $0.76 \pm 0.51 \text{ mm}^3$ , significantly greater than the averages of  $0.24 \pm 0.22 \text{ mm}^3$  for the high C wrought components ( $p = 0.035$ , Kruskal-Wallis and Bonferroni) and  $0.21 \pm 0.14 \text{ mm}^3$  for the high C cast implants ( $p = 0.013$ , Kruskal-Wallis and Bonferroni) (Table 3). The difference between the wrought and cast high C alloys was not significant ( $p = 0.999$ , Kruskal-Wallis and Bonferroni).

The steady-state wear rate of the low C wrought pairings averaged  $0.11 \pm 0.055 \text{ mm}^3$  per million cycles compared with the high C wrought and high C cast implants that experienced lower average wear rates of  $0.067 \pm 0.018 \text{ mm}^3$  per million cycles and  $0.063 \pm$

TABLE 3. Wear of CoCrMo Hip Implants

Test Number	Run-in Wear at $1 \times 10^6$ cycles ( $\text{mm}^3$ )	Total Volumetric Wear at $3 \times 10^6$ cycles ( $\text{mm}^3$ )	Steady State Wear Rate for 1 to $3 \times 10^6$ cycles ( $\text{mm}^3/\text{million cycles}$ )
1*	0.27	0.46	0.075
2*	0.68	0.81	0.057
3	0.58	0.96	0.112
4	0.77	1.02	0.080
5	0.81	1.13	0.111
6*	0.81	1.45	0.214
7	1.90	2.56	0.180
8*	0.24	0.52	0.079
Mean $\pm$ SD	$0.76 \pm 0.51$	$1.11 \pm 0.67$	$0.11 \pm 0.055$
9	0.16	0.34	0.070
10	0.22	0.46	0.089
11	0.38	0.62	0.086
12	0.61	0.74	0.054
13	0.02	0.15	0.047
14	0.06	0.23	0.055
Mean $\pm$ SD	$0.24 \pm 0.22$	$0.42 \pm 0.23$	$0.067 \pm 0.018$
15	0.04	0.37	0.153
16	0.10	0.47	0.126
17	0.28	0.40	0.038
18	0.24	0.38	0.038
19	0.28	0.45	0.045
20	0.03	0.16	0.034
21	0.25	0.40	0.039
22	0.42	0.54	0.033
Mean $\pm$ SD	$0.21 \pm 0.14$	$0.40 \pm 0.11$	$0.063 \pm 0.048$

SD = standard deviation.

\*Implants tested without ethylenediaminetetraacetic acid additive.

0.048  $\text{mm}^3$  per million cycles, respectively. However, these differences were not significant ( $p = 0.065$ , Kruskal-Wallis).

The average total volumetric wear after 3 million cycles of  $1.11 \pm 0.67 \text{ mm}^3$  for the low C wrought implants was significantly greater ( $p = 0.022$ , ANOVA and Bonferroni) than the  $0.42 \pm 0.23 \text{ mm}^3$  for the high C wrought pairings and  $0.40 \pm 0.11 \text{ mm}^3$  for the high C cast components ( $p = 0.010$ , ANOVA and Bonferroni) (Table 3). There was also no significant difference between the wear of the high C wrought and cast components ( $p = 0.999$ , ANOVA and Bonferroni). Although these statistical comparisons suggest higher wear for the low C implants, they do not account for

variations in parameters, such as clearance and roughness, within each group.

To show the independent effect of material processing on wear, the average total wear of groups of three high C wrought and four cast implants with clearances and roughness values ranging from 66 to 87  $\mu\text{m}$  and 5 to 10 nm, respectively, were compared. The average total wear was  $0.61 \pm 0.14 \text{ mm}^3$  for the wrought implants and  $0.43 \pm 0.074 \text{ mm}^3$  for the cast parts, an insignificant difference ( $p = 0.114$ , two-tailed Mann-Whitney test).

To show the independent effect of C content on wear, the average total wear of groups of low and high C implants with clearance and roughness values within 75 to 105  $\mu\text{m}$  and 5 to 10 nm,

respectively, were compared. The average wear volumes of  $0.75 \pm 0.25 \text{ mm}^3$  for five low C implants and  $0.49 \pm 0.12 \text{ mm}^3$  for four high C parts were not significantly different ( $p = 0.190$ , two-tailed Mann-Whitney test).

To show the independent effect of clearance on wear, the total wear of 16 implants (seven low C wrought, two high C wrought, and seven cast) with roughness values from 5 to 10 nm was plotted against head-cup diametral clearance (Fig 6). With roughness held relatively constant, the results clearly showed that wear increased with increasing diametral clearance. Regression analysis indicated that the data were well described by a quadratic relationship ( $R^2 = 0.65$ ,  $p = 0.001$ ).

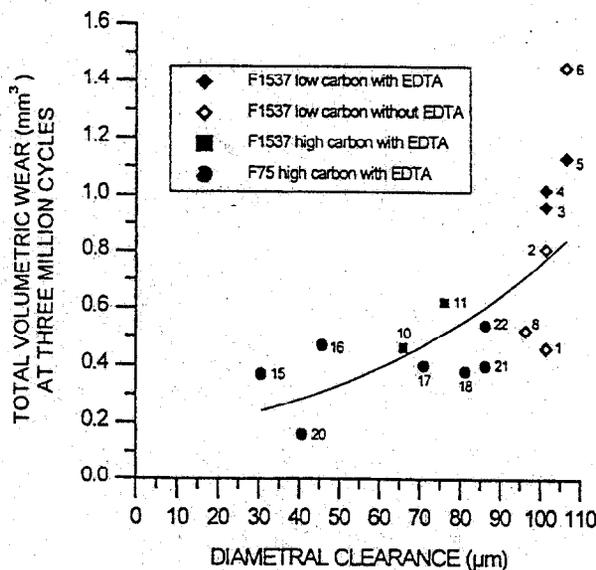
To show the independent effect of surface roughness on wear, the total wear of 10 implants (seven low C wrought and three cast) with clearances between 81 and 107  $\mu\text{m}$  were plotted against centerline-average roughness measured at the apex of each femoral head (the position within the contact zone during loading) (Fig 7). Linear regression analysis showed that wear increased with increasing surface roughness ( $R^2 = 0.85$ ,  $p = 0.001$ ).

The ANCOVA was performed with results for all implants, excluding implant Number 7 to avoid possible confounding effects of an

outlier. The analysis indicated a weak material effect on wear ( $p = 0.818$ ), whereas evidence existed for clearance and roughness effects ( $p = 0.245$  and  $p = 0.260$ , respectively). These results supported the previous analyses in which the independent effects of various parameters were analyzed by judicious grouping of the data. However, the ANCOVA also identified an effect of C content ( $p = 0.081$ ), a result that differed from the analysis of the wrought data with clearance and roughness accounted for by selective implant groups.

Minimum lambda values were calculated for 21 implants (implant Number 7 was excluded from this analysis). Regression analysis indicated that wear decreased exponentially ( $R^2 = 0.48$ ,  $p = 0.001$ ) as lambda ratio increased (as film thickness became progressively larger than the surface roughness) (Fig 8). With average wear volumes of  $0.881 \pm 0.384 \text{ mm}^3$  ( $n = 7$ ),  $0.461 \pm 0.0905 \text{ mm}^3$  ( $n = 8$ ), and  $0.367 \pm 0.230 \text{ mm}^3$  ( $n = 6$ ), a comparison of these data groups indicated a significant difference between implants with lambda values less than one and greater than three ( $p = 0.041$ , ANOVA and Tamhane). Differences were not significant between implants with lambda values less than one and

Fig 6. Total volumetric wear after 3 million cycles of wrought F1537-94 and cast F75-92 implants with average centerline-average surface roughness values within 5 to 10 nm plotted against head-cup diametral clearance. A quadratic curve ( $R^2 = 0.65$ ,  $p = 0.001$ ) was fitted to the data and indicated that increasing diametral clearance resulted in increased wear. Numbers in the graphs represent implant numbers in Tables 2 and 3. EDTA = ethylenediaminetetraacetic acid.



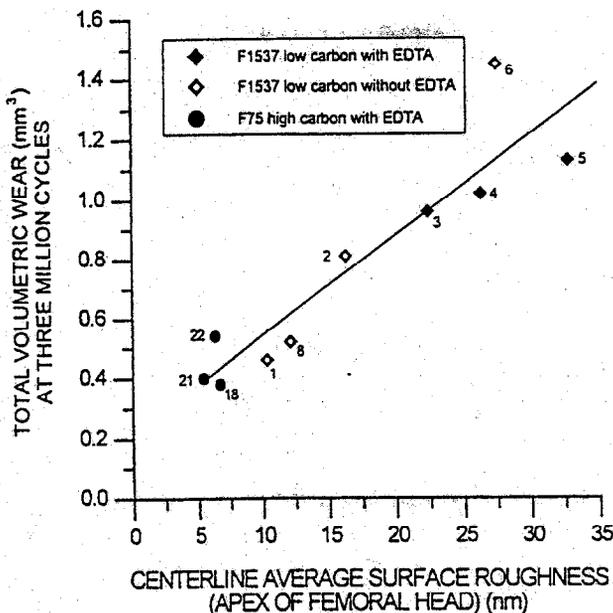


Fig 7. Total volumetric wear after 3 million cycles of wrought F1537-94 and cast F75-92 implants with diametral clearances between 81 and 107  $\mu\text{m}$  plotted against the centerline-average surface roughness measured at the apex of the femoral head. A best-fit linear regression line ( $R^2 = 0.85$ ,  $p = 0.001$ ) was fitted to the data and indicated that increasing surface roughness resulted in increased wear. Numbers in the graphs represent implant labels in Tables 2 and 3. EDTA = ethylenediaminetetraacetic acid.

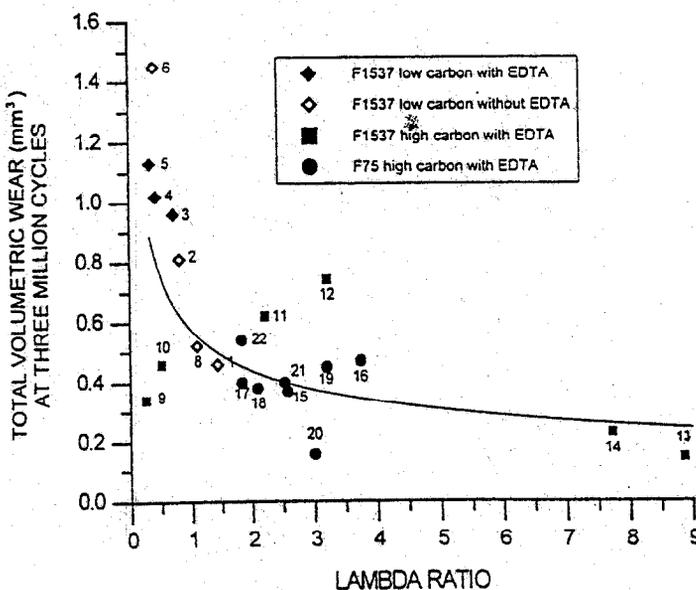


Fig 8. Total volumetric wear after 3 million cycles of wrought F1537-94 and cast F75-92 implants plotted against lambda ratio. An exponential curve ( $R^2 = 0.48$ ,  $p = 0.001$ ) was fitted to the data and indicated that wear decreased as the lambda ratio of the implant increased. Numbers in the graphs represent implant labels in Tables 2 and 3. EDTA = ethylenediaminetetraacetic acid.

between one and three ( $p = 0.080$ , ANOVA and Tamhane) and between implants with lambda values between one and three and greater than three ( $p = 0.758$ , ANOVA and Tamhane).

## DISCUSSION

All 22 metal-on-metal implants had substantially less wear compared with that of conventional metal-on-polyethylene articula-

tions.<sup>1,15,17,26</sup> The volumetric wear of polyethylene has been calculated from the radiographic measurements of linear wear to range from approximately 20 to 100 mm<sup>3</sup> per year, depending on the implant design.<sup>1</sup> In hip simulator studies using the same apparatus as in the current study, typical volumetric polyethylene wear rates of approximately 20 mm<sup>3</sup> per million cycles were reported.<sup>15,17</sup> In the current study, the total volumetric wear at 3 million cycles for the lowest and highest wearing implant pairs was 0.15 and 2.56 mm<sup>3</sup>, respectively, representing a difference of up to 400 times compared with the *in vivo* data<sup>1</sup> and 2000 times compared with the *in vitro* data.<sup>15,17</sup> From the standpoint of volumetric wear, the wear performance of metal-on-metal implants is clearly superior to that of conventional metal-on-polyethylene articulations in hip simulator testing.

The accelerated wear within the first 1 million cycles probably resulted in part from the removal of surface asperities of either the passive oxide surface layer or the substrate by abrasive (removal of softer material by harder material) and adhesive (removal of asperities by forces generated from direct bonding at contacting asperity tips) wear mechanisms active on initial loading. It also could have been influenced by the forced conformity of the components during loading until the correction of any asphericity between head and cup.

Despite surface analyses indicating some qualitative differences in implants tested with and without ethylenediaminetetraacetic acid, the comparison of average wear for implants tested with and without ethylenediaminetetraacetic acid indicated a difference that was not significant. Although surface deposits have been found to varying degrees on retrieved metal-on-metal implants,<sup>12,18</sup> ethylenediaminetetraacetic acid was used in all subsequent tests to suppress deposit formation, because their presence on *in vitro* components was a potential confounding factor in wear analysis. It also has been suggested that these deposits may act as effective boundary lubricants that would shear in preference

to the articulating metal surfaces themselves, thereby protecting the head and cup from wear to some extent.<sup>19</sup> If this were the case, by using ethylenediaminetetraacetic acid the wear results generated in this study would represent a worst case test scenario or a conservative estimate of wear performance.

A comparison of high C wrought and cast implants indicated that the difference in wear was not significant. In previous work, differences in wear between wrought and cast CoCrMo implants were attributed to metallurgical phenomena such as grain size and distribution, carbide size and distribution, and different surface roughness values achieved by the processing of the implants.<sup>7,9,19,21</sup> With uniform surface finish among the implants in the current study, any strong independent effect on wear of material processing appears to have been overshadowed. Certainly, with similar ranges in clearance and roughness values (Table 2), no statistical difference between the high C wrought and high C cast implants was identified. This is in contrast to data from Streicher<sup>27</sup> and Streicher et al<sup>28,29</sup> who suggested superior wear performance of wrought compared with cast CoCrMo alloy.

Carbon content has been discussed in the past as a potential parameter controlling the wear of CoCrMo self bearings, with hard carbide-on-carbide interaction contributing to improved wear performance of the higher C material. The results of the ANCOVA supported this premise, whereas controlling the analysis for variations in clearance and roughness by selective grouping of data resulted in a difference that was not significant. This discrepancy may have resulted because the low C implants, which had the highest average wear, also had the largest clearances in the study (Table 2). Overall, the data may not have been sufficiently robust to prevent the ANCOVA model from falsely recognizing this as a strong C content effect. Testing of additional implants would be required to discern more clearly whether an independent effect of C content existed. Based on the data from this study, any real difference is likely to be small,

with low and high C implants having exceptionally low wear compared with conventional metal-on-polyethylene implants.

The results from the current study have confirmed suggestions from earlier studies<sup>7,19</sup> by identifying head-cup diametral clearance as an important design parameter controlling the wear of metal-on-metal bearing surfaces. In the clearance analysis, the effect of variations in roughness was minimized by examining results for implants with similar surface roughness values. Nonetheless, the differences in roughness values may have been sufficient enough to cause some of the scatter seen in the clearance and wear plot (Fig 6).

The proportional relationship between clearance and wear could suggest that additional reduction in clearance may reduce wear additionally. However, there are practical issues that must be considered in selecting the optimum clearance for clinical implants. Because of manufacturing difficulties in tightly controlling dimensional tolerances below 20  $\mu\text{m}$ , very small nominal head-cup clearances could increase the probability for off-the-shelf parts to be matched with an excessively tight fit that could adversely affect mechanical function and lubrication mechanisms and cause increased wear. The optimum clearance must be a balance between maximizing contact area (smaller clearance) and maximizing the ability for fluid ingress and wear particle egress (larger clearance). Thus, from an engineering standpoint, it may be necessary to accept slightly larger clearances (and slightly more wear) to increase the margin of design safety.

The results of the ANCOVA and the roughness analysis where clearance was held relatively constant identified an effect of surface roughness on wear. The centerline-average surface roughness values were those measured before tests were begun. Wear depends on the initial surface roughness, because early surface damage may continue to influence the course of subsequent wear. However, surface roughness changes as tests proceed and the instantaneous rate of wear also depends, to some

extent, on the instantaneous surface roughness. In particular, the fact that wear rates reached a steady state may be because of the achievement of some constant value of surface roughness after the head-cup articulation has run in or perhaps to an increase in asperity tip radii (as asperity tips become dull). Determination of surface roughness and the evaluation of changes in asperity tip radii after testing would be necessary to determine the correlation between steady-state wear rate and final surface roughness.

Compared with the experimental implants from previous work,<sup>7,9,19,21</sup> a substantial improvement in surface finish (Table 2) was achieved for all 22 implants with the superfinishing process in the current study. The improved surface finish may account for the superior wear performance of the implants in the current study. For example, the average volumetric wear after 3 million cycles of the 28-mm diameter implants (seven pairs) examined by Medley et al<sup>19</sup> was 3.71  $\text{mm}^3$ . With average roughness values estimated to be 25 to 51 nm, these implants had approximately three to eight times greater wear than implants from the current study.

The mechanism by which the low wear was achieved in the current implants may have been attributable to fluid film lubrication of the articulation. As discussed by Chan et al,<sup>7,8</sup> the development of a thin fluid film, typically in the 20 to 70 nm range, at the head-cup interface would separate the surfaces and carry the applied load between the components. Although fluid film lubrication is a complex phenomenon involving lubricant rheology, simulator kinematics and dynamics, implant geometry, and component topography, the small clearances and low surface roughness values are important parameters that would be favorable for fluid film lubrication to occur. As lambda ratio is directly influenced by lubricant film thickness, which is a function of implant clearance, low clearance values would result in larger film thicknesses and contribute to a greater degree of head-cup separation. This was shown by the reduction in total wear for implants with in-

creasing lambda ratios, indicating that progressive surface separation by a continuous lubricant film may have occurred. However, the continuous motion of the hip simulator may have facilitated the development of a lubricant film and, therefore, would not represent a realistic loading environment which would include periods of starting and stopping.<sup>6</sup> In this case, breakdown of the lubricant film may occur, resulting in harsher but more realistic test conditions and assessment of wear performance.

The current study, in which parametric changes were limited and more strictly controlled, provided for the determination of the individual effect on wear of different design variables. In general, head-cup diametral clearance and surface roughness of the components were identified as design parameters affecting the wear of metal-on-metal bearings. Increased clearance and increased surface roughness resulting in the increased wear.

All implants evaluated in the current study were finished to uniformly low surface roughness values, the effect on wear of material processing and C content, in which there were large differences in grain and carbide size, was not apparent in the results. The low wear of the implants may have resulted from fluid film lubrication at the head-cup interface. Overall, the high quality manufacturing of the experimental metal-on-metal implants evaluated in the present study resulted consistently in substantial improvement in wear performance over conventional metal-on-polyethylene articulations. Given that wear particle-induced osteolysis may be dose-dependent, the data suggest that metal-on-metal articulations may mitigate the problems associated with wear-related osteolysis. The results from the authors' laboratory and theoretical studies on wear and lubrication coupled with positive information from past and recent clinical studies justify the continued development of this alternative bearing technology.

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