USER:	**WEEKS, SUSAN M (smw)**
FOLDER:	**K011110 - 154 pages (FOI:05009302)**
COMPANY:	**BIOMET, INC. (BIOMET)**
PRODUCT:	**PROSTHESIS, HIP, SEMI-CONSTRAINED (METAL UNCEMENTED ACETABULAR COMPONENT) (KWA)**
SUMMARY:	**Product: M2A ACETABULAR SYSTEM**

DATE REQUESTED:	**Fri Sep 21 24:00:00 2007**
DATE PRINTED:	**Thu Nov 15 08:20:33 2007**
Note:	**Releasable Version**

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 2 2001

Ms. Michelle L. McKinley
Regulatory Specialist
Biomet Orthopedics, Inc.
P.O. Box 587
Warsaw, Indiana 46581-0587

Re: K011110
Trade Name: M2a™ Acetabular System
Regulatory Number: 888.3330
Regulatory Class: Class III
Product Code: KWA
Dated: March 30, 2001
Received: April 11, 2001

Dear Ms. McKinley:

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

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

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

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

Sincerely yours,

DSMitchell TWD 001

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

Enclosure

510(k) Number if Known: K011110
Device Name: M2a™ Acetabular System

The M2a™ Acetabular System is indicated for used in patients requiring total hip replacement due to the following:

a.) Non-inflammatory degenerative joint disease including avascular necrosis, diastrophic variant, fracture of the pelvis, fused hip, leg perthes, 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.) Revision of previously failed total hip arthroplasty.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per CFR 801.109)

or

Over the Counter Use_____
(Optional Format 1-2-96)

Donna Chellous for CMW
(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K011110

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

From: Reviewer(s) - Name(s) Glenn Stegman 6/22/01

Subject: 510(k) Number K011110

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

- ☐ Refused to accept.
- ☐ Requires additional information (other than refuse to accept).
- ☒ Is substantially equivalent to marketed devices.
- ☐ NOT substantially equivalent to marketed devices.
  - De Novo Classification Candidate? ☐ YES ☐ NO
- ☐ Other (e.g., exempt by regulation, not a device, duplicate, etc.)

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

This 510(k) contains:

Truthful and Accurate Statement ☐ Requested ☒ Enclosed
(required for originals received 3-14-95 and after)

☒ A 510(k) summary OR ☐ A 510(k) statement

☒ The required certification and summary for class III devices

☒ The indication for use form (required for originals received 1-1-96 and after)

Material of Biological Origin ☐ YES ☒ NO

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

☒ No Confidentiality ☐ Confidentiality for 90 days ☐ Continued Confidentiality exceeding 90 days

Predicate Product Code with class: 87 KWA, III, 888.3330

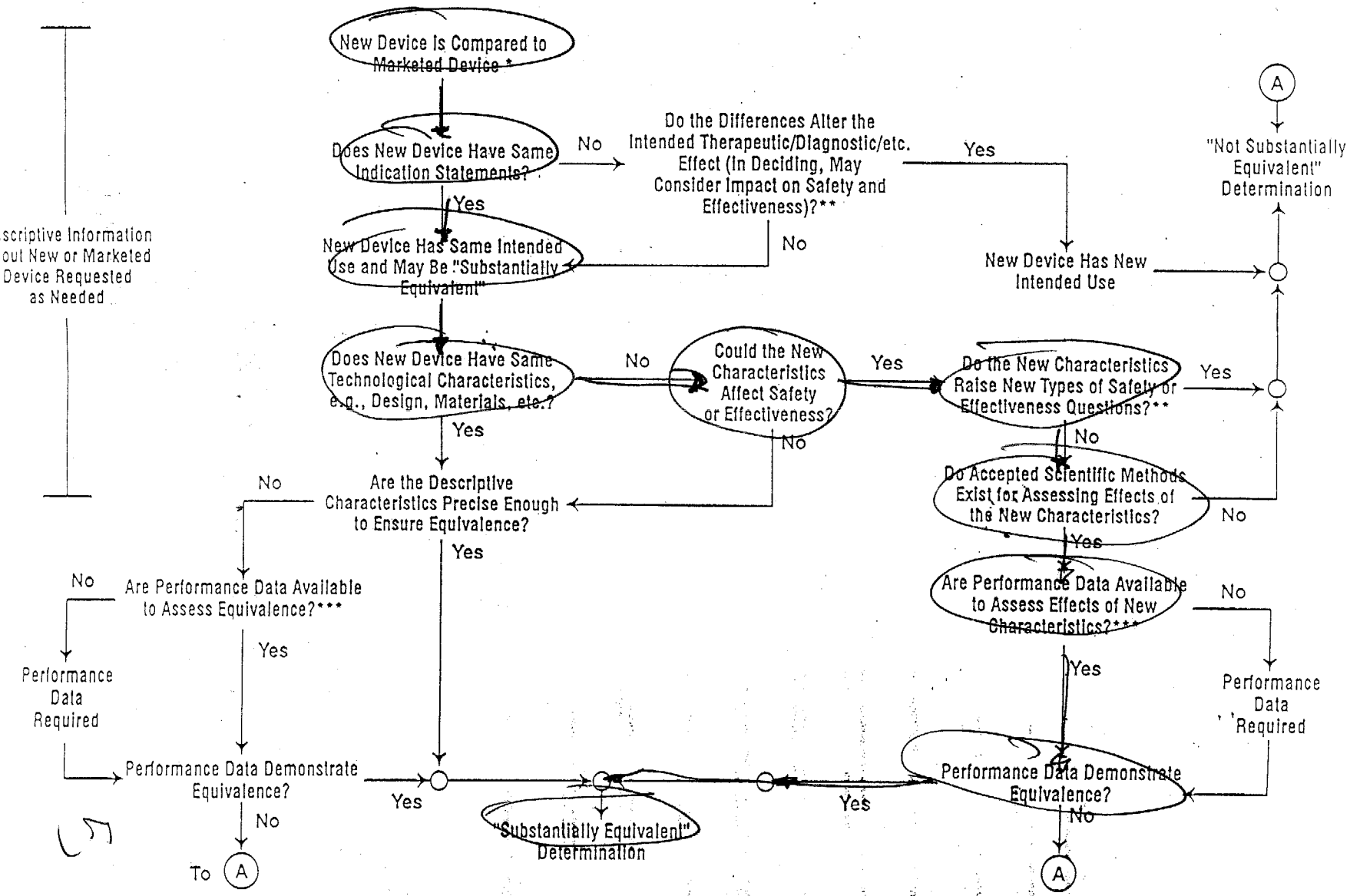
Additional Product Code(s) with panel (optional):

Review: [signature] (Branch Chief) ORDB (Branch Code) 6-28-01 (Date)

Final Review: DSMT [illegible] for CMW 7/2/01 (Division Director) (Date)

Revised:8/17//99

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



* 510(k) Submissi[illegible] pare New Devices to Marketed Devices. FDA Requests Additional Infor[illegible] the Relationship Between Marketed and "Predicate" (Pre-Amendments or Reclassified Post-Amendments) Devices Is Unclear.

** This Decisio[illegible] mally Based on Descriptive Information Alone, But Limited Tes[illegible] ormation Is Sometimes Required.

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

Screening Checklist
For all Premarket Notification 510(k) Submissions

3-30-01

Device Name: M2a Acetabular System | K 011110

Submitter (Company): Biomet, Inc

Items which should be included (circle missing & needed information)	SPECIAL YES	SPECIAL NO	ABBREVIATED YES	ABBREVIATED NO	TRADITIONAL YES	TRADITIONAL NO	✓ IF ITEM IS NEEDED AND IS MISSING
1. Cover Letter clearly identifies Submission as: a) "Special 510(k): Device Modification" b) "Abbreviated 510(k)" c) Traditional 510(k)	GO TO # 2,3		GO TO # 2,4,5		X GO TO #2, 5		

2. GENERAL INFORMATION: REQUIRED IN ALL 510(K) SUBMISSIONS	SPECIALS YES	SPECIALS NO	ABBREVIATED YES	ABBREVIATED NO	TRADITIONAL YES	TRADITIONAL NO	✓ IF ITEM IS NEEDED AND IS MISSING
Financial Certification or Disclosure Statement for 510(k)s with a Clinical Study 807.87(i) including forms 3454 and/or 3455	NA		YES		NO		
a) trade name, classification name, establishment registration number, device class					X		
b) OR a statement that the device is not yet classified	FDA-may be a classification request; see coordinator						
c) identification of legally marketed equivalent device	NA				X		
d) compliance with Section 514 - performance standards	NA				X		
e) address of manufacturer					X		
f) Truthful and Accurate Statement					X		
g) Indications for Use enclosure					X		
h) SMDA Summary or Statement *(FOR ALL DEVICE CLASSES)*					X		
i) Class III Certification & Summary *(FOR ALL CLASS III DEVICES)*					X		
j) Description of device (or modification) including diagrams, engineering drawings, photographs, service manuals					X		
k) Proposed Labeling:					X		
i) package labeling (user info)					X		
ii) statement of intended use					X		
iii) advertisements or promotional materials					X		
i) MRI compatibility (if claimed)					X		
l) Comparison Information (similarities and differences) to named legally marketed equivalent device (table preferred) should include:					X		
i) Labeling					X		
ii) intended use					X		
iii) physical characteristics					X		
iv) anatomical sites of use					X		
v) performance (bench, animal, clinical) testing	NA				X		
vi) safety characteristics	NA				X		
m) If kit, kit certification					X		

3. "SPECIALS" - ONLY FOR MODIFICATIONS TO MANUFACTURER'S OWN CLASS II, III OR RESERVED CLASS I DEVICE				
a) Name & 510(k) number of legally marketed (unmodified) predicate device				
b) *STATEMENT - INTENDED USE AND INDICATIONS FOR USE OF MODIFIED DEVICE AS DESCRIBED IN ITS*			* If no - STOP not a special	

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

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

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

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

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

Passed Screening ✓ **Yes** _____ **No**
Date: 5/27/01

Reviewer: Glenn Sherman
Concurrence by Review Branch:

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

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

April 11, 2001

BIOMET, INC.
P.O. BOX 587
WARSAW, IN 46581
ATTN: MICHELLE L. MCKINLEY

510(k) Number: K011110
Received: 11-APR-2001
Product: M2A ACETABULAR SYSTEM

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

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

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

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

Sincerely yours,

Marjorie Shulman
Consumer Safety Officer
Premarket Notification Staff
Office of Device Evaluation
Center for Devices and Radiological Health

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K011110

BIOMET

CORPORATE HEADQUARTERS

March 30, 2001

Document Mail Center (HFZ-401)
Center of Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20856

RE: 510(k) Premarket Notification
M2a™ Acetabular System

Dear Sir or Madam:

Enclosed is a 510(k) notification for the M2a™ Acetabular System. We feel this device is substantially equivalent* to other devices on the market.

The sponsor of this 510(k) considers the existence of this notification confidential until a determination of substantial equivalence is made.

Sincerely,

Michelle L. McKinley

Michelle L. McKinley
Regulatory Specialist

FDA/CDRH/ODE/DHC
2 30 PM '01

* Any statement in conjunction with this submission regarding and/or determination of substantial equivalence to any other product is intended only to relate to whether the product can be lawfully marketed without premarket approval or reclassification and is not intended to be interpreted as an admission or any other type of evidence in patent infringement litigation. [Establishment Registration and Premarket Notification Procedures, Final Regulation, Preamble, August 23, 1997, 42 FR4520 (docket No. 76N-0355)].

SK33 OR

MAILING ADDRESS
P.O. Box 587
Warsaw, IN 46581-0587

SHIPPING ADDRESS
56 E. Bell Drive
Warsaw, IN 46582

OFFICE
219.267.6639

FAX
219.267.8137

E-MAIL
biomet@biomet.com

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PREMARKET NOTIFICATION

TRUTHFUL AND ACCURATE STATEMENT
(As Required by 21 CFR 807.87 (j))

I certify, in my capacity as Vice President of Regulatory Affairs and Quality Assurance, Biomet, Inc., I believe to the best of my knowledge that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

Typed Name

April 9, 2001
Date

M2a™ Acetabular System

Device

PREMARKET NOTIFICATION

TRUTHFUL AND ACCURATE STATEMENT
(As Required by 21 CFR 807.87 (j))

I certify, in my capacity as Development Engineer of Biomet Manufacturing Corp., I believe to the best of my knowledge that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

Typed Name

4-9-2001
Date

M2a™ Acetabular System

Device

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510(k) Number if Known: _____
Device Name: M2a™ Acetabular System

The M2a™ Acetabular System is indicated for used in patients requiring total hip replacement due to the following:

a.) Non-inflammatory degenerative joint disease including avascular necrosis, diastrophic variant, fracture of the pelvis, fused hip, leg perthes, 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.) Revision of previously failed total hip arthroplasty.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____ (Per CFR 801.109) or Over the Counter Use_____ (Optional Format 1-2-96)

510(k) Notification

A. ADMINISTRATIVE INFORMAITON

Applicant or Sponsor: Biomet, Inc.
P.O. Box 587
Warsaw, Indiana 46581-0587

Contact Person: Michelle L. McKinley
Phone: (219) 267-6639
Fax: (219) 372-1683

Manufacturing Site(s):
Specification holder:
Biomet Manufacturing, Corp.
56 Bell Drive
Warsaw, Indiana 46582
Establishment Registration Number: 1825034

Manufacturer/Contract Manufacturer:
Biomet Manufacturing, Corp.
56 Bell Drive
Warsaw, Indiana 46582
Establishment Registration Number: 1825034

Contract Sterilizer(s):

Sterigenics International
305 Enterprise Drive
Westerville, OH 43081
Registration Number: 1526534

Isomedix, Inc (previously RSI)
1880 Industrial Drive
Libertyville, IL 60048
Registration Number: 1450662

B. DEVICE IDENTIFICATION

Proprietary Name: M2a™ Acetabular System

Common or Usual Name: Acetabular component

Classification Name: Hip joint metal/metal semi-constrained, with an uncemented acetabular component, prosthesis (888.3330)

Device Classification: Pre-Amendment Class III

Device Product Code: 87 KWA

Performance Standards: No Performance Standards have been developed for this type of device.

Previous FDA Status: M2a™ 28mm Acetabular System: K993438, M2a™ 28mm Ringloc® Acetabular System: K002379, M2a™ 32mm Acetabular System: K003363

C. DEVICE DESCRIPTIVE INFORMATION

Intended Use: The M2a™ Acetabular System is indicated for use in patients requiring total hip replacement due to the following:

a.) Non-inflammatory degenerative joint disease including avascular necrosis, diastrophic variant, fracture of the pelvis, fused hip, leg perthes, 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.) Revision of previously failed total hip arthroplasty.

Device Description

A complete listing of component sizes and configurations along with engineering drawings are presented in

Materials

Labeling

A sample of the proposed package label can be found in

Sterility Information

The device is provided sterile by radiation as follows:

Radiation Type: Gamma
Radiation Source: Cobalt 60
Minimum Dose: 2.5 Megarads

Table I: Mean Total Wear Comparison

Mean Total Wear (mm^3)	2.2 at 3 million cycles	1.5 at 5 million cycles	0.7 at 5.5 million cycles

C. Clinical Relevance

A literature search was completed and supports the following two claims regarding change in clinical outcome:

1. Variation in diameter does not change the clinical outcome
2. Wear simulator results showing less wear with a 38mm metal articulation predicts good clinical outcomes.

In addition to the literature, design analysis was used to verify the similarity between the contact stresses and contact areas for the 28mm, 32mm, and 38mm metal articulations. Based on this information, the 28mm, 32mm, and 38mm diameter articulations are equivalent and predict similar *in vivo* wear mechanisms. Please refer to Exhibit V, which contains copies of the reported literature as well as a comparison of articulation of the M2a™ Hip Simulator Results and a design analysis of the contact stresses for the M2a™ metal articulations.

Summary of Safety and Effectiveness

Exhibit VI contains a summary of safety effectiveness pertaining to the M2a™ Acetabular System.

Class III Certification and Summary

Exhibit VII contains the Class III Certification and Summary for the M2a™ Acetabular System.

Tyvek® is a registered trademark of E.I. DuPont de Nemours and Company
M2a™ is a trademark of Biomet Orthopedics, Inc.

SAMPLE LABEL

REF. 11-173660 LOT 123123

M2A(TM) MODULAR HEAD COMPONENT
38 MM HEAD DIAMETER
MINUS 6 MM NECK

TYPE I TAPER/METAL ON METAL
CO-CR-MO ALLOY

LOT 123123 QTY. 1

BIOMET ORTHOPEDICS, INC.
56 EAST BELL DRIVE
P.O. BOX 587
WARSAW, IN 46581 USA

STERILE
2001-03

REF. 15-105048 LOT 123123

M2A(TM) ONE-PIECE ACETABULAR CUP
38 MM X 48 MM CUP / POROUS COAT

CO-CR-MO ALLOY / TI 6AL 4V ALLOY
WARNING: USE WITH M2a MODULAR
HEADS 11-173660/66 ONLY

LOT 123123 QTY 1

BIOMET ORTHOPEDICS, INC.
56 EAST BELL DRIVE
P.O. BOX 587
WARSAW, IN 46581 USA

STERILE
2001-03

Biomet Orthopedics, Inc.
56 East Bell Drive
P.O. Box 587
Warsaw, Indiana 46581 USA

01-50-0960
Date: 3/01

Biomet M2[a]

ATTENTION OPERATING SURGEON

Description:

The Biomet metal on metal Hip Joint Replacement Prosthesis is intended for use in primary and revision hip joint replacement procedures. The metal liners are intended for use with specific metal on metal femoral articulating heads. The specialized femoral heads and metal on metal liners are to be used with Biomet primary and revision femoral components.

Materials:

Femoral Heads	CoCrMo Alloy
One Piece Cup	CoCrMo Alloy
Porous Coating	Titanium Alloy

Indications:

1) Noninflammatory degenerative joint disease including avascular necrosis, diastrophic variant, fracture of the pelvis, fused hip, leg perthes, osteoarthritis, slipped capital epiphysis, subcapital fractures, and traumatic arthritis.
2) Rheumatoid arthritis
3) Correction of functional deformity
4) Treatment of non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques.
5) Revision total hip arthroplasty.

Patient selection factors to be considered include: 1) need to obtain pain relief and improve function, 2) ability and willingness of the patient to follow instructions, including control of weight and activity level, 3) a good nutritional state of the patient, and 4) the patient must have reached full skeletal maturity.

Porous coated devices are marketed for non-cemented use in the United States for skeletally mature patients undergoing primary hip replacement surgery as a result of non-inflammatory degenerative joint disease.

Contraindications:

Absolute contraindications include: infection, sepsis, and osteomyelitis.
Relative contraindications include 1) uncooperative patient or patient with neurologic disorders who are incapable of following directions, 2) osteoporosis, 3) metabolic disorders which may impair bone formation, 4) osteomalacia, 5) distant foci of infections which may spread to the implant site, 6) rapid joint destruction, marked bone loss or bone resorption apparent on roentgenogram, 7) vascular insufficiency, muscular atrophy, or neuromuscular disease.

Warnings:

Improper selection, placement, positioning, alignment and fixation of the implant components may result in unusual stress conditions which may lead to subsequent reduction in the service life of the prosthetic components. Malalignment of the components or inaccurate implantation may lead to excessive wear and/or failure of the implant or procedure. Inadequate preclosure cleaning (removal of surgical debris) may lead to excessive wear. Use clean gloves when handling implants. Laboratory testing indicates that implants subjected to body fluids, surgical debris, or fatty tissue have lower adhesion strength to cement than implants handled with clean gloves. Improper preoperative or intraoperative implant handling or damage (scratches, dents, etc.) may lead to crevice corrosion, fretting, fatigue fracture, and/or excessive wear. Do not modify implants.

The surgeon is to be thoroughly familiar with the implants and instruments, prior to performing surgery.

1. Use Biomet metal on metal acetabular liners with specified Biomet metal on metal femoral heads.
2. Firmly seat modular head components to prevent dissociation. Thoroughly clean and dry taper prior to attachment of the modular head component to avoid crevice corrosion and improper seating.
3. Tight fixation of all non-cemented components at the time of surgery is critical to the success of the procedure. Each component must properly press fit into the host bone which necessitates precise operative technique and the use of specified instruments. Bone stock of adequate quality must be present and appraised at the time of surgery.
4. Perforation entirely through the pelvic bone with rim screws is to be completely avoided. Caution is to be used when determining and selecting the length of screws to be used, as perforation through the pelvic bone with screws that are too long may cause damage to body structures (blood vessels, etc.) located on the interior side of the pelvis.
5. Care is to be taken to assure complete support of all parts of the device embedded in bone cement to prevent stress concentrations, which may lead to failure of the procedure. Complete preclosure cleaning and removal of bone cement debris, metallic debris and other surgical debris at the implant site is critical to minimize wear of the implant articular surfaces. Implant fracture due to cement failure has been reported.

Biomet joint replacement prostheses provide the surgeon with a means of reducing pain and restoring function for many patients. While these devices are generally successful in attaining these goals they cannot be expected to withstand the activity levels and loads of normal healthy bone and joint tissue.

Accepted practices in postoperative care are important. Failure of the patient to follow postoperative care instructions involving rehabilitation can compromise the success of the procedure. The patient is to be advised of the limitation of the reconstruction and the need for protection of the implants from full load bearing until adequate fixation and healing have occurred. Excessive activity, trauma and weight have been implicated with premature failure of the implant by loosening, fracture, and/or wear. Loosening of the implants may result in increased production of wear particles, as well as accelerate damage to bone making successful revision surgery more difficult. The patient is to be made aware and warned of general surgical risks, possible adverse effects as listed, and to follow the instructions of the treating physician including follow-up visits.

Precautions:

Specialized instruments are designed for Biomet joint replacement systems to aid in the accurate implantation of the prosthetic components. The use of instruments or implant components from other systems may result in inaccurate fit, sizing, excessive wear and device failure. Intraoperative fracture or breaking of instruments has been reported. Surgical instruments are subject to wear with normal usage. Instruments, which have experienced extensive use or excessive force, are susceptible to fracture. Surgical instruments should only be used for their intended purpose. Biomet recommends that all instruments be regularly inspected for wear and disfigurement.

Do not reuse implants. While an implant may appear undamaged, previous stress may have created imperfections that would reduce the service life of the implant. Do not treat patients with implants that have been, even momentarily, placed in a different patient.

Possible Adverse Effects:

1. Material sensitivity reactions. Implantation of foreign material in tissues may result in histological reactions involving various sizes of macrophages and fibroblasts. The clinical significance of this effect is uncertain, as similar changes may occur as a precursor to or during the healing process. Particulate wear debris and discoloration from metallic and polyethylene components of joint implants may be present in adjacent tissue or fluid. It has been reported

that wear debris may initiate a cellular response resulting in osteolysis or osteolysis may be a result of loosening of the implant.

2. Early or late postoperative, infection, and allergic reaction.
3. Intraoperative bone perforation or fracture may occur, particularly in the presence of poor bone stock caused by osteoporosis, bone defects from previous surgery, bone resorption, or while inserting the device.
4. Loosening or migration of the implants may occur due to loss of fixation, trauma, malalignment, bone resorption, excessive activity.
5. Periarticular calcification or ossification, with or without impediment of joint mobility.
6. Inadequate range of motion due to improper selection or positioning of components.
7. Undesirable shortening of limb.
8. Dislocation and subluxation due to inadequate fixation and improper positioning. Muscle and fibrous tissue laxity may also contribute to these conditions.
9. Fatigue fracture of component may occur as a result of loss of fixation, strenuous activity, malalignment, trauma, non-union, or excessive weight.
10. Fretting and crevice corrosion may occur at interfaces between components.
11. Wear and/or deformation of articulating surfaces.
12. Trochanteric avulsion or non-union as a result of excess muscular tension, early weight bearing, or inadequate reattachment.
13. Problems of the knee or ankle of the affected limb or contralateral limb aggravated by leg length discrepancy, too much femoral medialization or muscle deficiencies.
14. Intraoperative or postoperative bone fracture and/or postoperative pain.
15. Metal on metal articulating surfaces have limited clinical history. Although mechanical testing demonstrates that metal on metal articulating surfaces produce a relatively low amount of particles, the total amount of particulate produced remains undetermined. Because of the limited clinical and preclinical experience, the long-term biological effects of the particulate are unknown.

Sterility:

Prosthetic components are sterilized by exposure to a minimum dose of 25 kGy of gamma radiation. Do not resterilize. Do not use after expiration date.

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

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20-Year Results of McKee-Farrar Versus Charnley Prosthesis

Sven-Arne Jacobsson, MD; Krister Djerf, MD; and Ola Wahlström, MD

The results of 107 consecutive McKee-Farrar and 70 Charnley total hip arthroplasties performed in 169 patients between 1975 and 1976 are reviewed. At an average followup of 20 years (range, 19–21 years), 29 patients with 20 McKee-Farrar and 11 Charnley prostheses were available for clinical and radiologic evaluation; 102 patients (107 hips) had died, 3 patients were lost to followup, and 5 patients (6 hips) were unavailable for review because of medical problems. There were 5 revisions for sepsis and 1 Girdlestone procedure for recurrent dislocation. Sixteen McKee-Farrar and 8 Charnley prostheses were revised for aseptic loosening, giving a 20-year aseptic probability of survival of 77% and 73%, respectively. Radiographic signs of loosening were present in 52% of the surviving prostheses. Clinical scores showed weak correlation with the radiographic loosening in both groups, and 18 McKee-Farrar and 8 Charnley prostheses were still considered satisfactory by the patients. The mean annual linear polyethylene wear was 0.12 mm. Osteolytic lesions were observed in association with 2 McKee-Farrar and 5 Charnley prostheses in surviving hips. The long term results of the McKee-Farrar prosthesis are comparable with those of the low friction arthroplasty in this series. Wear of the polyethylene bearing and accumulation of polyethylene particles in the periprosthetic tissue may become an increasing problem. Second generation all metal implants seem to be worth considering in patients with long life expectancy.

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During the 1960s, McKee and Watson-Farrar developed a metal on metal hip joint prosthesis made of a CoCr alloy.[17] Large numbers of this system were used as an alternative to Charnley's metal on polyethylene prosthesis. By the mid1970s the low friction arthroplasty principles became dominant and the all metal systems were abandoned, although their design inferiority was never proven in a prospective randomized study. Thirty years later, with an increasing number of reports implicating polyethylene debris as a major contributor to periprosthetic osteolysis,[22] the metal on metal concept has regained interest and second generation all metal implants have been introduced.[19,26]

In 2 previous studies, the results of arthroplasties using McKee-Farrar and Charnley replacements were prospectively compared. No major differences in loosening or revision were found at 5 and 12 years.[8,13] The aim of the present study was to evaluate the long term performance of these 2 types of total hip replacements after approximately 20 years.

MATERIALS AND METHODS

The series was comprised of 177 consecutive total hip arthroplasties in 169 patients who were observed for 20 years (range, 19–21 years). They

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were performed at the authors' institution during a 2-year period from 1975 to 1976. The choice of prosthesis depended on the surgeon's preference. Details of the patients' gender, age, and diagnosis are shown in Table 1.

The McKee-Farrar (Howmedica International Inc, Limerick, Ireland) prosthesis had been in regular use since 1972, and the Charnley (Chas. F. Thackray Ltd, Leeds, United Kingdom) system was introduced in 1974. The operations were performed with the patient under general anesthesia. Prophylaxis against infection was not routine at the time, and 23 patients (13%) received no antibiotics. The operative techniques were similar to those described by McKee and Watson-Farrar[17] and by Charnley.[6] A dorsolateral approach was used for the McKee-Farrar prostheses and a lateral approach with osteotomy of the greater trochanter was used for Charnley prostheses. The procedures were performed by 8 surgeons experienced in arthroplasty. High viscosity cement (CMW Laboratories Ltd, Blackpool, United Kingdom) was used without a cement gun and without distal femoral plugging.

The patients were observed annually for the first 5 years and at approximately 12 and 20 years postoperatively. Serial clinical assessments were made using the Harris hip score.[11] At an average followup of 20 years (range, 19–21 years), 29 patients with 20 McKee-Farrar and 11 Charnley implants were available for evaluation. The average followup period for the McKee-Farrar group was 20 years (range, 20–21 years) and for the Charnley group, 19 years (range, 19–20 years). One hundred two patients (107 hips) had died with their prosthesis still functioning at an average of 11 years (range, 2–20 years) from the index operation. Three patients with 3 McKee-Farrar prostheses were lost to followup. Five patients (4 McKee-Farrar, 2 Charnley) were unavailable for review because of medical problems. Nineteen McKee-Farrar and 11 Charnley prostheses were revised because of mechanical failure or sepsis (Fig 1).

Radiographic evaluation was made using standard projections (anteroposterior [AP] and lateral). Linear polyethylene wear was measured on the AP view and the 22.25-mm head was used for correction of magnification.[28] Wear of the McKee-Farrar prosthesis could not be assessed radiographically. The occurrence of ectopic bone and localized osteolysis (scalloping) was recorded. Loosening was defined as an extensive bone cement interface radiolucency greater than 2 mm in width, any radiolucency between cement and stem, or gross migration of the cup or stem.[24]

Survivorship analysis of the prostheses was performed according to Armitage[3] and Dobbs[9] and revision for aseptic loosening was defined as the end point. This analysis is based on the assumption that patients who withdraw from followup have the same probability of failure as patients who are observed, and that the probability of survival for each time interval remains constant with time.

The statistical methods applied were simple regression analysis, Student's t test for continuous variables, Fisher's exact test for discrete variables, and the log rank test for the survival study. Differences were considered significant when p was less than 0.05, and, unless otherwise stated, values are expressed as means ± standard deviation.

TABLE 1. Data on the Series of 169 Patients

	Preoperatively		12 Year Followup		20 Year Followup	
Parameter	*McKee-Farrar (n = 102)*	*Charnley (n = 67)*	*McKee-Farrar (n = 51)*	*Charnley (n = 39)*	*McKee-Farrar (n = 18)*	*Charnley (n = 11)*
Men (%)	45	52	37	48	39	27
Women (%)	55	48	63	52	61	73
Age (years)	66 ± 8	68 ± 8	75 ± 9	76 ± 7	81 ± 9	80 ± 6
Osteoarthritis (%)	76	85				
Rheumatoid arthritis (%)	11	6				
Fracture (%)	13	9				

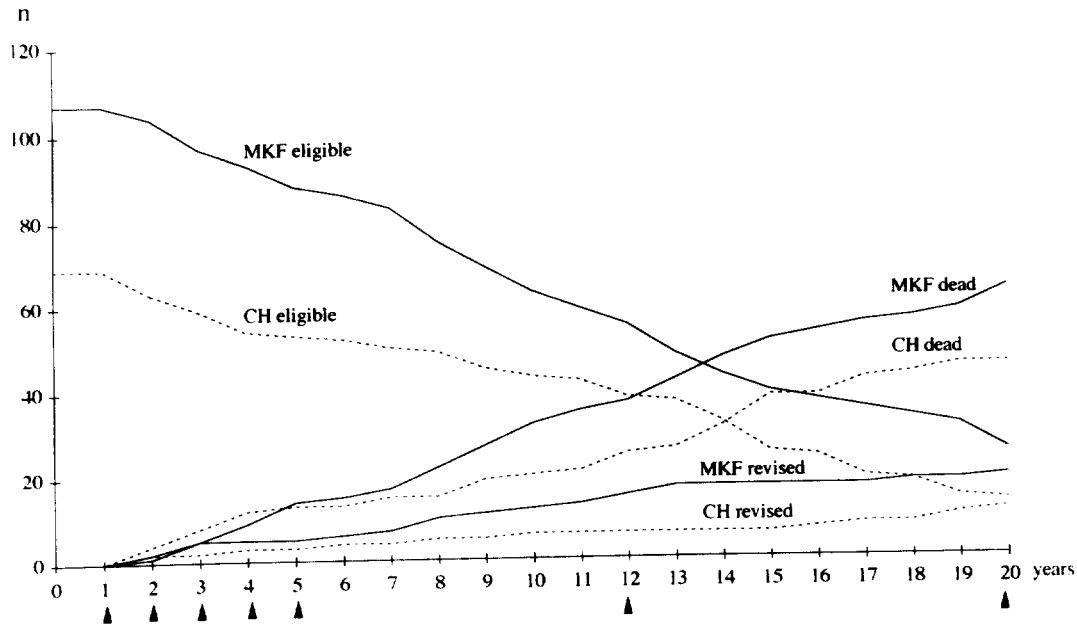

Fig 1. The number of patients who were eligible, who were dead, and who underwent revision in the 2 groups during the period of observation. MKF = McKee-Farrar; CH = Charnley.

RESULTS

Complications

Complications are shown in Table 2. Primary deep infection developed in 4 patients (2 McKee-Farrar and 2 Charnley implant) who had not received antibiotic prophylaxis. Late hematogenous infection occurred in 2 patients (1 McKee-Farrar and 1 Charnley implants). In 4 of these patients the implant was successfully replaced by a new implant fixed with gentamicin impregnated cement. In 1 patient, healing took place 6 months after lavage, drainage, and antibiotic therapy. In the sixth patient, 2, 1-stage exchange procedures failed, and finally a Girdlestone proce-

TABLE 2. Complications

Complication	McKee-Farrar (n = 107)		Charnley (n = 70)		Total (n = 177)	
	%	n	%	n	%	n
Deep infection	2.8	3	4.3	3	3.4	6
Deep venous thrombosis	0	0	4.3	3	1.7	3
Pulmonary embolus	0	0	1.4	1	0.6	1
Trochanter related pain	0	0	7.1	5	2.8	5
Fracture during operation	0.9	1	0	0	0.6	1
Nerve damage	1.9	2	1.5	1	1.7	3
Dislocation	2.8	3	1.4	1	2.3	4
Ectopic bone with stiffness and pain	0	0	1.4	1	0.6	1
Total**	8.4	9	21.4	15	13.7	24

*p = 0.008.

**p = 0.11.

dure was performed. One patient with a Charnley prosthesis had recurrent dislocations 18 years after the index procedure and, because of poor medical and mental conditions, was treated with a Girdlestone procedure. The patients who had the McKee-Farrar implant had less complications ($p < 0.05$). If patients with trochanter problems are excluded from the Charnley group, however, no significant difference emerged.

Clinical Evaluation

The Harris hip scores at 12- and 20-year followup are shown in Table 3. Only occasional pain or no pain (40–44 points) was reported in 16 of 20 patients who had the McKee-Farrar prostheses and in 7 of 11 of the patients who had the Charnley prostheses. Patients with a loose component scored 72 ± 15 points, whereas those with well fixed components scored 80 ± 14 points. The correlation between these clinical scores and the radiographic findings was not statistically significant ($p = 0.16$). Twenty-six of 31 hips (84%) were reported by the patients as still satisfactory.

At last followup the patients who were reviewed were still highly independent of social care, 28 living in their own household and only 1 living in a nursing home. Twenty-two patients managed without domestic help, whereas 7 were dependent in a varying degree on social workers. Seventeen patients were granted community transportation aid.

Aseptic Revisions

There were 24 revisions due to aseptic loosening during the study period, 16 McKee-Farrar and 8 Charnley prostheses in 9 male and 15 female patients. Twelve cups and 12 stems were recorded as loose in the McKee-Farrar group. Four cups and 8 stems of the Charnley prosthesis were loose according to the surgical records. No black discoloring of the periprosthetic tissues was described among the McKee-Farrar prosthesis revisions. Localized osteolysis was seen on the preoperative radiographs around 2 Charnley stems and around 1 McKee-Farrar stem.

Radiography

At the 12-year followup, signs of loosening of either the cup or stem were observed in 32% of the hips (13 females and 17 males). After 20 years, this figure had increased to 52% (7 females and 9 males). In the McKee-Farrar implant group, 5 cups and 6 stems in 11 hips were considered loose. The corresponding figures in the Charnley implant group were 4 cups and 4 stems in 5 hips. Scalloping in various degrees on the femoral side was observed in 5 of 11 of the Charnley prostheses compared with 2 of 20 in the McKee-Farrar group. The osteolytic areas were more extensive in the Charnley implant group. In all these 7 cases the cup or the stem or both showed signs of loosening. There were no localized osteolytic lesions seen radiographically on the acetabular side. The mean annual linear wear of the Charnley cup was 0.12 mm (range, 0.07–0.37 mm) (Figs 2, 3).

Varus position (> 5°) was noted in 6 of 20 of the McKee-Farrar stems and in 1 of 11 of the Charnley stems. Five of these were considered loose. Patients with a stable McKee-Farrar prosthesis had a mean lateral opening of the ac-

TABLE 3. Clinical Results Assessed With the Harris Hip Score 12 and 20 Years Postoperatively

	McKee-Farrar		Charnley		Total	
Score	*12 year*	*20 year*	*12 year*	*20 year*	*12 year*	*20 year*
Harris hip score pain score	39 ± 7	40 ± 7	39 ± 9	37 ± 8	39 ± 8	39 ± 7
Harris hip score (total)	82 ± 12	75 ± 15	83 ± 17	77 ± 15	82 ± 13	76 ± 15

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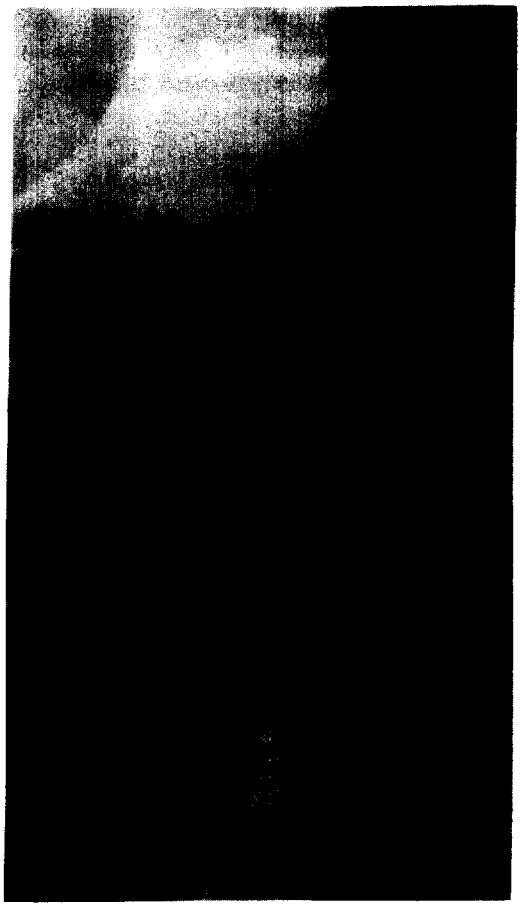


Fig 2. The McKee-Farrar prosthesis after 20 years of use in a woman with excellent clinical (97 points) and radiographic results at the long term followup.

etabular component of 34° ± 5°. Those who had undergone revision surgery or showed radiographic signs of loosening had a more vertically placed cup, 41° ± 8°, p = 0.029 (unpaired Student's t test). The corresponding figures for the Charnley implant group were 43° ± 4° and 46° ± 7° respectively (p = 0.398).

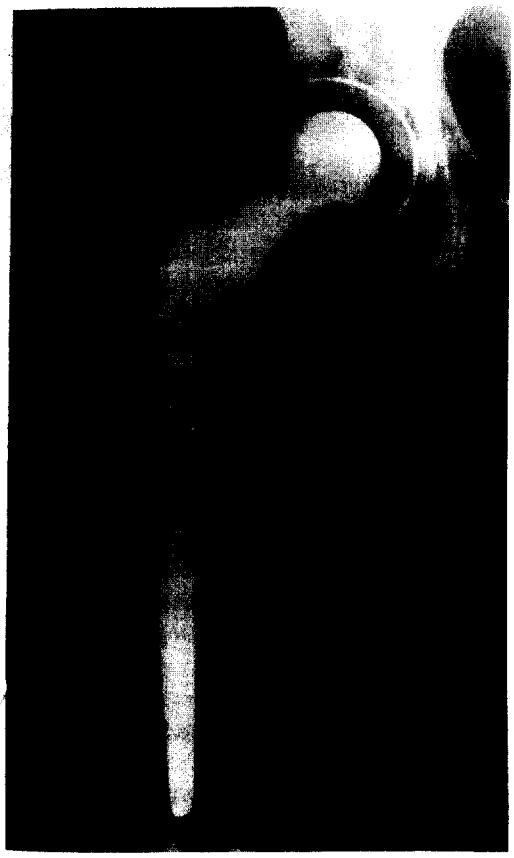
There was a significant difference between the preoperative weight of the patients who had a loose component or who had undergone revision surgery because of aseptic loosening and the patients who had a stable implant at the 20-year followup, 76 ± 12 kg and 67 ± 13 kg, respectively (p = 0.012). The mean age in the failure group was 62 ± 8 years and in the stable group it was 63 ± 6 years. There were 22 hips in women and 18 hips in men in the failure group. In the stable group there were 13 hips in women and 2 hips in men (Table 4).

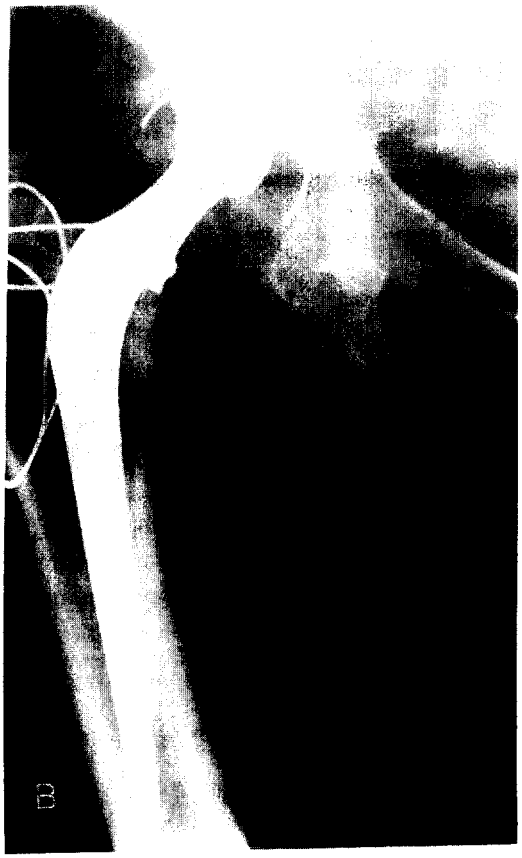
Survivorship Analysis

Comparative survivorship analysis of the 2 groups at 20 years showed 77% aseptic survival for the McKee-Farrar and 73% for the Charnley prostheses (Table 5). This difference was not significant. Survival in patients with a primary diagnosis of osteoarthritis was 81% and 73%, respectively. The cumulative probability of aseptic survival at 20 years in the entire series was 69% for patients younger than 65 years of age and 84% for patients 65 years of age or older.

DISCUSSION

The prosthetic survival of metal on metal arthroplasties varies from 53% to 89% at 10 to 15 years.[2,4,9,25] The survival of low friction arthroplasties with a similar observation time ranges from 89% to 98%.[7,10,15,21,23,27] However, to the authors' knowledge, there are no comparative studies that prove the superiority of the Charnley prosthesis over the McKee-Farrar prosthesis. The 2 systems differ in more than 1 respect: the bearing surface, head diameter, stem design, and implantation technique. These differences make comparison and interpretation of results difficult tasks. In this study, the 20-year cumulative probability of aseptic survival was 77% for the McKee-Farrar prosthesis and 73% for the Charnley prosthesis. Jantsch et al[14] reported a McKee-Farrar implant revision rate of 18% at a mean followup of 14 years. Kreusch-Brinker[16] had 20% revisions in his series of McKee-Farrar prostheses followed for 11 to 18 years (mean, 13 years). No survivorship analyses were performed. Ahnfelt et al[1] reported on revisions of total hip replacements in Sweden during 1968 to 1979, with a cumulative survival rate of 92% (10 years) in Charnley prostheses. The





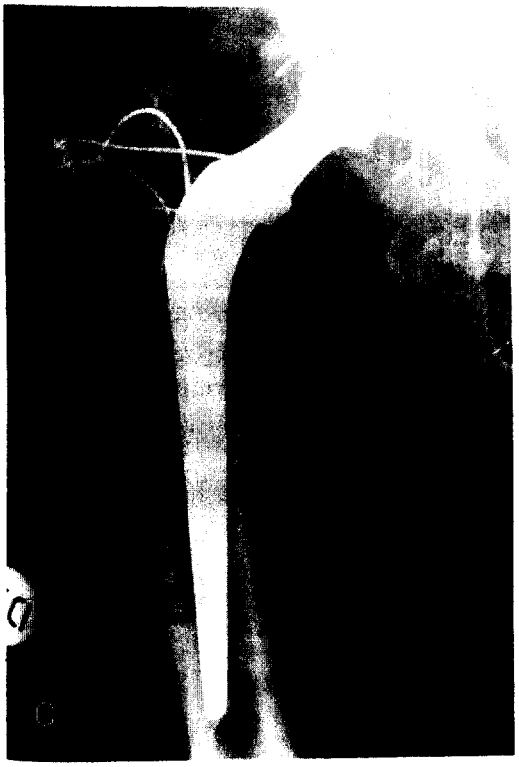


Fig 3A–C. The Charnley prosthesis with a recorded annual polyethylene wear of 0.37 mm in a women who was 54 years of age at the time of operation and who had Harris hip score of 97 points at the 20-year followup. Both components had migrated during the study period and were considered loose. Only minor osteolytic lesions were seen in the calcar area. Radiographs at (A) postoperative, (B) 11-year followup, and (C) 20-year followup.

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TABLE 4. Revised and Examined Hips Divided as to Diagnosis, Gender, and Age

Parameter	McKee-Farrar			Charnley		
	Revised	*Loose*	*Stable*	*Revised*	*Loose*	*Stable*
Osteoarthritis	11	9	9	7	4	6
Rheumatoid arthritis	3	1	—	—	—	—
Fracture	2	1	—	1	1	—
Male	7	6	2	2	3	—
Female	9	5	7	6	2	6
<65 years	8	8	4	6	5	4
≥65 years	8	3	5	2	—	2

McKee-Farrar prosthesis had a total revision rate of 10% (250 of 2510) and the Charnley prosthesis, 4% (971 of 24,499).

From the results reported here it cannot be concluded whether the Charnley concept is to be preferred in favor of the McKee-Farrar total hip replacement. However, a difference was found as to the occurrence of localized osteolysis, though not statistically significant. The osteolytic lesions tended also to be more extensive in the metal on plastic prostheses. Particulate debris has been a topic for extensive research during the past 10 years. Polyethylene, polymethylmethacrylate, and metal wear debris have been implicated in periprosthetic osteolysis. As many as 500,000 submicron polyethylene wear particles have been calculated to be generated during each step taken.[18] In the current series, a linear wear rate of 0.12 mm per year of the polyethylene is recorded, which is in line what other authors have reported.[12,28] The wear rate of metal to metal has been measured to be 100 times less than that of metal on plastic.[14] The absence of macroscopic metallic debris in the periprosthetic tissues in the current series is corroborated by the findings of Jantsch et al[14] who noted metallic staining in only 1 of 36 revisions. It may be that the total production of wear particles of the McKee-Farrar prosthesis is lower and therefore gives rise to less foreign body reactions or that metal ions can be removed more easily than polyethylene particles.

At the 12-year review ⅓ of the surviving implants were recorded as radiographically loose. Eight years later, ½ of the replacements were classified as loose with no major differences between the 2 types of prostheses. High rates of radiographic loosening were also observed by Jantsch et al[14] in their series of metal on metal prostheses, and in a series of low friction, metal on plastic arthro-

TABLE 5. Cumulative Probability of Prosthetic Survival (%) in the 2 Groups of Prostheses, in Patients With Osteoarthritis, and in Different Age Groups

Followup (year)	5	10	15	20
McKee-Farrar	98 (3)	88 (8)	82 (12)	77 (18)
Charnley	98 (3)	93 (8)	89 (12)	73 (25)
McKee-Farrar osteoarthritis	96 (5)	88 (9)	85 (12)	81 (17)
Charnley (osteoarthritis)	96 (5)	94 (7)	90 (12)	73 (26)
<65 years (McKee-Farrar and Charnley)	96 (5)	83 (12)	80 (14)	69 (19)
≥65 years (McKee-Farrar and Charnley)	97 (3)	95 (5)	89 (10)	84 (19)

95% Confidence limits are in parentheses.

plasties studied by Wejkner et al.[27] Of the 30 hips at risk for revision at the 12-year review, only 7 have been revised. The patients with the other 23 hips have not been subjected for any operative consideration because of mild or no symptoms, death, or poor general health. Although there are series reporting successful revision surgery on octogenarians[5] this must be considered highly risky, which deters both surgeon and patient from such procedures. The variation in policy between hospitals will, therefore, greatly influence the revision rate in each center. Despite having a loose implant many of the patients seem to manage their daily activities without disabling pain.

In contrast to the findings at the 12-year followup,[13] weight seemed to influence the 20-year outcome. Other risk factors that may have promoted loosening were varus positioning of the stem and more vertical placement of the acetabular component. The Harris hip score seems to be a poor indicator of impending implant failure, at least in this group of patients with reduced activity level and/or other disabilities that decrease the functional score. Questionnaires like the Nottingham Health Profile of the Hip have been shown to be more sensitive tools for detecting loosening.[20]

The long term results of the McKee-Farrar prosthesis are comparable with those of the low friction replacement in this series. Wear of the polyethylene bearing and accumulation of polyethylene particles in the periprosthetic tissues may become an increasing problem of metal on plastic replacements in the long perspective. Therefore, the second generation all metal implants seem to be worth considering in patients with long life expectancy.

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Cobalt and Chromium Concentrations in Patients With Metal on Metal Total Hip Replacements

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There has been a resurgence of interest in the use of metal on metal bearings in total hip arthroplasty. Although the use of metal on metal bearing couples would eliminate or substantially reduce particulate polyethylene generation (depending on the presence or absence of polyethylene in the implant system), there is concern about the potential for increased particulate and ionic metal generation in comparison with polyethylene on metal bearings. These metallic degradation products may be transported away from the implant site and distributed systemically. Chromium concentrations in the serum and urine and cobalt concentrations in the serum were measured in subjects with cobalt chromium alloy metal on metal total hip replacements and in controls without implants. Eight subjects with long term (> 20 years) McKee-Farrar total hip replacements had 9-fold elevations in serum chromium, 35-fold elevations in urine chromium, and at least 3-fold elevations in serum cobalt concentrations in comparison with controls. Six subjects with short term (< 2 years) metal on metal surface replacement arthroplasties had 3-fold elevations in serum chromium, 4-fold elevations in urine chromium, and 4-fold elevations in serum cobalt concentrations in comparison with subjects with McKee-Farrar implants. Although the toxicologic importance of these trace metal elevations has not been established, serum and urine metal concentrations may be useful markers for the tribologic performance of metal on metal bearings.

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Conventional total hip replacement arthroplasty in the 1990s routinely uses cobalt chromium (CoCr) alloy femoral heads articulating with ultrahigh molecular weight polyethylene. Although this combination has proven highly successful, wear and fretting produce ultrahigh molecular weight polyethylene debris implicated in osteolysis and aseptic loosening, resulting in the need for revision surgery.[12] Furthermore, there is evidence that clinical problems leading to the need for revision occur more frequently in the younger and in the more active patient.[4,17]

As a result, there is a revival of interest in older total hip replacement designs using metal on metal articulations.[27] These include designs by McKee-Farrar,[19] Ring,[25] and Müller.[24] Although these devices were relatively commonly used in the 1960s, albeit in an era of rare total hip replacement arthroplasty, they fell into disuse with the successful introduction of the polymethylmethacrylate

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cemented stainless steel/ultrahigh molecular weight polyethylene total hip replacement by Charnley in the late 1950s.[8] In 1988, Weber[35] reintroduced the concept with newer material, design, and fabrication technology.

However, there remain concerns about the true magnitude of metal wear and the long term effects of local and systemic exposure to metal ions and particles in association with metal on metal articulating couples. This study determines the concentration of Co and Cr in the serum and of Cr in urine of 2 groups of patients with total hip replacements with metal on metal articulations. The first group has clinically successful long term McKee-Farrar total hip replacement and the second (smaller) group has current design surface replacement (double cup) total hip replacement of the Wagner[32] and McMinn[20] types.

MATERIALS AND METHODS

This was a retrospective, single time point study of 3 groups of individuals. The first group consisted of 8 patients (3 males and 5 females) with cemented CoCr alloy (ASTM F75)[1] metal on metal total hip replacements of the McKee-Farrar type (Table 1). One patient (Case 2) had bilateral McKee-Farrar implants, 1 of which had been previously revised to an ATH CoCr stem with a ceramic head and a Ti alloy S-ROM acetabular component 21 months before the present study. A second patient (Case 3) had a contralateral DF-80 Ti alloy stem implanted in 1980 and bilateral total knee arthroplasties of unknown composition in situ for 10 and 15 years, respectively. In addition, this patient had stainless steel wires inserted in his right hand in 1993. Two patients (Cases 4 and 5) had previous stainless steel internal fixation devices in situ for 53 and 46 years, respectively. One patient (Case 8) had a contralateral cementless Harris-Galante total hip replacement with a Ti alloy femoral stem, unalloyed Ti acetabular component and a CoCr alloy head implanted in 1987. The mean age at operation was 54 years (range, 33–67 years). The mean implantation time of the total hip replacements still in situ was 295 months (range, 266–324 months), approximately 25 years. The indication for the index total hip replacement was osteoarthritis in 6 patients and developmental dysplasia of the hip in 2 patients. The femoral head size was 35 mm (1⅜ inches) in 2 patients and 41 mm (1⅝ inches) in 6 patients (mean, 39.5 mm).

The second group consisted of 6 patients (3 males and 3 females) with metal on metal CoCr alloy surface replacement arthroplasties (Table 2). Four surface replacements were of the McMinn type[20] (ASTM F75)[1] and 2 were of the Wagner[32] type (ASTM F799).[2] In patients with the McMinn surface replacement, both the acetabular and femoral sides were fixed with bone cement, except for Case 14, in which the acetabular component was fixed without bone cement. Both patients with Wagner surface replacements had their components fixed without bone cement. One patient (Case 11) had simultaneous bilateral surface replacements and bilateral trochanteric osteotomies with CoCr wires. Discomfort developed in the right hip of this patient, and revision surgery was done 3 months after this study. One patient (Case 9) had multiple stainless steel internal fixation devices (ankle hardware in situ for > 24 years, spinal hardware in situ for 212 months, and CoCr trochanteric wires in situ for 19 months). One patient (Case 14) had a contralateral CoCr ultrahigh molecular weight polyethylene surface replacement in situ for 87 months. The mean age at operation was 48 years (range, 41–54 years). The mean implantation time was 12.4 months (range, 2–19 months). The indication for the index procedure was osteoarthritis in 3 patients (4 hips), developmental dysplasia of the hip in 2 patients (2 hips), and avascular necrosis in 1 patient (1 hip). The femoral head sizes were 38, 44 (n = 3 hips), 46, 48, and 52 mm (mean, 45.1 mm).

The third group consisted of 3 contemporaneous controls (2 men and 1 woman) with a mean age of 61 years (range, 52–67 years) from the same geographic area as patients who had total hip replacements in the first 2 groups, but with no metallic implants and no known systemic diseases.

Blood and 24–hour urine samples were obtained from all subjects using techniques previously reported to ensure lack of contamination.[13] Serum was assayed for Cr and Co and urine for Cr concentration using Zeeman background corrected graphite furnace atomic absorption spectrophotometry.[14,29] The detection limits in serum were 0.03 ng/ml (ppb) and 0.3 ppb for Cr and Co, respectively, and 0.015 ppb for Cr in urine. Intergroup comparisons were made with the Kruskal-

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TABLE 1. Serum and Urine Metal Concentrations for Patients with McKee-Farrar Total Hip Replacements

Case Number, Gender	Implant Time (months)	Original Diagnosis	Age at Operation	Side	Head Diameter (mm)	Serum Cobalt (ppb)	Serum Chromium (ppb)	Urinary Chromium (ppb)	Total Urinary Chromium (µg/day)
1,F	286	Osteoarthritis	53	R	41	0.41	1.59	1.78	2.34
2,F	324	Osteoarthritis	33	L[1]	35	0.71	2.56	NA	NA
3,F	279	Developmental Dysplasia of the Hip	56	L[2]	35	0.90	0.64	1.23	2.15
4,M	305	Osteoarthritis	43	L[3]	41	<0.3	0.21	0.26	0.76
5,F	301	Developmental Dysplasia of the Hip	67	L[4]	41	0.66	1.03	0.51	1.20
6,M	302	Osteoarthritis	59	R	41	0.55	0.45	0.83	1.36
7,F	298	Osteoarthritis	59	L	41	2.00	2.42	1.34	2.47
8,M	266	Osteoarthritis	66	L[5]	41	1.65	0.85	2.59	4.37
Mean	295		54		39.5	0.90	1.28	1.22	2.09

[1]R hip: 1968–1993, 35-mm head McKee-Farrar; revised to ATH CoCr stem with a ceramic head and Ti alloy S-ROM acetabular component.

[2]R-hip: 1980-present DF-80 stem (Ti alloy); R-hand: 1993–present, stainless steel wires; Bilateral total knee replacement (unknown composition) implanted L-1980 and R-1985.

[3]L-Hand: 1942–present, stainless steel wires.

[4]R-Hip: 1949–present, stainless steel pins.

[5]R-Hip: 1987–present, Harris-Galante total hip replacement (Ti alloy stem, CoCr head).

Wallis, Wilcoxon-Mann-Whitney, and/or analysis of variance (ANOVA) tests. The Pearson test was used to establish correlations between 2 variables. The level of significance was p less than 0.05.

RESULTS

Using the optimized protocols, 0.22 ppb of Cr and 1.14 ppb of Co were found in the National Institute of Standards and Technology Standard Reference Material 1498 (certified for 0.14 ± 0.08 ppb Cr and 1.24 ± 0.18 ppb Co). For the control individuals (n = 3) the mean Cr concentrations were 0.14 ng/ml (2.7 nmol/l), (range, 0.07–0.30 ng/ml) in serum and 0.035 ng/ml (0.66 nmol/l), (range, 0.03–0.04 ng/ml) in urine, respectively, whereas the serum Co concentrations were all below the detection limit of 0.3 ng/ml (5.2 nmol/l). In the control population, the mean total 24-hour urinary Cr excretion was 0.071 µg per day (1.37 nmol/day), (range, 0.051–0.088 µg/day). These values for the control subjects are comparable with recently published normal values.[7,10] In addition, the control means compare well with control values obtained earlier for a group of 10 individuals, from another geographic area, using slightly different protocols: serum Cr, less than 0.41 ppb (detection limit); urine Cr, less than 0.21 ppb (detection limit), and serum Co, less than 0.30 (detection limit).[14,15]

Table 1 presents the serum Co and Cr and urine Cr concentrations for subjects with McKee-Farrar total hip replacements. In addition, total urinary Cr is given. These patients had a mean serum SrCr concentration 9-fold greater than controls ($p < 0.03$, Wilcoxon-Mann-Whitney). The serum Co concentration was at least 3–fold higher than controls ($p < 0.03$, Wilcoxon-Mann-Whitney). The mean urinary Cr concentration was 35-fold greater ($p < 0.02$, Wilcoxon-Mann-

TABLE 2. Serum and Urine Metal Concentrations for Patients with Surface Replacements

Case Number, Gender	Implant Time (months)	Original Diagnosis	Age at Operation	Side	Head Diameter (mm)	Serum Cobalt (ppb)	Serum Chromium (ppb)	Urinary Chromium (ppb)	Total Urinary Chromium (μg/day)
9*,F	19	Developmental Dysplasia of the Hip	47	R[1]	38	3.5	5.72	7.86	4.80
10*,F	18	Osteoarthritis/	50	L	46	1.45	2.64	1.33	3.74
11**,F	12/12	Osteoarthritis	54	L/R[2]	44/44	9.6	3.5	2.67	4.87
12**,F	13	Developmental Dysplasia of the Hip	52	R	44	1.0	4.15	1.87	3.83
13**,M	11	Osteoarthritis	41	R	52	2.36	3.59	5.93	5.34
14**,M	2	Avascular Necrosis	42	L[3]	48	4.71	3.55	11.0	7.82
Mean	12.4		48		45.1	3.77	3.86	5.10	5.07

*Wagner type: Titanium shell with a CoCr liner. **McMinn type.

[1]L Ankle: Stainless steel pin (in situ >24 years); Spine: 1977–present, Stainless steel rod; CoCr trochanteric wires.

[2]Bilateral metal/metal surface replacements with trochanteric osteotomy (CoCr wires). Values for this patient are 2 times what is listed. The authors have divided by 2 to account for the fact that the patient had bilateral surface replacements.

[3]L Hip 1987–present CoCr metal/ultrahigh molecular weight polyethylene surface replacement.

Whitney) and the mean total urinary Cr value was 30-fold greater ($p < 0.02$, Wilcoxon-Mann-Whitney) than the control means.

Table 2 shows the results for the subjects with metal on metal surface replacements. For Case 11, the values listed in Table 2 represent the measured values divided by 2 to account for the fact that the patient had bilateral surface replacements. This patient's right hip was revised because of progressive pain 3 months after serum and urine samples were obtained. The mean serum Cr concentration was 3-fold higher ($p < 0.002$, Wilcoxon-Mann-Whitney) and the mean serum Co concentration 4-fold higher ($p < .01$, Wilcoxon-Mann-Whitney) than the mean for the McKee-Farrar prosthesis group. The mean urinary Cr concentration was 4-fold higher and the mean total urinary Cr is nearly 2.5-fold higher ($p < 0.02$) than the mean from the McKee-Farrar prosthesis group.

There was a high positive correlation between serum Cr and serum Co ($r^2 = 0.541$, $p < 0.003$, Pearson) for the 14 patients in this study. There was no correlation between head diameter and serum Co, serum Cr, urinary Cr or total urinary Cr.

DISCUSSION

There are limited data available on systemic metal concentrations in patients with metal on metal total hip replacement. Furthermore, nonstandard methods of specimen collection and analysis make comparisons between laboratories difficult. In a short term study (< 2 years) using neutron activation analysis, Coleman et al.[9] reported approximately 3-fold elevations of (whole) blood Cr, 11-fold elevations in blood Co, and 15-fold elevations of urine Cr in 9 patients with CoCr metal on metal total hip replacement in comparison with preoperative concentrations. No such elevations were observed in 3 patients with CoCr ultrahigh molecular weight poly-

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ethylene total hip replacements. For 3 patients for whom longitudinal data are provided, there was a strong pattern of Cr and Co concentration increases in blood and urine with time postoperative. However, in comparison with the present study, the preoperative concentrations in the study of Coleman et al[9] are as much as 10 times higher, reflecting that refinements have occurred in analytic techniques during the past 20 years.

More recently, Täger[31] reported the Co level in whole blood for 2 groups of patients who had received CoCr metal on metal McKee-Farrar total hip replacements. In the first study of patients observed 5 to 8 years postoperatively, with a method detection limit (by atomic absorption spectroscopy) of 20 ppb, 4 patients who had unilateral implants and 13 patients who had bilateral implants were at or below the detection limit, whereas dramatic elevations were observed in 2 patients with loose total hip replacements, 1 of whom had bilateral implants (whole blood Co 120 and 50 ppb, respectively). In the second study of patients 8 to 15 years postoperative, using the same technique but with a refined method, yielding a method detection limit of 10 ppb, 4 patients who had unilateral implants and 7 patients who had bilateral implants were at or below the detection limit, whereas 1 patient who had a unilateral implant had a value of whole blood Co of 15 ppb.

In a previously completed longitudinal study from the authors' laboratory,[29] using the same analytic techniques used in the present study, patients with conventional cemented CoCr ultrahigh molecular weight polyethylene total hip replacements showed mean values for serum Cr of 0.19 ppb and urinary Cr of 0.30 ppb at 3 years postoperative. Although the concentration of serum Cr was statistically elevated with respect to geographically matched controls without implants, it was far less than the serum Cr of both of the metal on metal patient groups in the present study. Similarly, serum Cr concentrations (measured by atomic absorption spectroscopy) in patients with ultrahigh molecular weight polyethylene/CoCr total knee replacement and total hip replacement in a study by Sunderman et al[30] were typically 10 times lower than concentrations in the metal on metal patient groups in the present study. Michel et al[22] reported serum Co levels (measured by neutron activation analysis) in 10 patients with ultrahigh molecular weight polyethylene/CoCr total hip replacement which, at 90 days postoperative, were comparable with the levels in the McKee-Farrar patients in the present study, but approximately 4-fold lower than the patients with surface replacements.[22]

Anderson et al[3] studied the relationship of daily urinary Cr excretion to serum Cr concentrations. For a range of serum Cr concentrations as high as 11 nmol/L (0.65 ppb) they obtained the following relationship:

$$\text{Total urinary Cr (nmol/day)} = 0.692 + 2.185 * \text{Serum Cr (nmol/L)} \quad (r^2 = 0.71,\ p < 0.001) \qquad (1)$$

Figure 1 shows the relationship between daily urinary Cr excretion and serum Cr concentration for all patients with metal on metal implants for whom data are available in this study. The regression from the study by Anderson et al[3] is shown as well as the fit obtained for these data:

$$\text{Total urinary Cr (nmol/day)} = 22.81 + 1.02 * \text{Serum Cr (nmol/L)} \quad (r^2 = 0.672,\ p < 0.0006) \qquad (2)$$

For values of serum Cr as high as approximately 70 nmol/L (3.6 ppb), data from the present study are apparently well represented by relation (1) above (Fig 1). However, 3 patients with serum levels above this apparent threshold (Cases 9, 11, 12) seem to be excreting approximately ½ of the Cr that would be expected, based on their serum Cr levels. This would imply systemic accumulation. However, such an observation should be made only with caution, because failure to collect total urinary output during the 24-hour test period would produce the same result. The urinary

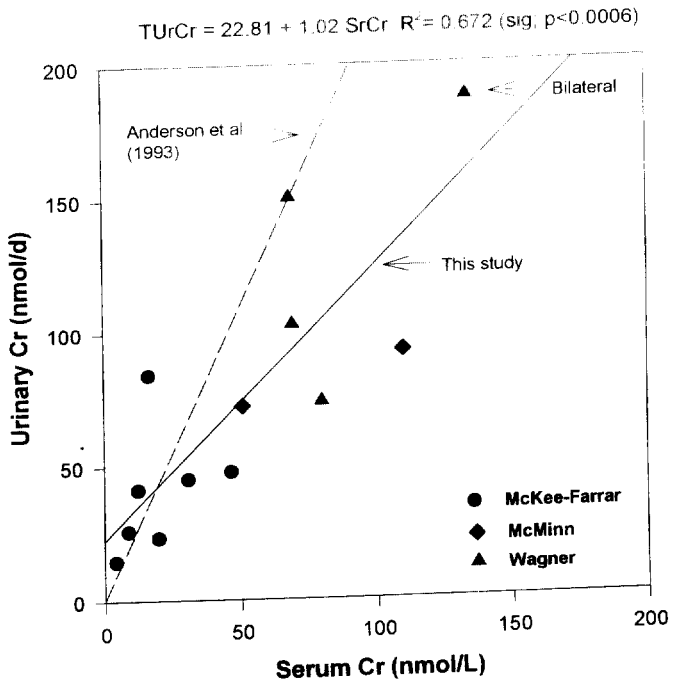

Fig 1. Linear regression analysis of 24-hour urinary Cr excretion (nanomoles per day) versus serum Cr (nanomoles per liter). The regression line for the present study is compared with the regression line of Anderson et al[3] who studied 17 healthy lactating women. The data points on this graph are all from the present study. The 3 patients with the highest serum Cr in the present study (>75 nmoles/L) are excreting approximately ½ of what is predicted by the regression line of Anderson et al. This suggests systemic accumulation of Cr within body stores. TUrCr = total urinary Cr.

volumes for the 3 patients were 0.616, 1.821, and 2.046 L, respectively. Of the volumes, the first is low, and thus suspect, whereas the other 2 volumes are considered appropriate.

The present study of McKee-Farrar implants is unique in reporting metal concentrations in individuals with more than 20 years followup. Although the relatively higher serum and urine Cr levels in the subjects with short term surface replacements may be related to larger bearing surface contact areas and thus more debris generation,[6] the difference in mean head size between the patients with McKee-Farrar implants and those with surface replacements, although statistically significant ($p < 0.02$, ANOVA), is not large (45.1 versus 39.5 mm). In addition, the true contact areas are not known. Furthermore, there was no correlation between head size and metal concentrations. More likely, the differences observed were due to the phenomenon of run in wear in which relatively high wear rates observed during initial usage are followed by lower steady state wear rates. However, because wear is a complex process and may be governed by many factors, including patient activity levels (number of cycles per day), a comparison of wear rates between these 2 groups must be made with caution. Both groups display evidence of metal release much in excess of that expected and encountered with the more common CoCr/ultrahigh molecular weight polyethylene total hip replacements.[29]

In addition to corrosion, which contributes to an estimated surface recession rate of 0.1 μm per year,[5] wear of CoCr femoral heads does occur even when they articulate against ultrahigh molecular weight polyethylene.[16] The mechanism of this wear is thought to be abrasive, secondary to particles released within the articulating interface itself, possibly from the CoCr alloy. More pronounced wear of metal on metal McKee Farrar total hip replacements has been reported previously.[34] Worn areas of 1 um depth, of as many as 10 mm in extent were found on femoral heads removed after 4 years for aseptic loosening. Wear was thought to be

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due to a succession of scratching (due to abrasive wear), polishing, and pitting (perhaps due to corrosive attack).

It has been estimated by 1 of the authors (JB)[5] that wear of modern metal on metal total hip replacements contributes to a metal loss rate of 4.5- to 8.5-fold elevated from that encountered in conventional CoCr ultrahigh molecular weight polyethylene total hip replacements. Thus, it is no surprise that elevated serum and urine Cr and serum Co levels are observed for patients with McKee-Farrar total hip replacement.

The still higher levels in patients with surface replacements suggest still further elevated rates of metal release. Because these surface replacements have a smaller combined surface area than the components of metal on metal total hip replacements, one would suppose that still higher wear and fretting rates occur for these devices. Unfortunately, no surface replacements were available for analysis to confirm this supposition.

The patient with the highest levels of serum Co, serum Cr, and total urinary Cr had bilateral surface replacements (Case 11, measured values for this patient are 2 times that listed in Table 2). It is of considerable interest that 3 months before the acquisition of serum and urine samples, symptoms of discomfort and ratcheting motion developed in the patient which ultimately necessitated revision of her right hip at 15 months postoperative. The ratcheting motion might have been caused by original out of roundness of the ball or cup or both. This acetabular component had an excessively vertical orientation. Thus, the dramatic elevations in this patient's serum Co level may be attributable not only to the fact that she had bilateral surface replacements but also to excessive wear as a consequence of suboptimal articulation of the components. Even if the values from this case are excluded from the statistical analysis, the surface replacement group had statistically significant 3-fold, 3-fold, and 2.5-fold elevations of serum Co, serum Cr, and total urinary Cr, respectively, in comparison with the McKee-Farrar replacement group.

An inherent limitation in the present retrospective study is that 5 of 8 patients with McKee-Farrar total hip replacements and 3 of 6 patients with metal on metal surface replacements have other implants that are potential sources of Co or Cr or both. Nonetheless, it is reasonable to infer that the large surface area metal on metal bearing is the primary source of circulating Co and Cr in these patients.

There is interest in the release of metal from CoCr metal on metal prostheses because there is increasing evidence that, as first suggested by Rogers,[26] significant proportions of Cr released as ions or in organometallic complexes, in animal models and in patients with total hip replacements is Cr^{6+} rather than the more common dietary form, Cr^{3+}.[21] Although Cr^{6+} can be rapidly reduced to Cr^{3+}, a far less biologically active and cell excluded form, this does not occur before significant cellular penetration occurs.[21,23] When the reduction takes place intracellularly, rather than extracellularly, Cr is active as a mutagen and carcinogen.[18] Furthermore, the binding avidity of Cr and Co for proteins[36] perhaps contributes to the observed phenomenon of respiratory burst response suppression that is observed in human monocytes exposed to even nonphagocytosable forms of CoCr (F-75 alloy).[28]

It is not known whether the observed elevations in serum and urine Cr concentrations, compared with controls and with patients who have metal on polymer total hip replacement, and the concomitant elevated release of high specific surface area particles,[33] are of clinical importance. Chromium metabolism, even of the more usual dietary Cr^{3+} form, is still imperfectly understood.[11] However, the findings in the present study suggest that larger, longitudinal studies are advisable. Finally, serum and urine metal concentrations may serve as useful markers for the performance of metal on metal total hip replacements.

Acknowledgments

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Device Classification Name	PROSTHESIS, HIP, SEMI-CONSTRAINED (METAL UNCEM ACETABULAR COMPONENT)
Regulation Number	888.3330
510(k) Number	K993438
Device Name	METAL ON METAL ACETABULAR SYSTEM
Applicant	BIOMET, INC. AIRPORT INDUSTRIAL PARK P.O. BOX 587 WARSAW, IN 46581 0587
Contact	MICHELLE L MCKINLEY
Product Code	KWA
Date Received	10/12/1999
Decision Date	05/18/2000
Decision	SUBSTANTIALLY EQUIVALENT
Classification Advisory Committee	Orthopedic
Review Advisory Committee	Orthopedic
Statement/Summary/Purged Status	Summary only
SUMMARY/Approval Letter	SUMMARY
Type	Traditional
Reviewed by Third Party	No

(Database Updated March 7, 2001)

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K993438

P.1/3

MAY 1 8 2000

SUMMARY OF SAFETY AND EFFECTIVENESS

SPONSOR: Biomet, Inc.
P.O. Box 587
Airport Industrial Park
Warsaw, Indiana 46581-0587

CONTANT PERSON: Michelle L. McKinley

DEVICE NAME: Metal on Metal Acetabular System

CLASSIFICATION NAME: Prosthesis, Hip, Semi-constrained (Metal Uncemented Acetabular Component)

INTENDED USE:

The Metal on Metal Acetabular System is indic..ted for used in patients requiring total hip replacement due to the following:

a.) Non-inflammatory degenerative joint disease including avascular necrosis, diastrophic variant, fracture of the pelvis, fused hip, leg perthes, 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.) Revision of previously failed total hip arthroplasty.

DEVICE DESCRIPTION:

Acetabular Shell

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The modular heads may be used in conjunction with any of Biomet's commercially available femoral components. At the time of surgery, the modular head is assembled with a femoral stem.

POTENTIAL RISKS:

The potential risks associated with this device are the same as with any joint replacement device. These include, but are not limited to:

Fracture of the component	Bone fracture
Cardiovascular disorders	Hematoma
Implant loosening/migration	Blood vessel damage
Soft tissue imbalance	Nerve damage
Deformity of the joint	Excessive wear
Tissue growth failure	Infection
Delayed wound healing	Dislocation
Metal sensitivity	Breakdown of the porous surface

K993738

SUBSTANTIAL EQUIVALENCE:

The Metal on Metal Acetabular System is similar to previously marketed devices. Direct comparison was made with the following predicate devices:

Mallory Head Finned Acetabular Cup
Universal Acetabular Cup
Biomet Co-Cr Femoral Components
Sulzer's Inter-Op Metasul

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 1 8 2000

Ms. Michelle L. McKinley
Regulatory Specialist
Biomet, Inc.
Airport Industrial Park
P.O. Box 587
Warsaw, Indiana 46581-0587

Re: K993438/S1
Trade Name: Metal on Metal Acetabular Component
Regulatory Class: III
Product Code: KWA
Dated: February 18, 2000
Received: February 22, 2000

Dear Ms. McKinley:

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

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

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

87

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

Sincerely yours,

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

Enclosure

88

510(k) Number if Known: K993438
Device Name: Metal on Metal Acetabular System

The Metal on Metal Acetabular System is indicated for used in patients requiring total hip replacement due to the following:

a.) Non-inflammatory degenerative joint disease including avascular necrosis, diastrophic variant, fracture of the pelvis, fused hip, leg perthes, 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.) Revision of previously failed total hip arthroplasty.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ (Per CFR 801.109) or Over the Counter Use_____ (Optional Format 1-2-96)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K993438

Return to Search

Device Classification Name	PROSTHESIS, HIP, HEMI-, FEMORAL, METAL/POLYMER, CEMENTED OR UNCEMENTED
Regulation Number	888.3390
510(k) Number	K003363
Device Name	M2A 32MM TAPER SYSTEM
Applicant	BIOMET, INC. 56 EAST BELL DRIVE WARSAW, IN 46581 0587
Contact	MICHELLE L MCKINLEY
Product Code	KWY
Date Received	10/27/2000
Decision Date	12/15/2000
Decision	SUBSTANTIALLY EQUIVALENT
Classification Advisory Committee	Orthopedic
Review Advisory Committee	Orthopedic
Statement/Summary/Purged Status	Summary only
SUMMARY/Approval Letter	SUMMARY
Type	Special
Reviewed by Third Party	No

(Database Updated March 7, 2001)

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DEC 1 5 2000

K003363

SUMMARY OF SAFETY AND EFFECTIVENESS

SPONSOR: Biomet, Inc.
P.O. Box 587
Airport Industrial Park
Warsaw, Indiana 46581-0587

CONTANT PERSON: Michelle L. McKinley

DEVICE NAME: M2a™ 32mm Taper System

CLASSIFICATION NAME: Prosthesis, Hip, Semi-constrained (Metal Uncemented Acetabular Component)

INTENDED USE:

The M2a™ 32mm Taper System is indicated for use in patients requiring total hip replacement due to the following:

a.) Non-inflammatory degenerative joint disease including avascular necrosis, diastrophic variant, fracture of the pelvis, fused hip, leg perthes, 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.) Revision of previously failed total hip arthroplasty.

DEVICE DESCRIPTION:

POTENTIAL RISKS:

The potential risks associated with this device are the same as with any joint replacement device. These include, but are not limited to:

Fracture of the component	Bone fracture
Cardiovascular disorders	Hematoma
Implant loosening/migration	Blood vessel damage
Soft tissue imbalance	Nerve damage
Deformity of the joint	Excessive wear
Tissue growth failure	Infection
Delayed wound healing	Dislocation
Metal sensitivity	Breakdown of the porous surface

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 5 2000

Ms. Michelle L. Mckinley
Regulatory Specialist
Biomet, Inc.
P.O.Box 587
Warsaw, Indiana 46582

Re: K003363
Trade Name: M2A 32 MM Taper System
Regulatory Class: III
Product Code: KWA
Dated: December 6, 2000
Received: December 7, 2000

Dear Ms. Mckinley:

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

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

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

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

Sincerely yours,

for Mark N Melkerson

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

Enclosure

510(k) Number (if known): K003363

Device Name: M2a™ 32mm Taper System

Indications for Use:

The M2a™ 32mm Taper System is indicated for use in patients requiring total hip replacement due to the following:

1) Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis; 2) rheumatoid arthritis; 3) correction of functional deformity; 4) revision procedures where other treatment or devices have failed; 5) treatment of non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE OF ANOTHER PAGE IS NEEDED)

for Mark N Milkerson

(Division Sign-Off)
Division of General Restorative Devices

510(k) Number K003363

Return to Search

Device Classification Name	PROSTHESIS, HIP, SEMI-CONSTRAINED (METAL UNCEM ACETABULAR COMPONENT)
Regulation Number	888.3330
510(k) Number	K003523
Device Name	DEPUY PINNACLE METAL-ON-METAL ACETABULAR CUP
Applicant	DEPUY ORTHOPAEDICS, INC. P.O. BOX 988 WARSAW, IN 46581 0988
Contact	LYNNETTE WHITAKER
Product Code	KWA
Date Received	11/15/2000
Decision Date	12/13/2000
Decision	SUBSTANTIALLY EQUIVALENT
Classification Advisory Committee	Orthopedic
Review Advisory Committee	Orthopedic
Statement/Summary/Purged Status	Summary only
SUMMARY/Approval Letter	SUMMARY
Type	Special
Reviewed by Third Party	No

(Database Updated March 7, 2001)

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DEC 1 3 2000

K003523

DePuy
a Johnson & Johnson company

SUMMARY OF SAFETY AND EFFECTIVENESS

DePuy Orthopaedics, Inc.
700 Orthopaedic Drive
PO Box 988
Warsaw, Indiana 46581-0988
USA
Tel: +1 (219) 267 8143
Fax: +1 (219) 267 7196

NAME OF FIRM: DePuy Orthopaedics, Inc.
P.O. Box 988
700 Orthopaedic Drive
Warsaw, IN 46581-0988

510(k) CONTACT: Lynnette Whitaker
Manager, Regulatory Affairs

TRADE NAME: DePuy Pinnacle Metal-On-Metal Acetabular Cup Liners

COMMON NAME: Acetabular Cup Prosthesis

CLASSIFICATION: 888.3330 Hip joint metal/metal semi-constrained, with an uncemented acetabular component, prosthesis

DEVICE PRODUCT CODE: 87 ~~DWI~~ KWA

SUBSTANTIALLY EQUIVALENT DEVICES: DePuy Pinnacle Metal-On-Metal Acetabular Cup Inter-Op™ Durasul™ Acetabular Inserts, Sulzer Orthopaedics, Inc.

DEVICE DESCRIPTION AND INTENDED USE:
The Pinnacle Metal-On-Metal (MOM) Acetabular Cup Liner is a metal liner that is intended for use with the Pinnacle Acetabular Shells that have been cleared previously. The liner has a 36mm inner diameter and is offered in a neutral style only. The Pinnacle MOM liner is mechanically locked with the shell via a taper junction, and articulates with commercially available prosthetic femoral heads.

It is indicated for use as the acetabular component in total hip replacement procedures for patients suffering severe pain and disability due to structural damage in the hip joint from rheumatoid arthritis, osteoarthritis, post-traumatic arthritis, collagen disorders, avascular necrosis, and non-union of femoral fractures. Use of the prosthesis is also indicated for patients with congenital hip dysplasia, *protrusio acetabuli*, slipped capital femoral epiphysis and disability due to previous fusion, where bone stock is inadequate for other reconstruction techniques.

The Pinnacle 36mm Metal-On-Metal Acetabular Cup Liners are intended for use with DePuy Pinnacle Acetabular Shells and 36mm diameter Co-Cr-Mo femoral heads only.

BASIS OF SUBSTANTIAL EQUIVALENCE:
The Pinnacle 36mm Metal-On-Metal Acetabular Cup Liners are nearly identical to the Pinnacle Metal-On-Metal Acetabular Cup Liners that were cleared previously. The intended use, articular surface characteristics, material and locking mechanism with the outer shell are the same. The only minor change to the cup is to inner diameter of the cup, which is now 36mm.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 13 2000

Ms. Lynetter Whitaker, RAC
Manager, Regulatory Affairs
DePuy Orthopaedics, Inc.
700 Orthopaedic Drive
P.O. Box 988
Warsaw, Indiana 46581-0988

Re: K003523
Trade Name: Pinnacle 36mm Metal-on-Metal Acetabular Cup Liners
Regulatory Class: III
Product Code: KWA
Dated: November 13, 2000
Received: November 15, 2000

Dear Ms. Whitaker:

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

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

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

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

Sincerely yours,

for Mark N Melkerson

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

Enclosure

510(k) Number (if known) K003523

Device Name DePuy Pinnacle Metal-On-Metal Acetabular Cup Liners

Indications for Use:
The Pinnacle Metal-On-Metal Acetabular Cup Liners are indicated for use as the acetabular component in total hip replacement procedures for patients suffering severe pain and disability due to structural damage in the hip joint from rheumatoid arthritis, osteoarthritis, post-traumatic arthritis, collagen disorders, avascular necrosis, and non-union of femoral fractures. Use of the prosthesis is also indicated for patients with congenital hip dysplasia, *protrusio acetabuli*, slipped capital femoral epiphysis and disability due to previous fusion, where bone stock is inadequate for other reconstruction techniques.

The Pinnacle 36mm Metal-On-Metal Acetabular Cup Liners are intended for use with DePuy Pinnacle Acetabular Shells and 36mm diameter Co-Cr-Mo femoral heads only.

Concurrence of CDRH, Office of Device Evaluation

for Mark N Melkerson
(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K003523

Prescription Use _____ OR Over-The Counter Use
(Per 21 CFR 801.109)

Clinical Tribological Performance of 144 Metal-on-Metal Hip Articulations

C.B. Rieker, P. Köttig, R. Schön, M. Windler, U.P. Wyss

Introduction

A healthy human hip joint has minimum friction and almost no wear due to optimal lubrication [1] which, under normal conditions, completely separates the two articulation surfaces. In the case of osteoarthritis or rheumatoid arthritis, the lubricating capacity decreases, leading to wear of the hip joint surfaces, which in turn leads to increased friction and also intense pain [2]. Under such circumstances the natural joint has to be replaced by an artificial hip prosthesis.

As all the materials actually used to manufacture hip prostheses are unable to produce a permanent lubricating film, the prosthesis's surfaces are always subject to wear. The amount of wear particles released controls the longevity of the implant fixation [3]. Polyethylene liners wear at an average linear wear rate of 0.1–0.2 mm per year depending on the material combination (metal-on-polyethylene or ceramic-on-polyethylene) [4]. This linear wear rate produces a very large number of polyethylene particles overloading the elimination capacities of the lymphatic tissues, leading to the late loosening of the hip joints [5]. Excellent results of some of the old metal-on-metal prostheses [6] led to a reassessment of metal-on-metal hip bearings by Sulzer Orthopedics in 1992. The first implantation of the second generation metal-on-metal META-SUL bearing (Sulzer Orthopedics Ltd., Switzerland) was made in 1988. To date, more than 65,000 second generation metal-on-metal hip joints (130,000 single components) have been produced.

The wear behaviour of 30 single metal-on-metal retrievals of the first generation (Müller design) and 114 single metal-on-metal retrievals of the modern second generation is examined. The in vivo wear behaviour is compared with in vitro experiments (hip simulator).

Experimental Method

Materials

The 30 single metal-on-metal retrievals of the first generation (Müller design) manufactured between 1966 and 1970 were made of cast Co-28Cr-6Mo-0.2C alloy (ASTM F-75/ISO 5832–4). The diameters of the heads were either 37 mm or 42 mm. The implantation time varied between 3 and 28.1 years (mean follow-up: 15.6 years). Most revisions were due to a late aseptic loosening. Due to an incomplete documentation, a precise statistic for the reasons of these revisions cannot be given.

The 114 single metal-on-metal retrievals (head or cup – 71 reoperations) of the second

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modern generation manufactured after 1987 were made of a wrought high Carbon Co-28Cr-6Mo-0.2C alloy (ASTM F-1537/ISO 5832–12). The initial roughness R_a (Mahr-Perthometer stylus surface analyser) of these components is about 0.020–0.025 µm. 111 retrievals had a 28 mm diameter and 3 retrievals a 32 mm diameter. The implantation time varied between 2 and 100 months (mean follow-up: 23 months). Due to the different causes of revision, most of the retrieved components were single component (head or cup). The reasons for revision are given in **Table 1**.

Table 1: Reasons for retrievals

Reasons for retrievals	–
Dislocations	24 %
Stem loosening	17 %
Cup loosening	28 %
Others (infection, ossification)	31 %

Wear Measurements

The wear of the components is measured by a co-ordinate measuring machine (CMM5 manufactured by SIP, Geneva, Switzerland) having a spatial resolution lower than 1 µm in the area of measurement. A measurement is made every 7.5 degrees on 12 concentric circles as well as on the pole of the component (577 measurements for each component).

For the retrieved components (1st and 2nd generation of the metal-on-metal bearings), the wear is simply defined by the maximum deviation from the ideal sphericity. This method gives the local deepest wear (worst case) and not the mean wear of the component.

Due to a permanent deposited organic film found on the components, the precision of the wear measurements is estimated to be around ±2 µm.

Results

Retrieved Müller Metal-on-Metal Prostheses (1st Generation)

Figure 1 shows the in vivo wear rate (maximum wear rate for the components [head or cup] as a function of in vivo implantation time) for the 30 Müller metal-on-metal prostheses. The wear rate of 24 Müller metal-on-metal prostheses has already been published [7]. The maximum wear rate (6.2 µm/year) was found for a head having an implantation time of 10 years. The wear amount of the heads and of the cups is identical. The mean wear rate for all of the retrieved Müller metal-on-metal components (cup or head) is 2.2 µm/year.

Retrieved Modern Metal-on-Metal Prostheses

Figure 2 shows the in vivo wear rate (maximum wear rate for the components [head or cup] as a function of in vivo implantation time) for the 114 modern metal-on-metal components. The wear rate of 44 modern metal-on-metal components has already been published [7]. Two wear behaviours can be observed: a moderate wear rate (between 20 and 80 µm/year) and a low wear rate (below 20 µm/year). The 5 retrievals with the moderate wear rate were revised for mechanical problems: 2 for recurrent dislocations, 2 for cup tilting and one for a "squeaking hip". Figure 2 shows some cups have virtually zero wear. Unfortunately, most of these cups were revised without the corresponding head and therefore it is not possible to investigate this very low wear phenomenon.

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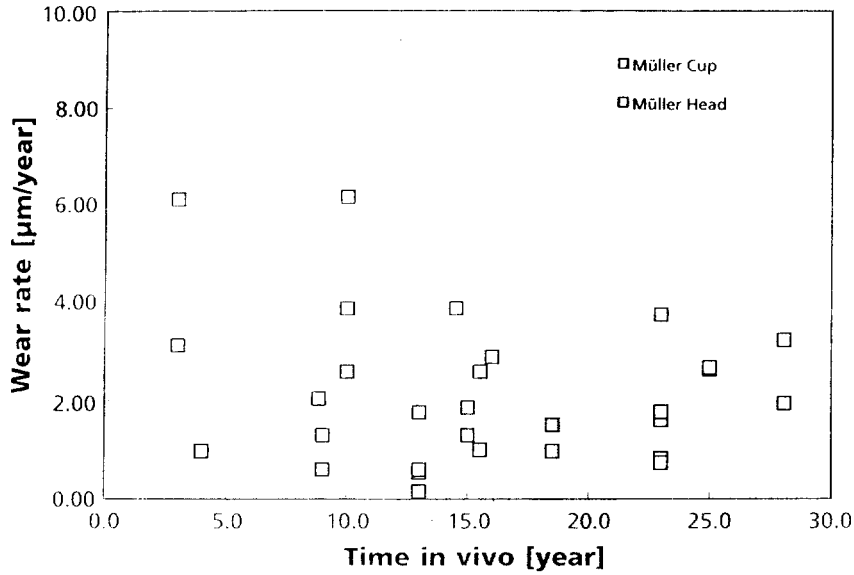

Figure 1: In vivo wear rate of retrieved Müller metal-on-metal prostheses (1st generation).

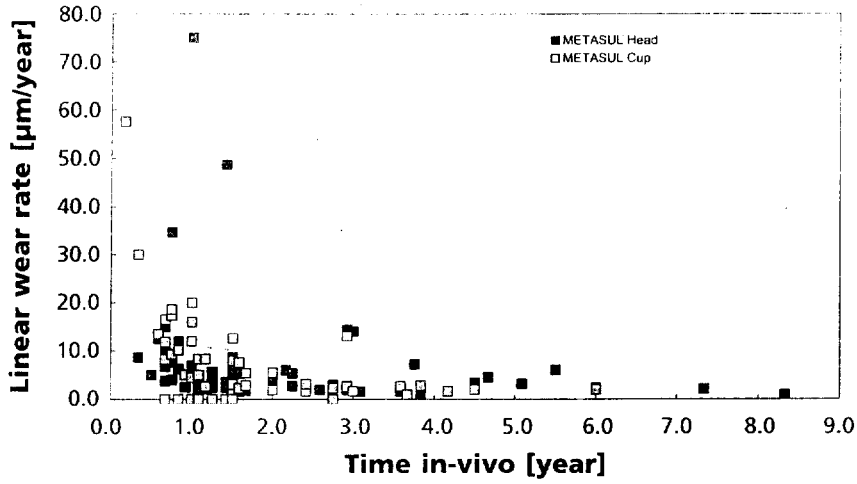

Figure 2: In vivo wear rate of retrieved modern metal-on-metal prostheses (2nd generation).

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Figure 3 shows the mean in vivo annual wear rate and its standard deviation of the 114 modern metal-on-metal prostheses calculated for every year spent in vivo. This representation of the annual wear rate shows that the wear rate decreases with implantation time (wear rate for the 1st in vivo year: about 25 µm/year for the whole bearing, wear rate after the 2nd year in vivo: about 5 µm/year for the whole bearing). Figure 3 also shows that the wear rate of the heads is higher than the wear rate of the cups.

Comparison Using the Hip Simulator

Figure 4 shows the comparison between the wear values measured in vitro (hip simulator) [8] with the wear values obtained in vivo (retrievals). This comparison supposes that a patient walks a million steps per year. Generally, a very good agreement is found between the two types of wear values. Only a small number of retrieved components show a higher wear than the wear measured with the hip simulator.

Retrieved Metal-on-Metal Prostheses (1st and 2nd Generation)

Figure 5 shows the wear rate for the two generations of metal-on-metal prostheses. The ordinate of Figure 5 only shows the low wear rate of the modern metal-on-metal retrievals to improve the readability of the figure. It can be observed that the two generations of metal-on-metal prostheses seem consistent in describing the same general phenomenon.

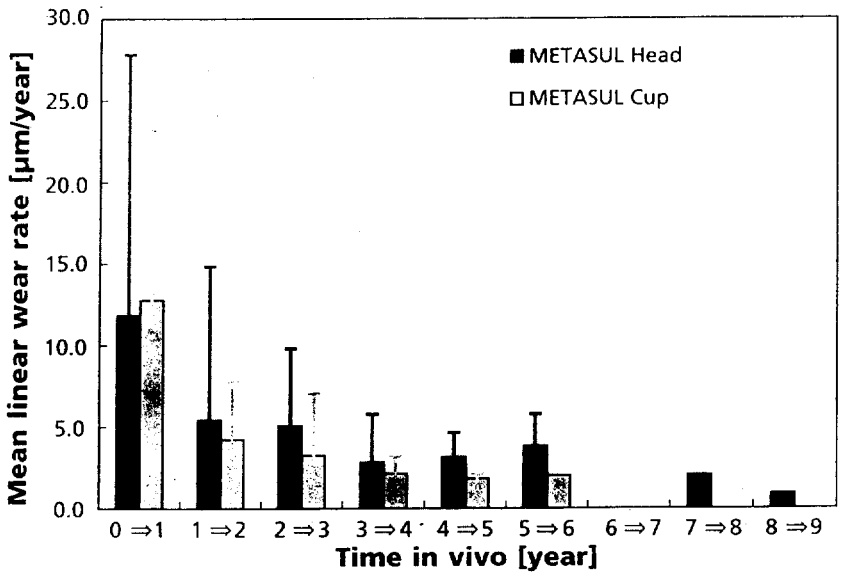

Figure 3: In vivo annual wear rate of retrieved modern metal-on-metal prostheses (2nd generation).

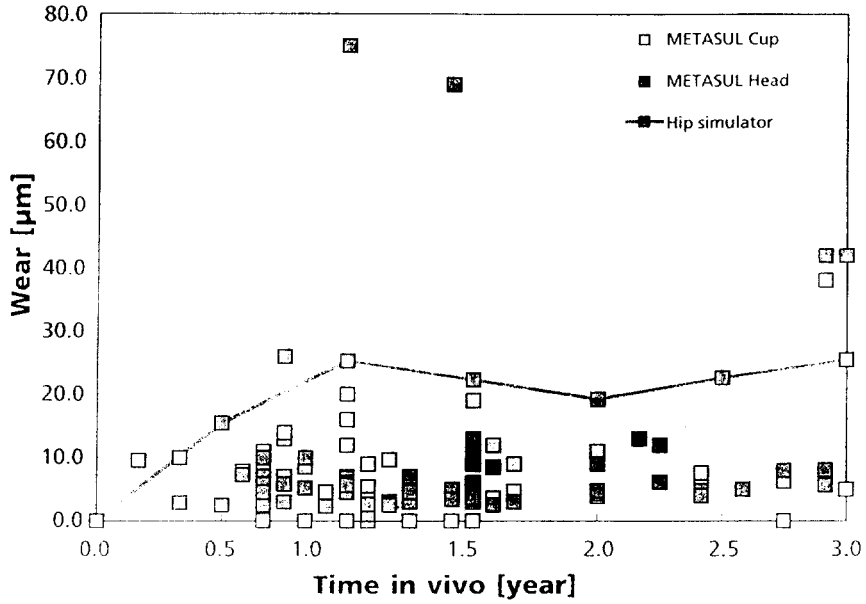

Figure 4: In vivo wear (retrieved components) compared with in vitro wear (hip simulator).

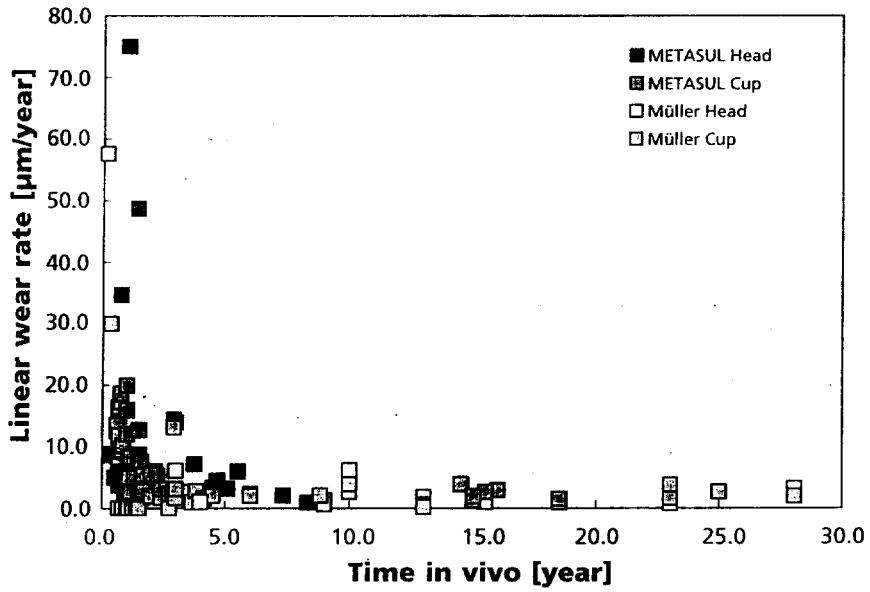

Figure 5: In vivo wear rate of retrieved metal-on-metal prostheses (1st and 2nd generation).

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Wear Mechanisms of Retrieved Modern Metal-on-Metal Prostheses (2nd Generation)

Figures 6 and 7 show two SEM micrographs of typically worn surfaces of modern metal-on-metal retrievals. The wear pattern on Figure 6 is seen on all the specimens and can be characterised by two types of scratches. The first type is relatively large scratches (width: about 5 µm, depth: about 5 µm, and some millimetres in length). The second type of scratches is described as minor scratches and they can be described as polished large scratches. The arrow on Figure 6 points to this polishing procedure.

The wear pattern in Figure 7 is seen on loaded areas on about 10 per cent of the specimens. Without magnification, these micro-pit areas are seen as "smoky" areas. The SEM investigation allows to characterise these "smoky" areas as micro-pit areas having a size of about 1–2 µm in diameter. The depth of these micro-pits was measured by two methods: by SEM micrograph in the transversal plane and by a laser profilometer. These two methods give a 0.3– 0.5 µm depth for these micro-pits. Components with micro-pit areas have the same wear rate as components without any "smoky" areas.

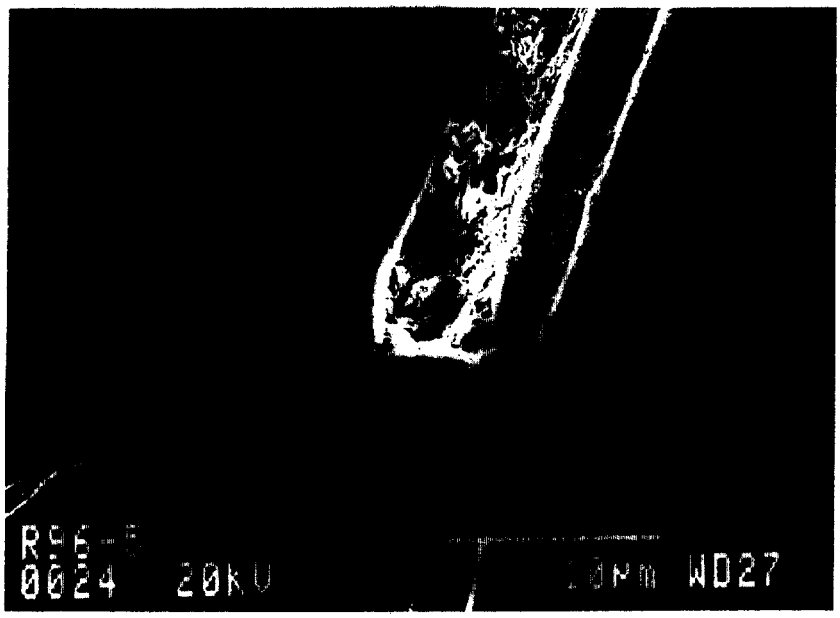

Figure 6: Worn surface of modern metal-on-metal retrievals – scratched areas.

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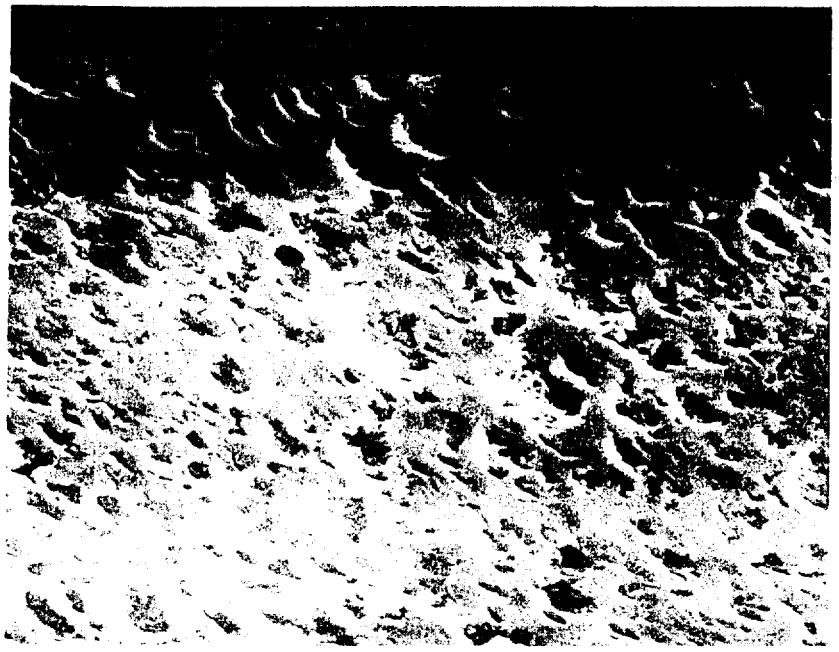

Figure 7: Worn surface of modern metal-on-metal retrievals – micro-pit areas.

Discussion

The in vitro results are consistent with the in vivo results (under the supposition that a patient walks one million steps per year). The mean wear rate for the modern metal-on-metal components retrieved in the first year in vivo (global wear rate: about 25 µm/year for the whole bearing – cup and head) is higher than the wear rate for the modern metal-on-metal components revised after more than two years (global wear rate: about 5 µm/year). The same global behaviour is observed with the hip simulator experiments.

The linear wear rate of the metal-on-metal bearings is at least 20 times less than the linear wear rate observed for metal-on-polyethylene or ceramic-on-polyethylene bearings, and this low wear rate is a very plausible explanation for the excellent preliminary clinical results of metal-on-metal bearings observed in Europe [9, 10].

The 5 implants with a wear rate above 20 µm/year had a mechanical instability (recurrent dislocations or cup tilting). These mechanical instabilities modify the geometry of the bearings, resulting in a moderate wear rate (between 20 and 80 µm/year). Even if this wear rate is about 10–15 times higher than the normal wear rate for metal-on-metal bearings, it is much smaller than the polyethylene wear rate observed in similar cases in metal-on-polyethylene or ceramic-on-polyethylene bearings. A possible explanation for the "squeaking" head (the fifth retrieval with a wear rate higher than 20 µm/year) may be a deficiency of lubrication allowing some resonance mechanisms to take place between the head and the cup.

As shown in Figure 5, the wear rate of the two types of retrievals (Müller metal-on-metal prostheses of the 1st generation [ball diameter 37/42 mm and CoCrMo cast alloy] and modern

metal-on-metal prostheses of the 2nd generation [ball diameter 28/32 mm and CoCrMo wrought alloy]) is consistent with a wear rate of about 5 µm/year, even if the alloy types (cast versus wrought) are different.

As shown in Figure 6, the abrasive wear is the typical wear mechanism for metal-on-metal bearings. Due to the remarkable ductility of the cobalt alloy, the abrasive scratches are closed by the normal relative movements between the two components of the bearing. This polishing procedure improves the surface finish in time, allowing a reduction of the wear rate. This mechanism was already observed for the 1st and 2nd generation of metal-on-metal bearings [11, 12].

As shown in Figure 7, the micro-pits are always situated in the load bearing area of the surface. The corrosion resistance of these retrievals was measured according to the ASTM standard G5 (solution: 0.9% NaCl for pH 4.0 and 0.15 mol HCl for pH 1.0, temperature: 40°C). The results of these measurements (E_{Break} = 575 mV_{SCE} for a pH 4.0 and E_{Break} = 800 mV_{SCE} for a pH 1.0) allow us to exclude any types of pitting corrosion. Due to the typical morphology of these micro-pits, the wear mechanism forming them can be characterised as adhesive/fatigue wear. The adhesive/fatigue wear is a typical wear phenomenon if the two components of a bearing are made of the same metal [13]. This type of wear has already been observed in retrieved metal-on-metal prostheses of the 1st generation [14] and in hip simulator experiment with modern metal-on-metal bearings made by another manufacturer [15]. This adhesive/fatigue wear cannot be regarded as a catastrophic wear mechanism, because the wear rate for the components with this adhesive/fatigue wear is exactly the same as the one measured for the components with the more conventional abrasive wear pattern.

Conclusions

This study of more than 140 metal-on-metal retrievals shows that the wear rate for this type of bearing is significantly lower (at least 20 times lower) than the wear rate for metal-on-polyethylene or for ceramic-on-polyethylene bearings. As this wear rate shows no tendency to increase with the implantation time, the metal-on-metal bearing can be a possible solution to improve the life expectancy of hip joint prostheses.

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Wear Morphology of Metal-Metal Implants: Hip Simulator Tests Compared with Clinical Retrievals[1]

S.-H. Park, H. McKellop, B. Lu, F. Chan, R. Chiesa

There is growing interest in metal-metal hip prostheses as a potential solution to the problem of osteolysis induced by polyethylene wear debris. Although some of the first-generation metal-metal hips experienced a high failure rate, many metal-metal implants have survived twenty years or more of active use without apparent wear-related problems [1, 4, 6]. For the second-generation metal-metal implants now being developed, joint simulator wear tests can be used to evaluate new materials and designs prior to their clinical use. However, care must be taken that the wear produced in the laboratory is the same as that which will occur in vivo. This study compared the bearing surfaces of modern-generation metal-metal implants worn in five different hip joint simulators with those of metal-metal implants worn in vivo.

Experimental Method

Hip Simulator Wear Tests

The seventeen modern-generation, metal-metal total hip replacements examined in this study had been tested up to three million cycles in five different joint simulators, manufactured by three companies and located in five different laboratories **(Table 1)**. The cobalt-chromium-molybdenum alloys included those satisfying ASTM F75 (cast, high carbon) and ASTM F1537 (wrought, low and high carbon). Five pairs of implants were tested in the "anatomical" position, i.e., with the cup mounted in the simulator above the ball, and twelve pairs were tested in the inverted position with the cup below the ball. Bovine serum was used as the lubricant in each case, but with varying concentrations and with additives **(Table 2)** that included antibiotics to retard bacterial degradation and, in some cases, ethylenediaminetetraacetic acid (EDTA) to minimize precipitation of calcium phosphate on the bearing surfaces [5]. Wear morphology analysis was performed after finishing the wear simulation. However, implants tested at the J. Vernon Luck Orthopaedic Research Center were analyzed after every million cycles of wear simulation.

Retrieved Implants

The clinically retrieved implants included eight METASUL (Sulzer Orthopaedics Ltd., Switzerland) cobalt-chromium-molybdenum alloy

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Table 1: Summary of simulators and specimens tested.

Laboratory	Type simulator	Test position	Implant manufacturer & ASTM specification
J. Vernon Luck Orthop. Res. Center	MMED	anatomical & inverted	Sulzer Orthopaedics (METASUL) F1537 (high carbon, wrought)
Jo Miller Laboratory	MMED	inverted	Wright Medical F75 (high carbon, cast) F1537 (low carbon, wrought)
Intermedics Orthopaedics	MMED	inverted	Sulzer Orthopaedics (METASUL) F1537 (high carbon, wrought)
Sulzer Medical Technology	STANMORE MK III	anatomical	Sulzer Orthopaedics (METASUL) F1537 (high carbon, wrought)
Massachusetts General Hospital	AMTI	anatomical	Sulzer Orthopaedics (METASUL) F1537 (high carbon, wrought)

Table 2: Summary of test conditions.

Laboratory	Lubricant	Antibiotic	EDTA	Test duration
J. Vernon Luck Orthopaedic Research Center	bovine serum 90%	sodium azide or Proxel GXL*	added	3×10^6
Jo Miller Laboratory	bovine serum 90%	penicillin, fungizone	added or without	3×10^6
Intermedics Orthopaedics	bovine serum 90%	sodium azide	added	3×10^6
Sulzer Medical Technology	bovine serum 33%	propylene-phenoxetol	without	2×10^6
Massachusetts General Hospital	bovine serum 90%	sodium azide	added	1×10^6

* Zenaca Inc., Wilmington, DE.

ASTM F1537 (ISO5832-12), wrought, 0.2% C) metal-metal total hip replacements. These were retrieved from five male and three female patients, 52 to 84 years of age. The implants were revised after 19 to 58 months *in situ*, two for aseptic loosening, two for infection, and one for dislocation, and three were obtained post-mortem.

Wear Morphology Analysis

Each of the simulator-tested and clinical retrieved implants was inspected with a light microscope for mapping of the original surfaces and worn areas. The components were then ultrasonically cleaned in a detergent solution and dried with filtered nitrogen gas. The surface

morphologies were then characterized on a Zeiss DSM 960 scanning electron microscope, using a GW backscattered electron detector in the topographic mode.

Results

Wear Morphology of Simulator-Tested Implants

There were three distinct zones on the surfaces of the simulator-tested specimens: the non-contact zone showing the original polishing marks, the main wear zone, and the transition zone in the form of a roughly circular band around the main wear zone. The main wear zones were concentrated near the load axis on a component that was fixed relative to the load axis, and were more distributed on the moving component. These features were comparable regardless of whether the implants had been tested in the anatomical or inverted position.

The non-contact zone of the METASUL implants displayed fine finishing scratches on the soft matrix, and round chromium carbide bumps averaging 5 μm in diameter **(Fig. 1)**. In contrast, the non-contact zone of the Wright implants, (whether cast high carbon or wrought low carbon alloy), included only finishing scratches without any obvious surface carbides **(Fig. 2)**.

In the main wear zone, the surface had been polished smoother than the original, noncontact zone. Residual polishing scratches and larger scratches were worn away, leaving a smooth surface with only fine scratches **(Fig. 3)**. Early

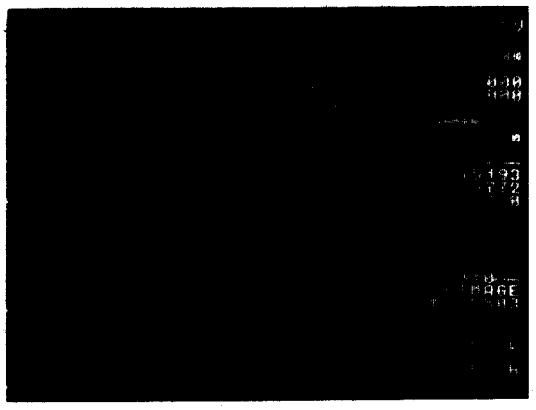

Figure 1: Non-contact area of a METASUL ball. The surface was covered with polishing scratches on the soft matrix, and smeared round bumps (top: ×1000). Atomic number contrast mode of the same field revealed that the round bumps were chromium carbides (bottom: ×1000).

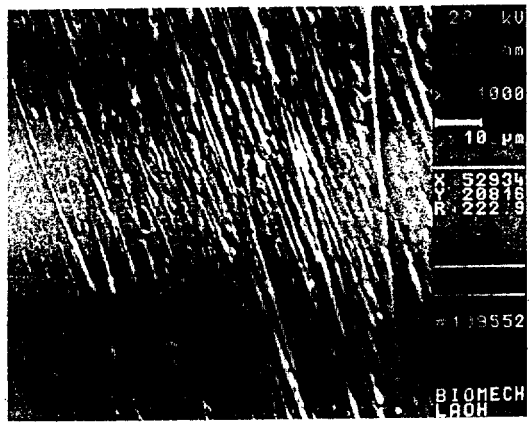

Figure 2: Non-contact area of a Wright Medical high carbon ball (×1000). Surface was covered with polishing scratches, but without visible carbide bumps.

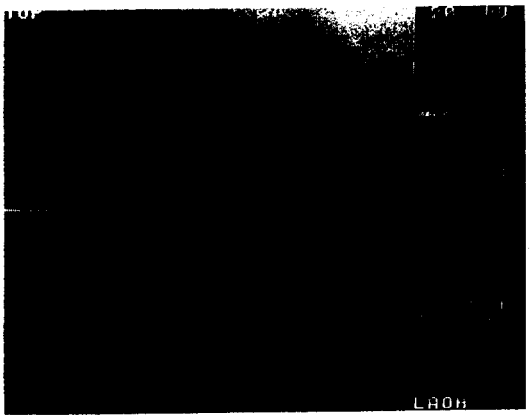

Figure 3: Main wear area of a METASUL ball tested in the Stanmore MK III simulator (top: ×200, bottom: ×800). The original rough surface was worn away, and fine scratches and carbide craters were present.

in the wear test (i.e., less than one million cycles), dislodged surface carbides on the METASUL implants had apparently produced large, third-body scratches (carbide "comets", **Fig. 4**). In contrast, after the initial wear-in, dislodging of the carbide was stopped, and most of the large third-body scratches had been polished smooth, leaving only fine scratches. In addition, in the main wear zone, there were numerous shallow, flat-bottomed, round craters or depressions, less than 1 μm deep and an average 5 μm in diameter **(Fig. 3 and 5)**. These depressions contained elevated concentrations of chromium and carbon (i.e., consistent with carbides), and were comparable in size and distribution to the original carbide bumps. The surfaces of the Wright F75 high carbon implants also showed these shallow carbide depressions but, in this case, they were more irregularly shaped, up to 20 μm in the largest dimension. Some areas of the F75 surfaces contained etched grain boundaries, as well as a few pits around the carbides **(Fig. 6)**. The carbide depressions were not observed on the surfaces of the Wright F1537 low carbon implants. Micropits about 1 to 3 μm in

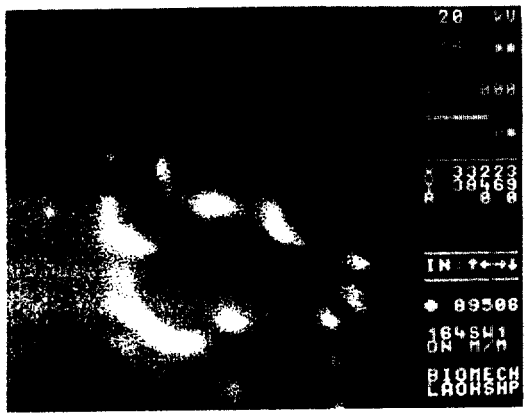

Figure 5: Carbide depressions in the main wear area of METASUL ball tested in the Intermedics Orthopaedics Laboratory simulator (×7000). The carbide was below the level of the worn surface, possibly due to dissolution.

Figure 4: METASUL ball tested in the JVL Laboratory simulator (one million cycles, inverted position, ×1350). Left side shows two large "ghost" carbides holes and the right side shows scratches produced by a recently fragmented carbide (carbide "comet").

Figure 6: The main wear zone of a Wright Medical high carbon ball tested in the Jo Miller Laboratory simulator (×500). Micropits were present at the boundary of the irregular shaped carbides.

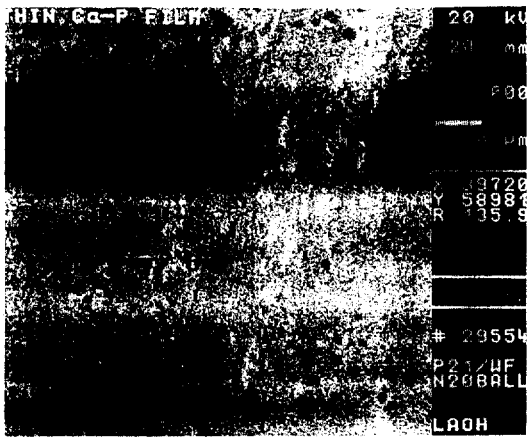

Figure 7: Transition zone of a METASUL implant tested in the AMTI simulator (×1000). The surface was covered with a tenacious thin film deposit containing calcium and phosphorous.

diameter and less than 1 μm deep were occasionally present in the highly polished worn areas in all of the simulator-tested implants.

The transition zone around the main wear zone was visible to the naked eye as a 1 to 5 mm wide whitish and light brown, roughly circular band. The brownish area was covered with tenacious, thin deposits containing calcium phosphate **(Fig. 7)**. Thicker deposits were initially observed in the outer periphery of the transition zone, but these were substantially removed during the cleaning process. In some cases, areas in the transition zone had been polished smooth covered with fine third-body scratches. Under the SEM, the whitish area was seen to contain clusters of micropits, depressions without presence of third-body scratches **(Fig. 8 and 9)**. Numerous large third-body scratches were typically located between the polished area and the non contact zone.

The micropits were observed in the main wear zone and/or the transition on all of the simulator-tested implants except two out of seven of the Wright implants tested in the MMED machine at the Jo Miller Laboratory. One of these

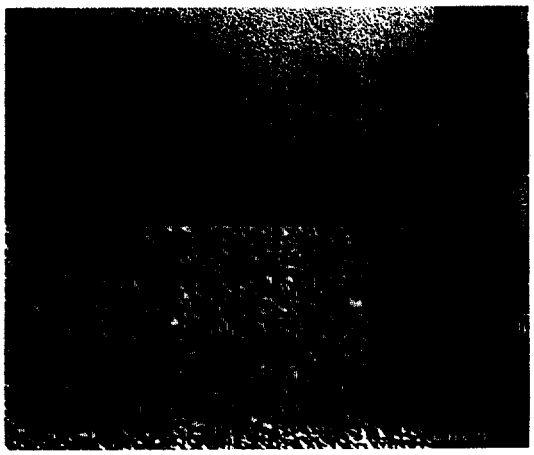

Figure 8: Transition zone of a METASUL ball tested in the AMTI simulator (top: ×200, bottom: ×800). A narrow band of the surface was covered with numerous micropits and round carbide craters.

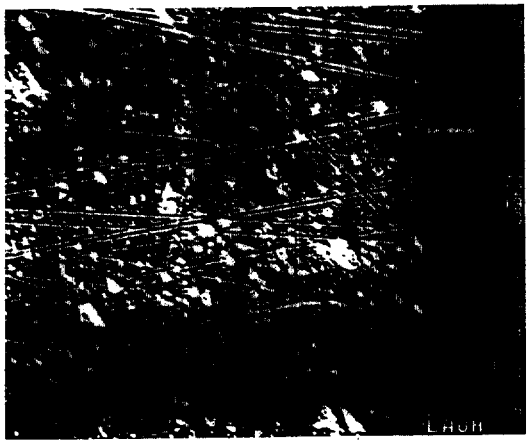

Figure 9: Transition zone of a Wright Medical low carbon ball (×1000). A narrow band of the surface was covered with numerous micropits and fine third-body scratches.

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was an F1537 alloy tested without EDTA and the second was an F75 alloy tested with EDTA. In both cases, the components were covered with a dense pattern of third-body scratches in the main wear and transition zones.

Wear Morphology of Clinically Retrieved Implants

Although the distribution of the main wear zone on the clinically retrieved METASUL implants was not as obvious as on the simulator-tested components, it appeared to be relatively concentrated on the balls and distributed on the cups, and the wear morphology was very comparable to the simulator-tested. In the transition area of the clinical retrievals, the protruding and bumpy surface was worn smooth without carbide dislodging **(Fig. 10)**. Even though evidence of dislodged carbides was not observed in the transition zone, most of the components had sustained considerable third-body abrasive scratching in the transition and main bearing zones. Most of the main bearing zone was smoothly polished, leaving fine, third-body scratches and shallow-bottomed carbide craters, comparable to the simulator-tested implants **(Fig. 11)**. One component that was revised for recurrent dislocation exhibited a large abrasive track across the center of the ball (apparently due to dragging across the rim of the metal acetabular socket). However, the edge of the track had been polished flat during subsequent use, and the extent of third-body damage in the implant was comparable to the other implants.

Two retrieved components exhibited a pattern of numerous micropits, from 1 to 3 µm in diameter and about 1 µm deep, covering much of the main bearing zones on the ball and cup **(Fig. 12)**. The micropits were located mostly in the matrix (i.e., between the large carbides) and at the edge of the carbide depressions, but not within the carbides. On one component, the area

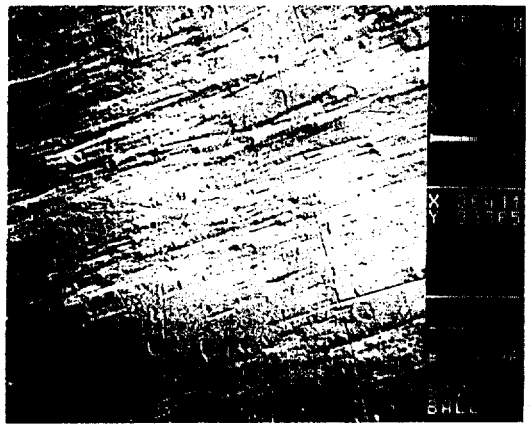

Figure 10: Transition zone of a retrieved METASUL ball. The mound containing carbides was polished smooth, and carbides bumps were transformed into shallow craters in the polished areas (×1000).

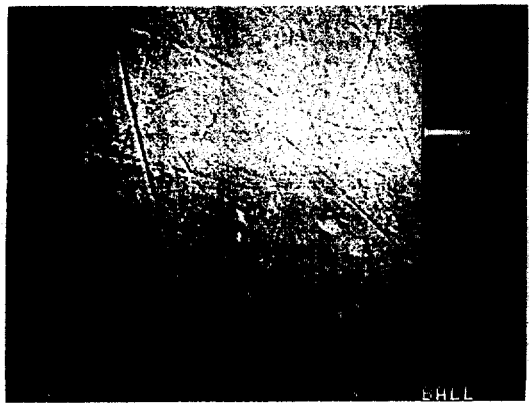

Figure 11: Main wear area of a retrieved METASUL ball. The surface was polished smooth and covered with fine third-body scratches and round carbide craters (×1000).

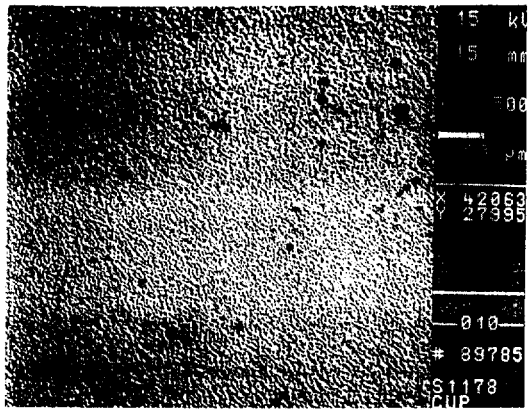

Figure 12: Area of a retrieved METASUL ball that appeared whitish to the eye. The surface was covered with numerous micropits and rounded carbide craters. Third-body scratches were rare in the micropitted area (×1000).

covered with micropits appeared whitish to the eye while, on the second, the micropitted area was not distinguishable except under SEM. The third-body scratches were less dense and shallower in the pitted area compared with the non-pitted, polished areas. As on the simulator-tested implants, thin, tenacious deposits of calcium phosphate-based precipitate were found in the transition areas of the retrieved implants, while the thicker deposits had been removed during the cleaning process.

Discussion

The similarity of the appearance of the bearing surfaces suggested that the wear mechanisms generated in the simulators were the same as those occurring in vivo with the metal-metal hip prostheses, both for first-generation [6, 11, 12] and second-generation implants. Both in vitro and in vivo, it was apparent that many of the surface carbides were dislodged from the surface of the contact zones during the wear-in phase and acted as third-body particles, generating extensive abrasive scratching and, probably, elevated early wear rates. The metal-metal bearings exhibited the ability to "self-polish", i.e., to polish out these third-body scratches, as well as the residual scratches from the original polishing. Even the severe damage that occurred during subluxation (i.e., as the ball was dragged across the metal rim of the acetabular shell) was substantially polished out during subsequent use. In contrast, such surface damage was not repaired outside of the contact zones.

Particularly in the high-carbon alloys, the surface carbides that were not dislodged were eventually worn to the level of the surrounding matrix. The shallow, flat-bottomed depressions, which also exhibited the typical composition of carbides on EDAX, were found only in the main wear zones of the simulator-tested specimens and the clinically retrieved implants, and only for the high carbon alloys. Muratoglu et al. [7] observed similar flat-bottomed carbide depressions on clinically retrieved cobalt-chrome-molybdenum balls, both from metal-polyethylene and first generation metal-metal hip prostheses. The texture of the floor of the depressions, measured using an atomic force microscope, suggested that they had been formed in part by corrosion. The fact that the carbide depressions observed in the present study were *below* the level of the surrounding matrix, and only formed in the area where the surface was polished smooth without dense scratches, was consistent with their being formed by dissolution of chrome carbides, rather than by mechanical wear (Fig. 3 and 5). That is, an initially protruding carbide may have been worn by abrasion to the level of the surrounding matrix, and then reduced below this level by dissolution (Fig. 10).

Micropits have also been observed previously on first and second generation metal-metal implants, however, a common denominator for their formation is not yet apparent. Walker [12] described "smoky" regions on the main contact

zones of some early retrieved McKee-Farrar metal-metal hips, which were found to contain extensive fine pits. He suggested that the micropits resulted from a fatigue-pitting mechanism. More recently, Rieker et al. [8] observed micropits on some first generation Muller type implant and second generation METASUL implants, and attributed their formation to adhesive wear, rather than corrosion. Rieker further reported that the wear rates of those METASUL implants with micropits were within the range of those without micropits.

In the present study, micropits were found on most of the simulator tested implants and on two out of eight second generation METASUL retrievals. The distribution of the micropits on the bearing surface was comparable to that of the matrix carbides in a cobalt-chrome-molybdenum alloy [10]. Metallographs of the METASUL implants showed large, rounded grain boundary carbides and fine dispersed carbides in the matrix **(Fig. 13)**, indicating that micropit formation was associated with fine matrix carbides, and was sensitive to the local contact conditions. That is, on clinically retrieved implants, the micropits were found primarily in the main contact zone and the transition zone, where the surface had been polished smooth and was almost free of third-body scratches. In contrast, on the simulator-tested specimens, micropits were observed primarily in a narrow band of well-polished surface in the transition zone. The fact that, in some cases, the micropits were observed clustered at the edge of large carbides suggested that the high energy state of the boundary, both for large grain boundary carbides and for fine matrix carbides, may have facilitated local chemical attack which, in turn, allowed the matrix carbides to be dissolved below the level of the surface and/or to be broken out by the repeated adhesive/abrasive wear processes. In fact, due to the lack of third-body scratches in the areas with micropits, dissolution of matrix carbides is a more reasonable explanation than dislodging.

Figure 13: Metallograph of a METASUL ball showing large round carbides and fine dispersed cabrides.

The formation of micropits was independent of the lubrication conditions used in the various simulators, which included variations in concentration of the serum, the presence of EDTA, or the particular antibiotic used. Originally, EDTA was added to the serum lubricant in hip simulator tests of metal-polyethylene and metal-ceramic implants to minimize precipitation of calcium phosphate onto the surface of the balls [5]. Since heavy layers of calcium phosphate were *not* typically observed on retrieved metal-polyethylene or ceramic-polyethylene implants, they were considered to be an artifact, possibly due to the elevated temperatures that are reached after several hours of uninterrupted running in the simulator [3]. However, since deposits containing calcium phosphate *are* typically present on retrieved metal-metal implants [6, 9, 11, 12], it has been suggested that EDTA should not be used in simulator tests of metal-metal implants. On the other hand, Chan et al. [2] have reported that the amount of wear in simulator tests was comparable whether or not EDTA was added to the serum and, since the formation of these interferes with the weighing and/or dimensional techniques used to determine the amount of

wear, it might be preferable to use EDTA in order to maximize the accuracy of the wear measurements. – This issue should be given careful consideration by investigators performing laboratory wear tests of the second-generation metal-metal implants.

Conclusion

Although the location and distribution of the worn zones on the implants differed somewhat among the various simulators, depending on the particular load-motion patterns applied, the type of wear induced in each of them appeared very comparable to that occurring with metal-metal implants in vivo. Thus, provided that the magnitude of the contact stresses applied and the sliding distance per cycle are reasonably comparable to those in vivo, it can be expected that these hip simulators would also generate relative amounts of wear for two candidate materials comparable to that in vivo [8]. Nevertheless, additional studies should be directed toward identifying the mechanisms of formation of the shallow depressions and the micropits and their effect on the wear rates of the metal-metal implants.

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CORPORATE HEADQUARTERS

Summary of Safety and Effectiveness

Applicant or Sponsor: Biomet, Inc.
P.O. Box 587
Warsaw, Indiana 46581-0587

Contact Person: Michelle L. McKinley
Regulatory Specialist

Proprietary Name: M2a™ Acetabular System

Common or Usual Name: acetabular cup prosthesis

Classification Name: prosthesis, hip, semi-constrained, metal/polymer, uncemented (888.3330)

Device Product Code: 87 KWA

Substantially Equivalent Devices: M2a™ Acetabular System, McKee Farrar, DePuy Pinnacle Metal-on-Metal Acetabular Cup Liners

Device Description:

123

MAILING ADDRESS
P.O. Box 587
Warsaw, IN 46581-0587

SHIPPING ADDRESS
56 E. Bell Drive
Warsaw, IN 46582

OFFICE
219.267.6639

FAX
219.267.8137

E-MAIL
biomet@biomet.com

a.) Non-inflammatory degenerative joint disease including avascular necrosis, diastrophic variant, fracture of the pelvis, fused hip, leg perthes, 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.) Revision of previously failed total hip arthroplasty.

Basis of Substantial Equivalence:

In terms of overall design and intended use, the M2a™ Acetabular System is equivalent to all other total hip acetabular components. Specifically, the geometry, materials, and fixation enhancements are similar to the following devices:

1. M2a™ Acetabular System: K993438, K003363
2. McKee Farrar: Pre-amendment Device
3. DePuy Pinnacle Metal-on-Metal Acetabular Cup Liners: K003523

Mechanical testing was also used to determine substantial equivalence.

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CLASS III CERTIFICATION AND SUMMARY

[As required by 21 CFR 807.94]

I certify in my capacity as Regulatory Specialist of Biomet, Inc., that I have conducted a reasonable search of all information known or otherwise available about the types and causes of safety and effectiveness problems that have been reported for metal on metal acetabular components. I further certify that I am aware of the types of problems to which metal on metal devices are susceptible, and to the best of my knowledge, the following summary of the types and causes of safety or effectiveness problems about metal on metal acetabular components is complete and accurate.

3/23/01
(Date)

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000108

CLASS III SUMMARY

Metal on Metal Articulating Surface

I. Medical Device Reports/Vigilance Reports

A reasonable effort was made to find all adverse reports made for these devices under the Medical Device Reporting (MDR) regulations and under the vigilance reporting requirement for medical devices under Article 10 of the European Medical Devices Directive (MDD). A search of publicly available information yielded four reports filed for the metal/metal semi-constrained total hip prostheses. They included the following:

1. The anti-rotation pin became dislodged from the polyethylene acetabular insert.
2. Developed deep infection.
3. Revision due to impingement between the femoral stem and the acetabular insert.
4. The pin in the insert came out after 1.5 years.

II. Literature Review of risks associated with metal on metal articulating surfaces.

The following is a list of types of safety and effectiveness concerns/problems associated with the metal on metal total hip arthroplasties reported in published literature. See the attached Bibliography and Metal on Metal clinical summary of the literature.

1. cancer risk
2. poor Harris Hip Scores (HHS) postoperatively
3. dislocation
4. revision
5. progressive pelvic osteolysis
6. metal particles (wear debris)
7. recurrent pain
8. aseptic loosening
9. ossification
10. metal sensitivity
11. infection
12. progressive cement-bone interface radiolucencies
13. increase serum cobalt levels (significance unknown)
14. osteolysis in the femur and acetabulum
15. debonding of the cup
16. periarticular calcification
17. trochanteric bursitis

Return to Search

BRAND NAME	ACET INS SZ 28X55 METASUL APR
TYPE OF DEVICE	HIP PROSTHESIS
BASELINE BRAND NAME	ACET INS SZ 28X55 METASUL APR
BASELINE GENERIC NAME	HIP PROSTHESIS
BASELINE CATALOGUE NUMBER	4340-28-055
BASELINE DEVICE FAMILY	NA
IS BASELINE PMA NUMBER PROVIDED?	NO
BASELINE PREAMENDMENT?	NO
TRANSITIONAL?	NO
SHELF LIFE(Months)	NA
DATE FIRST MARKETED	12/01/1999
MANUFACTURER	SULZER ORTHOPEDICS INC. 9900 SPECTRUM AUSTIN, TX 78717
MANUFACTURER CONTACT	RANDY JASEK, SUPERVISOR 9900 SPECTRUM DR AUSTIN , TX 78717 (512) 432 -9611
DEVICE EVENT KEY	269992
MDR REPORT KEY	278978
EVENT KEY	261599
REPORT NUMBER	2935620-2000-00012
DEVICE SEQUENCE NUMBER	1
PRODUCT CODE	KWA
REPORT SOURCE	MANUFACTURER
SOURCE TYPE	COMPANY REPRESENTATIVE
TYPE OF REPORT	INITIAL,FOLLOWUP
REPORT DATE	04/24/2000
***1* DEVICE WAS INVOLVED IN THE EVENT**	
***1* PATIENT WAS INVOLVED IN THE EVENT**	
DATE FDA RECEIVED	05/24/2000
IS THIS AN ADVERSE EVENT REPORT?	YES

PM

000110

IS THIS A PRODUCT PROBLEM REPORT?	NO
DEVICE OPERATOR	HEALTH PROFESSIONAL
DEVICE CATALOGUE NUMBER	4340-28-055
DEVICE LOT NUMBER	1251199
WAS DEVICE AVAILABLE FOR EVALUATION?	DEVICE NOT RETURNED TO MANUFACTURER
DATE RETURNED TO MANUFACTURER	04/24/2000
IS THE REPORTER A HEALTH PROFESSIONAL?	NO
WAS THE REPORT SENT TO FDA?	NO
DATE MANUFACTURER RECEIVED	04/24/2000
DATE DEVICE MANUFACTURED	08/01/1996
IS THE DEVICE SINGLE USE?	YES
TYPE OF DEVICE USAGE	INITIAL
PATIENT OUTCOME	HOSPITALIZATION

ADVERSE EVENT OR PRODUCT PROBLEM DESCRIPTION
REPORT DATE: 04/24/2000 MDR TEXT KEY: 953779 Patient Sequence Number: 1
ALLEGEDLY THE ANTI-ROTATION PIN BECAME DISLODGED FROM THE POLYETHYLENE ACETABULAR INSERT.

ADDITIONAL MANUFACTURER NARRATIVE
REPORT DATE: 04/24/2000 MDR TEXT KEY: 1012481
H6 METHOD REVIEWED MFG/INSPECTION RECORDS WITH NO FORM, FIT OR FUNCTION DISCREPANCIES NOTED. H6 CONCLUSIONS THE CAUSE OF DISSOCIATION OF THE ANTI-ROTATION PIN FROM THE INSERT CANNOT BE DETERMINED DUE TO INSUFFICIENT INFO PROVIDED.

PATIENT TREATMENT DATA

Date Received: 08/08/2000 Patient Sequence Number: 1

#	Treatment	Treatment Date
1	3442 28MM +4MM ALLOPRO BATORY FEM HD	01/01/1998
2	(LOT# B069262)(10/98).	01/01/1998

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BRAND NAME	SZ 28X57MM STD METASUL INS I-O
TYPE OF DEVICE	HIP PROSTHESIS
BASELINE BRAND NAME	SZ 28X57MM STD METASUL INS I-O
BASELINE GENERIC NAME	HIP PROSTHESIS
BASELINE CATALOGUE NUMBER	4372-28-057
BASELINE DEVICE FAMILY	NA
IS BASELINE PMA NUMBER PROVIDED?	NO
BASELINE PREAMENDMENT?	NO
TRANSITIONAL?	NO
SHELF LIFE(Months)	NA
DATE FIRST MARKETED	08/03/1999
MANUFACTURER	SULZER ORTHOPEDICS, INC. 9900 SPECTRUM DR. AUSTIN, TX 78717
MANUFACTURER CONTACT	RANDY JASEK, SUPERVISOR 9900 SPECTRUM DR AUSTIN , TX 78717 (512) 432 -9611
DEVICE EVENT KEY	275284
MDR REPORT KEY	284467
EVENT KEY	266856
REPORT NUMBER	2935620-2000-00022
DEVICE SEQUENCE NUMBER	1
PRODUCT CODE	KWA
REPORT SOURCE	MANUFACTURER
SOURCE TYPE	COMPANY REPRESENTATIVE
EVENT TYPE	INJURY
TYPE OF REPORT	INITIAL,FOLLOWUP
REPORT DATE	06/16/2000
***1* DEVICE WAS INVOLVED IN THE EVENT**	
***1* PATIENT WAS INVOLVED IN the EVENT**	
DATE FDA RECEIVED	07/05/2000

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000112

IS THIS AN ADVERSE EVENT REPORT?	YES
IS THIS A PRODUCT PROBLEM REPORT?	NO
DEVICE OPERATOR	HEALTH PROFESSIONAL
DEVICE CATALOGUE NUMBER	4372-28-057
DEVICE LOT NUMBER	1330653
WAS DEVICE AVAILABLE FOR EVALUATION?	DEVICE NOT RETURNED TO MANUFACTURER
DATE RETURNED TO MANUFACTURER	06/19/2000
IS THE REPORTER A HEALTH PROFESSIONAL?	NO
WAS THE REPORT SENT TO FDA?	NO
DATE MANUFACTURER RECEIVED	06/16/2000
DATE DEVICE MANUFACTURED	10/01/1998
IS THE DEVICE SINGLE USE?	YES
TYPE OF DEVICE USAGE	INITIAL
PATIENT OUTCOME	REQUIRED INTERVENTION

ADVERSE EVENT OR PRODUCT PROBLEM DESCRIPTION
REPORT DATE: 06/16/2000 MDR TEXT KEY: 974574 Patient Sequence Number: 1
PT WEIGHT BEARING FOR ONLY ONE WEEK ONLY THEN DEVELOPED DEBILITATING PAIN AND RETURNED TO BED UNTIL DEEP INFECTION WAS DETERMINED AND EXPLANTED IN 2000.

ADDITIONAL MANUFACTURER NARRATIVE
REPORT DATE: 06/16/2000 MDR TEXT KEY: 1026547
H6 METHOD REVIEWED (OTHER) REVIEWED MFR/INSPECTION RECORDS, WITH NO DISCREPANCIES NOTED. H6 CONCLUSIONS (OTHER) THE REVISION SURGERY WAS DUE TO DEEP SEPTIC INFECTION, AND WAS UNRELATED TO SULZER ORTHOPEDICS INC. IMPLANTS. H10 DOCUMENTATION PROVIDED FROM AGENT STATES "REVISION SURGERY WAS DUE TO DEEP SEPTIC INFECTION AND WAS UNRELATED TO ZULZER ORTHOPEDICS INC. IMPLANTS."

PATIENT TREATMENT DATA

Date Received: 08/24/2000 Patient Sequence Number: 1

#	Treatment	Treatment Date
1	7356-01-102 NATURAL HIP HA COLLARLESS SZ 2 LT	11/01/1999
2	(LOT # 1370384)(11/1999)	11/01/1999
3	7340-28-400 METASUL COCR HD 12/14 +4 NECK 28MM	11/01/1999
4	(LOT # 1340044)(11/1999).	11/01/1999

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Return to Search

BRAND NAME	ACET INS SZ 28X53 METASUL-APR
TYPE OF DEVICE	HIP PROSTHESIS
BASELINE BRAND NAME	ACET INS SZ 28X53 METASUL-APR
BASELINE GENERIC NAME	HIP PROSTHESIS
BASELINE CATALOGUE NUMBER	4340-28-053
BASELINE DEVICE FAMILY	NA
IS BASELINE PMA NUMBER PROVIDED?	NO
BASELINE PREAMENDMENT?	NO
TRANSITIONAL?	NO
SHELF LIFE(Months)	NA
DATE FIRST MARKETED	12/01/1999
MANUFACTURER	SULZER ORTHOPEDICS INC. 9900 SPECTRUM DR. AUSTIN, TX 78717
MANUFACTURER CONTACT	RANDY JASEK, SUPERVISOR 9900 SPECTRUM DR AUSTIN , TX 78717 (512) 432 -9611
DEVICE EVENT KEY	281298
MDR REPORT KEY	290650
EVENT KEY	272806
REPORT NUMBER	2935620-2000-00030
DEVICE SEQUENCE NUMBER	1
PRODUCT CODE	KWA
REPORT SOURCE	MANUFACTURER
SOURCE TYPE	COMPANY REPRESENTATIVE
EVENT TYPE	INJURY
TYPE OF REPORT	INITIAL,FOLLOWUP
REPORT DATE	07/21/2000
***1* DEVICE WAS INVOLVED IN THE EVENT**	
***1* PATIENT WAS INVOLVED IN THE EVENT**	
DATE FDA RECEIVED	08/17/2000

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000114

IS THIS AN ADVERSE EVENT REPORT?	YES
IS THIS A PRODUCT PROBLEM REPORT?	NO
DEVICE OPERATOR	HEALTH PROFESSIONAL
DEVICE CATALOGUE NUMBER	4340-28-053
DEVICE LOT NUMBER	1187760
WAS DEVICE AVAILABLE FOR EVALUATION?	DEVICE NOT RETURNED TO MANUFACTURER
DATE RETURNED TO MANUFACTURER	08/09/2000
IS THE REPORTER A HEALTH PROFESSIONAL?	NO
WAS THE REPORT SENT TO FDA?	NO
DATE MANUFACTURER RECEIVED	07/21/2000
DATE DEVICE MANUFACTURED	09/01/1995
IS THE DEVICE SINGLE USE?	YES
TYPE OF DEVICE USAGE	INITIAL
PATIENT OUTCOME	HOSPITALIZATION REQUIRED INTERVENTION

ADVERSE EVENT OR PRODUCT PROBLEM DESCRIPTION
REPORT DATE: 07/21/2000 MDR TEXT KEY: 997321 Patient Sequence Number: 1
IT WAS REPORTED: REVISION HIP SURGERY WAS PERFORMED DUE TO IMPINGEMENT BETWEEN THE FEMORAL STEM AND THE ACETABULAR INSERT.

ADDITIONAL MANUFACTURER NARRATIVE
REPORT DATE: 07/21/2000 MDR TEXT KEY: 1064198
ADDED SECTION H6. CORRECTED SECTION H3. H6: METHOD: REVIEW OF MFR/INSPECTION RECORDS WITH NO DISCREPANCIES NOTED. H6: RESULTS: INDICATIONS ARE THAT EARLY IMPINGEMENT WAS OCCURRING, POSSIBLY WITH SOFT TISSUE OR IMPROPERLY POSITIONED ACETABULAR OR FEMORAL COMPONENTS. H6: RESULTS: POSSIBLE SURGICAL TECHNIQUE. H6: CONCLUSIONS: THE CAUSE OF OCCURRENCE COULD NOT BE DETERMINED SINCE X-RAY AND THE FEMORAL STEM WERE NOT PROVIDED. SPECULATION IS THAT THE FEMORAL STEM IMPINGED ON THE ACETABULAR INSERT.

PATIENT TREATMENT DATA

Date Received: 10/05/2000 Patient Sequence Number: 1

#	Treatment	Treatment Date
1	1. 4310-02-053 APR II 12 SLOT SHELL 53MM (LOT#	01/01/2000
2	1195949)(11/2000).	01/01/2000
3	2. 7340-28-004 METASUL COCR HD 12/14-4 NECK 28MM	01/01/2000
4	(LOT#1181955)(11/2000)	01/01/2000
5	3. 7354-01-203 NATURAL-HIP POR COLL STM LT SZ 3	01/01/2000
6	(LOT# 1213577)(11/2000).	01/01/2000

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000115

BRAND NAME	ACET INS SZ 28X49 METASUL-APR
TYPE OF DEVICE	HIP PROSTHESIS
BASELINE BRAND NAME	ACET INS SZ 28X49 METASUL-APR
BASELINE GENERIC NAME	HIP PROSTHESIS
BASELINE CATALOGUE NUMBER	4340-28-049
BASELINE DEVICE FAMILY	NA
IS BASELINE PMA NUMBER PROVIDED?	NO
BASELINE PREAMENDMENT?	NO
TRANSITIONAL?	NO
SHELF LIFE(Months)	NA
DATE FIRST MARKETED	12/01/1999
MANUFACTURER	SULZER ORTHOPEDICS, LTD. GRABENSTRASSE 25 BAAR SWITZERLAND CH-6341
MANUFACTURER CONTACT	RANDY JASEK, SUPERVISOR 9900 SPECTRUM DR AUSTIN , TX 78717 (512) 432 -9611
DEVICE EVENT KEY	296783
MDR REPORT KEY	306697
EVENT KEY	288203
REPORT NUMBER	2935620-2000-00062
DEVICE SEQUENCE NUMBER	1
PRODUCT CODE	KWA
REPORT SOURCE	MANUFACTURER
EVENT TYPE	INJURY
TYPE OF REPORT	INITIAL
REPORT DATE	11/06/2000
***1* DEVICE WAS INVOLVED IN THE EVENT**	
***1* PATIENT WAS INVOLVED IN THE EVENT**	
DATE FDA RECEIVED	12/01/2000

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000116

IS THIS AN ADVERSE EVENT REPORT?	YES
IS THIS A PRODUCT PROBLEM REPORT?	NO
DEVICE OPERATOR	HEALTH PROFESSIONAL
DEVICE CATALOGUE NUMBER	4340-28-049
DEVICE LOT NUMBER	1303668
WAS DEVICE AVAILABLE FOR EVALUATION?	DEVICE NOT RETURNED TO MANUFACTURER
DATE RETURNED TO MANUFACTURER	11/13/2000
IS THE REPORTER A HEALTH PROFESSIONAL?	NO
WAS THE REPORT SENT TO FDA?	NO
DATE MANUFACTURER RECEIVED	11/06/2000
DATE DEVICE MANUFACTURED	09/01/1997
IS THE DEVICE SINGLE USE?	YES
TYPE OF DEVICE USAGE	INITIAL
PATIENT OUTCOME	REQUIRED INTERVENTION

ADVERSE EVENT OR PRODUCT PROBLEM DESCRIPTION
REPORT DATE: 11/06/2000 MDR TEXT KEY: 1055495 Patient Sequence Number: 1
IT WAS REPORTED: THE PIN IN THE METASUL INSERT CAME OUT AFTER 1.5 YEARS.

PATIENT TREATMENT DATA

Date Received: 12/01/2000 Patient Sequence Number: 1

#	Treatment	Treatment Date
1	3461 AP BALL HEAD 28/14 (LOT# B285607)(2000).	01/01/2000

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Metal on Metal Total Hip Arthroplasty
Bibliography

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3. Randle, R. and Gordiev, K.: Metal-on-metal articulation in total hip arthroplasty: preliminary results in 57 cases. Aust N Z J Surg 67 (9): 634-636, Sept 1997.

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6. Szuszczewicz, E.S., Schmalzried, T.P. and Petersen, T.D.: Progressive bilateral pelvic osteolysis in a patient with McKee-Farrar metal-metal total hip prostheses. J Arthroplasty 12 (7): 819-824, Oct 1997.

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1.

Clin Orthop 1996 Aug;(329 Suppl):S280-9

Cancer risk after metal on metal and polyethylene on metal total hip arthroplasty.

Visuri T, Pukkala E, Paavolainen P, Pulkkinen P, Riska EB

Central Military Hospital, Helsinki, Finland.

The incidence of cancer after metal on metal total hip arthroplasty (McKee-Farrar) and polyethylene on metal total hip arthroplasty (Brunswik, Lubinus) was compared with that of the general population in Finland. The mean followup time for the patients who had metal on metal total hip arthroplasty was 15.7 (9092 person years) and for the patients who had polyethylene on metal total hip arthroplasty it was 12.5 years (19,846 person years). One hundred thirteen malignant cancers were observed in patients who had metal on metal total hip arthroplasty and 212 were observed in patients who had polyethylene on metal total hip arthroplasty. The standardized incidence ratio for all cancers of the metal on metal arthroplasty group was 0.95 (95% confidence limits 0.79-1.13) and that of the polyethylene on metal arthroplasty group was 0.76 (95% confidence limits 0.68-0.86). The risk of total cancer in the patients who had metal on metal total hip arthroplasty was 1.23-fold compared with that of the patients who had polyethylene on metal total hip arthroplasty. Both groups had significantly less lung cancer than the general population: the leukemia incidence in the patients who had metal on metal total hip arthroplasty was slightly increased (observed to experienced 7/3.03, standardized incidence ratio 0.61; 95% confidence limits 0.17-1.56). The leukemia rate of the patients who had metal on metal total hip arthroplasty was 3.77-fold compared with that of the patients who had polyethylene on metal total hip arthroplasty, but this difference was not statistically significant. No sarcomas were observed at the site of the prosthesis. The incidence of the other forms of cancers did not differ significantly from those in the general population. The observed variation in the incidence of different cancers among patients who had total hip arthroplasty compared with the general population suggests that factors other than total hip arthroplasty play a major role in the origin of cancer.

2.

J Bone Joint Surg [Br] 1986 Aug;68(4):520-7

The McKee-Farrar hip arthroplasty. A long-term study.

August AC, Aldam CH, Pynsent PB

Between 1965 and 1973 a total of 808 McKee-Farrar metal-on-metal cemented total hip arthroplasties were performed in the Norfolk and Norwich Hospital. Of these, 230 surviving arthroplasties have been reviewed at average follow-up of 13.9 years. There were good or excellent results in 49% of the arthroplasties as judged by the Harris hip score with 78% of these having little or no pain. A comprehensive radiographic analysis was undertaken and a survivorship study of 81% of the total number of prostheses is presented.

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3.

Aust N Z J Surg 1997 Sep;67(9):634-6

Metal-on-metal articulation in total hip arthroplasty: preliminary results in 57 cases.

Randle R, Gordiev K

St Vincent's Hospital, Lismore, New South Wales, Australia.

BACKGROUND: Aseptic loosening of hip prostheses may lead to implant failure and necessitate revision surgery. Metal-on-metal hip articulation has characteristics that may minimize prosthesis loosening when compared with other forms of hip articulation. The purpose of the present prospective study was to identify early problems that may contraindicate the use of the 'prosthesis femorale modulaire' (PFM) metal-on-metal prosthesis. METHODS: The preliminary results of 57 metal-on-metal total hip arthroplasties performed by one surgeon (RR) from 1994 to 1996 in Lismore, New South Wales, are presented here. Data were obtained using patient questionnaires, physical examination and by examination of radiographs. RESULTS: A total of 87.6% of patients had an excellent or good outcome, according to the Harris rating system, at the latest review. The two patients with poor results had obvious alternative causes for their continuing symptoms. There was no radiological evidence of bone or prosthesis failure during the period of follow-up. CONCLUSIONS: The preliminary results are comparable with those of other authors who have examined the early results of metal-on-metal total hip arthroplasty.

4.

Clin Orthop 1996 Aug;(329 Suppl):S11-34

Metal on metal bearings in hip arthroplasty.

Amstutz HC, Grigoris P

Joint Replacement Institute, Orthopaedic Hospital, Los Angeles, CA, USA.

Periprosthetic osteolysis caused by wear debris released from the bearing surface of polyethylene components is the major problem in contemporary hip arthroplasty. Several types of metal on metal prostheses were developed in the 1960s, but by the mid 1970s they were completely displaced by polyethylene bearings. There have been several generations of all metal components with significant variation in design, tolerances, and bearing surface quality. A number of these hips have survived for more than 25 years because of low wear rates and minimal osteolysis. Identification of the characteristics that contributed to long term function is important. The historical development and clinical results of metal on metal hip arthroplasties are presented. Factors that led to the abandonment of the metal on metal bearings are related to: (1) the early success of the Charnley prosthesis; (2) the frictional torque issue; (3) carcinogenesis concerns; (4) metal sensitivity concerns; (5) high infection rates; and (6) increased strain rates in periprosthetic bone and fatigue fractures of the acetabular floor. The accumulated experience to date enables one to evaluate all the factors with a different perspective and makes the use of newer metal on metal bearings a viable option in younger patients.

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5.

Clin Orthop 1989 Sep;(246):39-47

Experience with total hip arthroplasty in Greece, the first 20 years. A particular reference to long-term results with the McKee-Farrar technique.

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Asklepion Red Cross Orthopaedic Hospital, Athens, Greece.

Total hip arthroplasty was introduced early in Greece (1966-1967) and was initially performed in very small numbers. However, even after the difficult early period, statistics are low compared to other countries. An estimate brings the total number of operations during a 20-year period to 9000 with a rate in recent years of 1000 per year. An early series of 143 arthroplasties (122 patients), mainly of the McKee-Farrar metal-to-metal technique, was reviewed. A final group of 52 arthroplasties, all primary prostheses of the McKee-Farrar type, were assessed with a follow-up period ranging from 12 to 20 years postoperatively. In the surviving cases, 53% were pain-free, and, in 79%, useful motion was maintained. The roentgenographic results were less satisfying but a fair roentgenographic picture did not preclude a good or very good clinical and functional outcome. Although the metal-to-metal technique now appears to be more of historic value, long-term results with this type of implant offer grounds for comparison with current cemented techniques.

6.

Arthroplasty 1997 Oct;12(7):819-24

Progressive bilateral pelvic osteolysis in a patient with McKee-Farrar metal-metal total hip prostheses.

Szuszczewicz ES, Schmalzried TP, Petersen TD

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As accumulating evidence indicates that polyethylene plays a central role in periprosthetic osteolysis, there is a renewed interest in alternatives such as metal-metal bearings. Several long-term studies report encouraging results with the McKee-Farrar total hip arthroplasty, but there is a paucity of data on the incidence, severity, and pathogenesis of osteolysis in metal-metal bearing total hip arthroplasties. This study presents a patient who had progressive bilateral pelvic osteolysis associated with his McKee-Farrar metal-metal total hip prostheses. His left hip was revised after 13.5 years of service. The tissues revealed no gross metal staining and fewer inflammatory constituents than are typically found in metal-polyethylene bearing hips. His right hip was still functioning after 22.5 years of service, although the acetabular component was loose by that point. An arthrogram of this hip demonstrated communication of the joint with the iliac osteolysis. The development of osteolysis in both hips followed a pattern similar to that seen in metal-polyethylene total hip arthroplasties. Bearing wear could not be detected in either of the hips. Accumulating evidence indicates that particulate debris of appropriate size and number is capable of fueling periprosthetic inflammation. Specific to this study, consideration should be given to particles of cobalt-chromium alloy, polymethyl methacrylate bone-cement, and barium sulfate. Other factors that should be considered are increased joint fluid pressure, soluble inflammatory mediators, and the effective joint space. When bone becomes part of the effective joint space, it is exposed to particulate debris, soluble factors, and potentially increased joint fluid pressures, which may promote localized bone resorption. It must be kept in mind that the development of osteolysis is multifactorial. Although bearings with better wear characteristics are desirable, the elimination of polyethylene will not eliminate osteolysis.

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7.

Clin Orthop 1996 Aug;(329 Suppl):S244-55

Metal on metal bearings. A practical alternative to metal on polyethylene total joints?

Black J

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Metal on metal articulation is proposed as an alternative to metal on polymer in total hip replacement arthroplasty as a technical means of reducing wear debris production and subsequent osteolysis leading to the need for surgical revision. The question of whether metal on metal articulation is a practical alternative to current practice is essentially that of whether it is as safe as, and more effective than, metal on polymer articulations in use for more than 20 years. Unfortunately, the metal on metal articulation introduces additional biologic risks associated with production of increased metallic corrosion and wear products. The clinical longevity and success of metal on polymer articulation in total hip replacements, as embodied in the Charnley type, is such that it may prove humanly impossible to determine that metal on metal articulations are more effective, even if that is objectively the case. Therefore, it is suggested that, consistent with modern technical and ethical standards, it cannot be concluded that metal on metal articulation is a practical alternative to current metal on polymer designs. It is suggested that future improvement in total hip replacement arthroplasty outcome is more likely to be through evolutionary than revolutionary designs.

8.

Clin Orthop 1996 Aug;(329 Suppl):S99-105

Contemporary total hip replacement with metal on metal articulation.

Hilton KR, Dorr LD, Wan Z, McPherson EJ

Center for Arthritis and Joint Implant Surgery, USC University Hospital, Los Angeles, CA, USA.

Between 1991 and 1994, 74 patients received total hip replacements with metal on metal articulation. The results of these patients with 74 hips who had a 6-month to 4-year (average, 2.2 years average) followup are reported. Patients were prospectively evaluated by the Harris hip score, a patient self assessment form, and radiographs. The average postoperative Harris hip score was 91. Patient self assessment forms showed that 95% of the patients scored their results as excellent or good. No patient had revision for loosening, but 1 underwent revision surgery for recurrent dislocation. Serial radiographs have not revealed loosening or osteolysis. Wear could not be measured radiographically. Twenty-seven of the patients had bilateral total hip replacements with 1 hip being metal on polyethylene; the patients could not detect any difference between the 2 hips. The satisfactory short term results from the contemporary metal on metal articulation investigated in this study are encouraging and warrant continued study.

141

9.

Orthopedics 1991 Feb;14(2):137-42

Cancer risk after Mckee-Farrar total hip replacement.

Visuri T, Koskenvuo M

Department of Public Health, University of Helsinki, Finland.

Cancer incidence in 433 McKee-Farrar total hip replacement patients, operated on between 1967 and 1973, was examined for 5729 person-years, to the end of 1981. The expected number of natural deaths was slightly higher than observed, suggesting some selection of the operated patients. The risk of total cancer incidence did not increase, but the risk for site-specific cancer did because there were no cases of kidney or bladder cancer, or rare forms of cancer. The risk of leukemias and lymphomas increased, and the risk of breast cancer decreased; these results were surprisingly similar to those of a study from New Zealand. This study concluded that patients with total hip prostheses have a cancer morbidity differing from the general population. The role of chrome-cobalt-molybdenum alloy in carcinogenesis requires further investigation.

10.

J Arthroplasty 1991;6 Suppl:S5-10

Survivorship analysis of the Ring hip arthroplasty.

Bryant MJ, Mollan RA, Nixon JR

Department of Orthopaedic Surgery, Musgrave Park Hospital, Belfast, Northern Ireland.

Two hundred fifty-three Ring mark 2 metal-on-metal hip arthroplasties performed between 1968 and 1974 were evaluated using survivorship analysis. Using revision as the criterion for failure, the authors found a cumulative survival rate of 60.4% after 21 years. The results are compared with data from previous studies that used survivorship analysis for metal-on-metal hip arthroplasties, and it is shown that the Ring hip arthroplasty performed as well as the McKee-Farrar prosthesis and better than the Stanmore prosthesis.

11.

Clin Orthop 1996 Aug;(329 Suppl):S256-63

Cobalt and chromium concentrations in patients with metal on metal total hip replacements.

Jacobs JJ, Skipor AK, Doorn PF, Campbell P, Schmalzried TP, Black J, Amstutz HC

Department of Orthopedic Surgery, Rush Arthritis and Orthopedics Institute, Chicago, IL, USA.

There has been a resurgence of interest in the use of metal on metal bearings in total hip arthroplasty. Although the use of metal on metal bearing couples would eliminate or substantially reduce particulate polyethylene generation (depending on the presence or absence of polyethylene in the implant system), there is concern about the potential for increased particulate and ionic metal generation in comparison with polyethylene on metal bearings.These metallic degradation products may be transported away from the implant site and distributed systemically. Chromium concentrations in the serum and urine and cobalt concentrations in the serum were measured in subjects with cobalt chromium alloy metal on metal total hip replacements and in controls without implants. Eight subjects with long term (> 20 years) McKee-Farrar total hip replacements had 9-fold elevations in serum chromium, 35-fold elevations in urine chromium, and at least 3-fold elevations in serum cobalt concentrations in comparison with controls. Six subjects with short term (< 2 years) metal on metal surface replacement arthroplasties had 3-fold elevations in serum chromium, 4-fold elevations in urine chromium, and 4-fold elevations in serum cobalt concentrations in comparison with subjects with McKee-Farrar implants. Although the toxicologic importance of these trace metal elevations has not been established, serum and urine metal concentrations may be useful markers for the tribologic performance of metal on metal bearings.

142

12.

Clin Orthop 1996 Dec;(333):108-17

Modern metal on metal articulation for total hip replacements.

Dorr LD, Hilton KR, Wan Z, Markovich GD, Bloebaum R

Center for Arthritis and Joint Implant Surgery, University of Southern California University Hospital, Los Angeles, CA 90033, USA.

Between 1991 and 1994, 70 patients received total hip replacements with metal on metal articulation. The results of 54 of these patients with 54 hips who have a 2- to 4-year (2.7-year average) followup are reported. Patients were prospectively evaluated using the Harris hip score, a patient self assessment form, and radiographs. Hip aspiration was performed preoperatively and 6 to 24 months postoperatively in 24 hips with metal on metal articulations. Implant retrieval was obtained from 2 patients. Harris hip score averages increased from 49 to 93. No patient had revision surgery for loosening, but 1 had revision surgery for dislocation. Patient self assessment forms showed 51 of 54 patients scored their results as good or excellent. Serial radiographs did not show loosening or osteolysis. Wear could not be measured radiographically. Synovial fluid samples had metal particles of 1 to 10 microm in 10 hips. Twenty patients had bilateral total hip replacements with 1 hip metal on polyethylene articulation, and patients could not determine any difference between the hips. Compared with historic results of previous metal on metal prostheses, the modern metal on metal articulation investigated in this study did not have early acetabular loosening or clinical symptoms of component impaction. Retrieval implants and synovial fluid analysis suggest early wear was minimal.

13.

Arthroplasty 1996 Apr;11(3):322-31

Long-duration metal-on-metal total hip arthroplasties with low wear of the articulating surfaces.

Schmalzried TP, Peters PC, Maurer BT, Bragdon CR, Harris WH

Joint Replacement Institute at Orthopaedic Hospital, Los Angeles, CA 90007, USA.

The 20-year performance of metal on metal hip articulations has not been reported. Five McKee-Farrar total hip prostheses and one Sivash prosthesis were obtained at revision surgery after a mean implantation time of 21.3 years. A radiographic, histologic, implant, and wear analysis was performed on these total hip implants with cobalt-chrome metal-on-metal articulations. All cases were associated with femoral component loosening, but the bearing surfaces performed remarkably well. The worst case estimate of combined femoral and acetabular linear wear was 4.2 microns per year, about 25 times less than that typically seen with polyethylene. Metal particles and foreign-body inflammation were seen in all cases, but the volume of reactive tissue was small compared with what is generally seen at revision of hips with a polyethylene acetabular bearing. This may be due to a reduced particle burden or a decreased inflammatory reaction to particulate metal, or both. In addition to articular wear, other sources of metal particles included femoral neck impingement on the acetabular rim, stem burnishing, and corrosion. Prosthetic hip reconstructions can fail for many reasons, including suboptimal femoral stem and/or acetabular cup design and/or fixation. By today's standards, the McKee-Farrar and Sivash stem and acetabular component designs are suboptimal; however, after more than 20 years of use, the metal-on-metal bearing surfaces in these cases demonstrated low wear and do not appear to be the cause of failure. Recent advances in total hip arthroplasty, which include improved implant design, materials, manufacturing, and fixation, combined with a better understanding of the mechanisms of implant loosening and failure, suggest that the cobalt-chrome metal-on-metal bearing be reexamined as an alternative to polyethylene when exceptional durability is required.

143

14.

Clin Orthop 1985 Dec;(201):111-22

Long-term review of ring total hip arthroplasty.

Andrew TA, Berridge D, Thomas A, Duke RN

In a five- to 12-year follow-up survey of 179 sequential cementless Ring metal-on-metal total hip arthroplasties, 55 (31%) of the patients were found to have died as a result of nonorthopedic conditions. Analysis of the records demonstrated that 20% of these patients had had poor results attributable to pain. Of the remaining 124 patients, 116 (94%) attended for full clinical and radiologic review yielding a total of 154 hips. Using Ring's classification, 75 hips were judged to have excellent or good results. Forty-one hips were graded as fair or poor as a result of pain, and an additional 15 hips were revised for symptomatic loosening. There were five cases of Brooker Grade IV periarticular ossification, four cases of gross metal reaction requiring prosthetic removal, and two cases of infection. There was considerable variation in the radiographic appearance of the hips, and at times radiographic changes were inconsistent with clinical symptoms. Eleven of the revised hips were converted to longer and larger-diameter uncemented Ring femoral components. Nine of these yielded only fair or poor results at the time of review, whereas both cases in which the femoral component was cemented were associated with good results.

15.

Clin Orthop 1996 Aug;(329 Suppl):S187-205

Tissue reaction to metal on metal total hip prostheses.

Doorn PF, Mirra JM, Campbell PA, Amstutz HC

Joint Replacement Institute, Los Angeles, CA, USA.

The periprosthetic tissue reaction to polyethylene wear debris in metal on polyethylene total hip replacements is strongly implicated as the cause of osteolysis. This has led to a renewed interest in metal on metal total hip replacements. However, little is known about the role of wear debris in failures of these prostheses. Capsular and interface tissues from 9 long and short term metal on metal total hip replacement retrievals were studied to assess the tissue reaction around these prostheses. As compared with metal on polyethylene cases, the extent of the granulomatous inflammatory reaction and the presence of foreign body type giant cells was much less intense in metal on metal cases, likely because of the lower numbers and overall smaller size of metal wear debris particles. This may lead to a better transport of the particles from the joint tissues and a lower incidence of periprosthetic osteolysis around metal on metal hip replacement.

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16.

Arch Orthop Trauma Surg 1986;105(5):263-7

evelopment of heterotopic ossification around the hip. A long-term follow-up of patients who underwent surgery with two different types of endoprostheses.

Lindholm TS, Viljakka T, Vankka E, Popov L, Lindholm TC

Heterotopic ossification has been reported in many pathological situations, most important clinically as a sequel to hip arthroplasty and spinal trauma. The etiology of heterotopic ossification is yet not clear, but the disease is supposed to be connected with trauma. Heterotopic bone was found in 53% (1.2% with the severe form) of 623 patients operated on at the Orthopaedic Hospital of the Invalid Foundation, Helsinki, Finland; the operations included 849 arthroplasties. The rate of heterotopic ossification was higher after revision arthroplasty, following operation of the contralateral side, in men, and in primary coxarthrosis, and the incidence was higher with the Brunswik (metal-on-plastic) endoprosthesis than in the McKee-Farrar type (metal-on-metal). Heterotopic bone formation generally seemed to increase and to be more manifest during long-term observation.

17.

Orthopade 1989 Sep;18(5):370-6

[Polyethylene wear and late loosening of a total prosthesis of the hip joint. New perspectives for metal metal pairing of the capsule

Weber BG, Fiechter T

venty-nine years' experience with total hip replacement surgery, including continuing quality control and follow-up studies, indicate that late loosening after 10-15 years is related to wear of the polyethylene cup. Metal-to-metal prostheses implanted 20 years ago and longer, on the other hand, show no signs of wear or loosening. In conclusion, polyethylene does not last long enough when compared to biocompatible precision-made artificial metal-metal hip joints.

18.

Clin Orthop 1996 Aug,(329 Suppl):S206-16

Metal versus polyethylene wear particles in total hip replacements. A review.

Doorn PF, Campbell PA, Amstutz HC

Joint Replacement Institute at Orthopaedic Hospital, Los Angeles, CA, USA.

Research has recently been focused on the development of hip replacements with alternative bearing surfaces with cobalt chrome alloy, to avoid the production of polyethylene wear particles in hip replacements and polyethylene wear debris mediated bone lysis. Cobalt chrome on cobalt chrome bearing surfaces are being reevaluated. Characterization of wear particles and studies on the reaction of the body to these particles, have played an important role in the determination of the factors that cause septic loosening and will therefore play an important role in the comparison of metal on polyethylene and metal on metal hip prostheses. In this paper, a comparison between the different aspects of metal and polyethylene wear particles is made using data from the literature and the authors' experience. The authors conclude that techniques need to be optimized to isolate and characterize individual metal wear particles from periprosthetic tissues and they advocate the performance of in vitro studies with these in vivo generated wear particles or comparable particles.

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19.

Clin Orthop 1996 Aug;(329 Suppl):S106-14

Ietal on metal surface replacement of the hip. Technique, fixation, and early results.

Schmalzried TP, Fowble VA, Ure KJ, Amstutz HC

Joint Replacement Institute at Orthopaedic Hospital, Los Angeles, CA, USA.

High volumetric wear of polyethylene plays a central role in periprosthetic bone resorption and the failure of metal on polyethylene total hip resurfacing prostheses. An assessment of technique, initial fixation, and the early results of 21 hips in 19 patients implanted with a metal on metal bearing total hip resurfacing prosthesis, 4 all cementless Wagner prostheses and 17 all cemented McMinn prostheses, is presented. Pain relief was equal to conventional total hip replacement with a better functional result with an average followup of 16 months (range, 10-25 months). The femoral component position and fixation is satisfactory in all 21 hips and there were no femoral neck notches or fractures. All 4 cementless Wagner acetabular components appear to be osseointegrated with stable interfaces. The cemented McMinn acetabular components, however, have shown progressive cement bone interface radiolucencies in 12 hips. This preliminary experience underscores the importance of obtaining secure initial fixation. There have been no problems directly attributable to the metal on metal bearing but the authors will continue to follow these hips and evaluate their performance. The metal on metal hip surface replacement procedure is in evolution. This ongoing experience will help guide total hip surface replacement component design and implantation techniques.

20.

r Med J 1975 Nov 15;4(5993):374-5

Metal sensitivity in patients with joint replacement arthroplasties.

Benson MK, Goodwin PG, Brostoff J

A high incidence of unexpected metal sensitivity was found in patients with metal-to-metal (McKee) hip arthroplasties. Patients with metal-to-plastic (Charnley) prostheses had no greater incidence of metal sensitivity than a control group awaiting operation. If metal sensitivity does occur loosening of the prosthesis may be a complication.

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21.

Bone Joint Surg Br 1997 Sep;79(5):885

Elevated serum cobalt with metal-on-metal articulating surfaces.

Brodner W, Bitzan P, Meisinger V, Kaider A, Gottsauner-Wolf F, Kotz R

Department of Occupational Medicine, University of Vienna, Austria.

We determined serum cobalt levels in 55 patients by atomic absorption spectrophotometry before and after implantation of uncemented total hip arthroplasties. In a randomised, prospective trial 27 wrought Co-28Cr-6Mo-0.2C metal-on-metal articulations were compared with 28 ceramic-on-polyethylene hips which did not contain cobalt. Other sources of iatrogenic cobalt loading were excluded. The metal-on-metal group produced detectable serum cobalt levels (median 1.1 microg/l after one year) which were significantly different ($p < 0.0001$) from those of the ceramic-on-polyethylene control group (median below detection limit of 0.3 microg/l after one year). Our findings indicate that metal-on-metal bearings generate some systemic release of cobalt.

22.

Clin Orthop 1996 Aug;(329 Suppl):S78-88

Preliminary results of uncemented metal on metal stemmed and resurfacing hip replacement arthroplasty.

Wagner M, Wagner H

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Seventy uncemented stemmed total hip replacements and 35 uncemented surface replacements with all metal Metasul articulating surfaces were followed up in a prospective study. There was no evidence that this metal on metal articulation causes new problems or complications that were not known already from other polyethylene-aluminum oxide ceramic articulating combinations. The results of 64 of 70 patients could be assessed as excellent and good. When tissue samples obtained during 2 reoperations for ectopic ossification were examined histologically, there was no light microscopic evidence of metal particles. In these cases, aseptic loosening seemed to be due to the lack of initial fixation with the original femoral component design, and was not related to the use of the Metasul bearing. The metal on metal articulation reduces the production of particles considerably according to experience to date. It is therefore hoped that foreign body reactions due to wear particles will be significantly reduced. The results support the continued investigation of metal on metal joint replacements for younger, active patients.

23.

Arch Orthop Trauma Surg 1986;105(3):158-62

Total hip replacement comparison between the McKee-Farrar and Charnley prostheses in a 5-year follow-up study.

Djerf K, Wahlstrom O

In a prospective study, 177 patients who underwent total hip replacement by the McKee-Farrar or Charnley techniques were followed up for 5 years with yearly clinical examinations, walking tests, and X-rays. The findings concerning pain, walking ability, and complications were satisfactory and similar to the inventors' own 5-year results. Comparison between the two techniques disclosed no major differences. Over 90% of the patients were free from pain; the infection rate was 3.4% and the loosening rate 6%. A walking test showed marked increase in speed over the first few years and a slight decrease after the third year. Our findings do not support the hypothesis that the metal-on-metal prosthesis is clinically inferior to the metal-on-polyethylene prosthesis.

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24.

·thopade 1997 Feb;26(2):142-51

[Changes in shape of the McKee-Farrar hip endoprosthesis].

[Article in German]

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The still unsolved problem of aseptic loosening in total hip arthroplasties with identification of polyethylene wear particles as one of its maior causes, has led to reintroduction of metal-to-metal articulations, as indicated by a few good clinical long-term results with all-metal McKee-Farrar arthroplasties. In this paper, data on 145 patients from a population of more than 1400, all with implanted McKee-Farrars, who underwent revision surgery for aseptic loosening, are collected and analysed for dependence of duration to brands of the implants and position of the cups. The surface of each of 55 revised implants was measured using a 3-D device. The results showed no interdependence between time of loosening, brand inclination of the cup and deviation in shape of ball and cup. Additionally, the deviations in shape were slight.

25.

Clin Orthop 1996 Aug;(329 Suppl):S60-8

Twenty-year results of McKee-Farrar versus Charnley ›rosthesis.

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The results of 107 consecutive McKee-Farrar and 70 Charnley total hip arthroplasties performed in 169 patients between 1975 and 1976 are reviewed. At an average followup of 20 years (range, 19-21 years), 29 patients with 20 McKee-Farrar and 11 Charnley prostheses were available for clinical and radiologic evaluation; 102 patients (107 hips) had died, 3 patients were lost to followup, and 5 patients (6 hips) were unavailable for review because of medical problems. There were 5 revisions for sepsis and 1 Girdlestone procedure for recurrent dislocation. Sixteen McKee-Farrar and 8 Charnley prostheses were revised for aseptic loosening, giving a 20-year aseptic probability of survival of 77% and 73%, respectively. Radiographic signs of loosening were present in 52% of the surviving prostheses. Clinical scores showed weak correlation with the radiographic loosening in both groups, and 18 McKee-Farrar and 8 Charnley prostheses were still considered satisfactory by the patients. The mean annual linear polyethylene wear was 0.12 mm. Osteolytic lesions were observed in association with 2 McKee-Farrar and 5 Charnley prostheses in surviving hips. The long term results of the McKee-Farrar prosthesis are comparable with those of the low friction arthroplasty in this series. Wear of the polyethylene bearing and accumulation of polyethylene particles in the periprosthetic tissue may become an increasing problem. Second generation all metal implants seem to be worth considering in patients with long life expectancy.

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26.

Clin Orthop 1996 Aug;(329 Suppl):S89-98

Metal on metal surface replacement of the hip. Experience of the McMinn prothesis.

McMinn D, Treacy R, Lin K, Pynsent P

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The historical failure of surface replacement has been due to the production of wear debris with subsequent bone resorption, loosening, and failure. To avoid these problems, a surface replacement using a metal on metal bearing allowing thin components and femoral design and instrumentation to avoid varus alignment has been designed. Two hundred thirty-five joints have been resurfaced with this prosthesis in almost 5 years. There have been no femoral neck fractures and no dislocations. There have been 4 designs differing in the method of fixation. In the press fit group, 6 of 70 hips had to be revised for aseptic loosening. In the cemented group, debonding of the cup occurred in 3 of 43 cases. Six patients had hydroxyapatite coated components and have had excellent clinical outcomes. The current design uses a peripherally expanded hydroxyapatite coated cup and a cemented metal head; 116 of this design have been implanted during a 19-month period with excellent outcome. Despite short followup the authors are hopeful that the combination of a polar metal on metal bearing with appropriate fixation will yield a method of preserving bone stock in the younger patient requiring arthroplasty.

27.

Clin Orthop 1996 Aug;(329 Suppl):S128-40

In vivo wear of three types of metal on metal hip prostheses during two decades of use.

McKellop H, Park SH, Chiesa R, Doorn P, Lu B, Normand P, Grigoris P, Amstutz H

J. Vernon Luck Orthopaedic Research Center at the Orthopaedic Hospital, Los Angeles, CA, USA.

Wear was analyzed on 21 metal on metal hip replacements, including McKee-Farrar, Muller, and Ring, that were retrieved from patients after as many as 25 years. Light and scanning electron microscopy indicated that early wear included substantial third body abrasion, possibly from particles generated while scratches from the original polishing were being eradicated and from dislodged surface carbides. However, the main contact zones were eventually worn smoother than the original surfaces. Wear was quantified by digitizing the shapes of the components on a coordinate measuring machine and identifying those areas that deviated from the original spheric surface. On the femoral heads, wear was typically concentrated in the superomedial region, that is, on the load axis. Three cases also had substantial wear inferiorly, but there were no cases with circumferential (equatorial) wear. The long term wear rates averaged approximately 6 micrometers per year or less and produced an average of approximately 6 mm3 of metallic wear debris per year or less. Wear rate tended to increase as clearance increased over the range of 127 to 386 micrometers, and a McKee-Farrar prosthesis with the extreme clearance of 1.7 mm wore approximately 16 times faster than the average, but there was no apparent relationship between clearance and time to revision. Larger McKee-Farrar balls had less volumetric wear, on average, than smaller balls, and the Muller balls had the greatest wear, which may have been due to contact with the edges of recesses machined into the bearing zones of the Muller cups.

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Clin Orthop 1996 Aug;(329 Suppl):S48-59

Factors correlating with long term survival of McKee-Farrar total hip prostheses.

Schmalzried TP, Szuszczewicz ES, Akizuki KH, Petersen TD, Amstutz HC

Joint Replacement Institute at Orthopaedic Hospital, Los Angeles, CA, USA.

Clinical and radiographic evaluations of 15 McKee-Farrar hip replacements in 13 patients with followup of 21 to 26 years were performed. The average Harris hip score was 86 with no patients having a poor result. These patients outscored the age matched controls in all categories of the SF-36 health survey. All patients were community ambulators with qualitative activity levels exceeding the average for their age. Quantitative activity assessment with a pedometer in 3 patients indicated a current average of approximately 900,000 cycles per year. This represents more than 21 million cycles when extrapolated during the life of the implants. None of the femoral components were radiographically loose. One acetabular component may be loose. Osteolysis developed in 3 apparently well fixed femurs and in 1 acetabulum. There were several features of these cases that may have contributed to the long survival: (1) relatively small stature of the patients who averaged 160.5 cm (5 feet 5 inches) in height and 66.9 kg (147 lbs) in weight; (2) favorable biomechanics of the reconstruction with the hip center of rotation being medialized by an average of 6.4 mm and the femoral offset increased by an average of 4.9 mm; (3) decreased potential for neck socket impingement with an average lateral acetabular opening of 54 degrees and all components were anteverted; (4) radiolucent cement in 13 of 15 hips; and (5) no radiographically measurable wear. Previous analyses and comparisons of the clinical performance of the McKee-Farrar implant have focused on the metal on metal bearing. As has been recognized with the many variations of total hip replacement using metal on plastic bearings, there are a myriad of variables that contribute to clinical outcome. The results of this study suggest that patient selection and technical factors may contribute to the long term survival, and conversely to the failure, of McKee-Farrar implants.

Rev Chir Orthop Reparatrice Appar Mot 1999 Jun;85(3):217-25

[Value and limits of determining serum cobalt levels in patients with metal on metal articulating prostheses].

[Article in French]

Gleizes V, Poupon J, Lazennec JY, Chamberlin B, Saillant G

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PURPOSE OF THE STUDY: The purpose of this study was to measure the serum cobalt levels and their correlation with clinical and radiological findings in patients with metal on metal hip articulating surfaces. METHOD: Forty-one patients with metal on metal hip arthroplasty were reviewed retrospectively at mean follow-up of 12.9 months. Serum cobalt levels were determined for each patient by atomic absorption spectrometry at the maximal follow-up and were compared to a control group (19 patients). Two patients and one control subjects also performed exercise on a treadmill in order to appreciate the influence of physical activity on serum cobalt levels. RESULTS: The metal on metal group presented higher serum cobalt levels than those of the control group ($p < 0.0001$). There was no correlation between serum cobalt and clinical and radiological findings at the exception of patient age ($n = 40$, $r = 0.37$). However, when the follow-up was greater than 18 months, mean serum cobalt was significantly higher compared to a follow-up less than 18 months. The physical exercise test led to a moderate elevation (around 10 p. 100) of cobalt in the two patients but not in the control subject. DISCUSSION AND CONCLUSION: The interpretation of an elevated cobalt serum level is difficult. Cobalt-containing drugs, other implants, excess of activity and diseases (renal failure) may influence serum cobalt level. In this study, the high serum cobalt levels seem not linked to a failure of the implant, mainly because of the short follow-up. They could rather be attributed to an increase of the patient activity beginning 18 months after the surgery. Because potential long-term cobalt toxicity and carcinogenicity is not well known, careful medical follow-up should be emphasized specially in young

30.

J Biomed Mater Res 1998 Oct;42(1):103-11

Metal wear particle characterization from metal on metal total hip replacements: transmission electron microscopy study of periprosthetic tissues and isolated particles.

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The less intense tissue reaction around metal on metal total hip replacements (THRs) compared to metal on polyethylene (PE) THRs may be explained by the differences in the characteristics of metal wear particles. In this study, transmission electron microscopy was used to study metal wear particles that were either in situ in cells or had been extracted from the cells by a new technique based on enzymatic tissue digestion. The tissues were obtained from 13 patients undergoing revision of metal on metal THRs with cobalt-chromium-molybdenum (CoCrMo) bearing couples. Most of the CoCrMo wear particles were smaller than 50 nm (range 6-834 nm) and round to oval in shape with irregular boundaries. This size range is considerably smaller than that reported for PE particles. While even a small volume of metal wear will produce high numbers of particles, the apparently less severe local tissue reaction to metal particles may be due to the possibility that corrosion, dissolution, and dissemination of metal particles may result in fewer local biological effects than the long-term retention of PE particles in the periprosthetic tissues.

31.

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Wear behavior and histopathology of classic cemented metal on metal hip endoprostheses.

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The authors reviewed their collection of retrieved all metal hip joints (9 McKee-Farrar, 7 Muller, and 3 Huggler type prostheses) and tissues from the joint capsules and implant beds. The amount of wear was measured, and the total volume was calculated. The tissues were analyzed by atomic absorption spectral analysis or inductively coupled plasma mass spectrometry and examined by light and scanning electron microscopy. The size of particles was measured with a texture analysis system. The articulating surfaces showed many delicate scratches which represent normal wear. The calculated annual wear averaged approximately 5 mm3 per year, which is low compared with polyethylene. The cellular reaction to metal wear particles was regarded as mild. The cellular reaction to scattered and worn bone cement was always more pronounced than to metallic debris. Scanning electron microscopy confirmed the irregular shapes and mostly submicron size of the metal particles. The analytically detected metal content of the periarticular tissue was relatively low and in accordance with the wear measurements from the articulating surfaces. The excess of chromium in the tissues is discussed in the light of the elimination of cobalt as well as the relation between elements representing either corrosion products or elements still bound in wear particles.

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32.

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Experience with the Metasul total hip bearing system.

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The author and Sulzer Medical Technology Ltd, Switzerland, have developed a new generation of metal on metal bearing total hip joints. The design is different than the McKee type prostheses in that the cobalt chrome alloy heads and cups (Metasul) are of the highest precision with controlled loose fitting. These allow low friction and low wear of approximately 5 micrometers per year. It is anticipated that debris related late loosening will be avoided by the use of this design. Approximately 30,000 Metasul hearings have been produced. The first 110 Weber metal on metal hip implants have been analyzed. No adverse effects from the wear of the new metal on metal components have been noted in this series.

33.

Rev Chir Orthop Reparatrice Appar Mot 1996;82(1):85-89

[15 years survival of the Mac-Kee Farrar metal hip prosthesis. Apropos of 58 cases and 4 explanted cups].

[Article in French]

Ray A

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PURPOSE OF THE STUDY: Despite a high percentage of loosening (femoral, iliac or both), many surgeons have been surprised by some excellents results of Mac Kee Farrar prosthesis after 15, or even 20 years follow-up. MATERIALS AND METHODS: 37 patients (on 58) were reviewed with a follow-up of more than 15 years (48 hips). Among 17 cases followed for more than 20 years, with very good results (clinical and radiological), only one femoral loosening was observed. A part, 4 paired explanted implants (loosening at 18 years for 3 and at 21 years for one) were examined for a dimensional and metallurgic study. RESULTS: The results showed: no wear, very good bearing surface statement and sphericity, We never observed agressive granulomatous lesions with metallic particles (metallosis), nor wear concerning the cup. CONCLUSION: The peripheric design appears able to give a very good pressure repartition from cup to bone, allowing a homogeneous coat of cement with an equal thickness, and avoids loosening. Finally, we think that the progressive polar cavity in the cup, could have a great importance on lubrification, as an hydrokinetic reserve and micropump for synovial fluid.

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