USER:	**CURTSINGER, MARGARET A (mac)**
FOLDER:	**K001523 - 197 pages (FOI:10008002)**
COMPANY:	**DEPUY ORTHOPAEDICS, INC. (DEPUORTHA)**
PRODUCT:	**PROSTHESIS, HIP, SEMI-CONSTRAINED (METAL UNCEMENTED ACETABULAR COMPONENT) (KWA)**
SUMMARY:	**Product: ULTIMA METAL-ON-METAL ACETABULAR CUP**

DATE REQUESTED:	**Fri Dec 03 24:00:00 2010**
DATE PRINTED:	**Thu Feb 03 16:27:17 2011**
Note:	**Releasable Version**

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K001523

AUG 1 0 2000

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SUMMARY OF SAFETY AND EFFECTIVENESS

NAME OF FIRM:	DePuy Orthopaedics, Inc. 700 Orthopaedic Drive Warsaw, Indiana 46581-0988
510(k) CONTACT:	Cheryl Hastings Director, Regulatory Affairs
TRADE NAME:	Ultima® Metal-On-Metal Acetabular Cup
COMMON NAME:	Total Hip Replacement System
CLASSIFICATION:	888.3330: Hip joint, metal/metal semi-constrained, with an uncemented acetabular component, prosthesis. Class III
DEVICE PRODUCT CODE:	87 ~~JDM~~ KWA
SUBSTANTIALLY EQUIVALENT DEVICES:	♦ ZTT II Acetabular Cup System (K951000) ♦ Sulzer Orthopedics Inc. Inter-Op Metasul Acetabular System (K974728) ♦ McKee-Farrar Metal-On-Metal Hip (pre-amendment) ♦ Ring Metal-On-Metal Hip (pre-amendment)

DEVICE DESCRIPTION AND INTENDED USE:
The Ultima Metal-On-Metal (MOM) Acetabular Cup is comprised of a metal shell and a metal liner. The outer acetabular cup is a near-hemispherical stepped and porous-coated shell with three dome screw holes, an apical hole used for visualization, and a peripheral female taper. The liner is offered in both standard (neutral) and augmented (10° lip) forms and has a 28mm inner diameter. The 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 Ultima Metal-On-Metal Acetabular Cup is intended for use with DePuy S-ROM and PFC 28mm diameter Co-Cr-Mo femoral heads only.

BASIS OF SUBSTANTIAL EQUIVALENCE:

The Ultima Metal-On-Metal Acetabular Cup is equivalent to the ZTT II Acetabular Cup in that they have the same intended use and the same basic design. The differences between the two designs are that the Ultima MOM Cup has a metal insert and a taper-lock locking mechanism, whereas the ZTT II Cup has a polyethylene insert which locks into the metal shell via polyethylene lugs on the insert that dial into slots in the shell.

Clinical data collected from two prospective, multi-center studies showed that at 24(+) month follow-up, mean total Harris Hip Scores and mean pain Harris Hip Scores for the metal-on-metal cases (using the Ultima Metal-On-Metal Acetabular Cup) were significantly higher than those for metal-on-polyethylene cases (using the ZTT II Acetabular Cup). Mean function scores, radiographic parameters and complication rates between the two groups were similar.

The Ultima Metal-On-Metal Acetabular Cup is also substantially equivalent to the Sulzer Inter-Op Metasul Acetabular System. Both are metal-on-metal acetabular cup systems, intended for cementless fixation. The liner of the Ultima MOM Cup is composed only of wrought Co-Cr-Mo. The liner of the Inter-Op Metasul Cup is composed of polyethylene with a wrought forged Co-Cr-Mo inlay. This creates a metal-polyethylene-metal "sandwich" when the liner is assembled with a metal shell.

The Ultima Metal-On-Metal Acetabular Cup is also substantially equivalent in basic design and intended use to several pre-amendment metal-on-metal hip systems. Of these, the McKee-Farrar and the Ring are probably the most widely known and documented. The McKee-Farrar and Ring metal-on-metal hips were implanted in the 1950's through the 1970's with moderate clinical success and are the fore-runners of today's metal-on-metal hip designs.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 0 2000

Ms. Cheryl Hastings
Director, Regulatory Affairs
DePuy, Inc.
P.O. Box 988
700 Orthopedic Drive
Warsaw, Indiana 46581-0988

Re: K001523
Trade Name: Ultima® Metal-On-Metal Acetabular Cup
Regulatory Class: III
Product Code: KWA
Dated: May 12, 2000
Received: May 16, 2000

Dear Ms. Hastings:

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,

Russell Pape

for 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) K001523

Device Name DePuy Orthopaedics Ultima® Metal-On-Metal Acetabular Cup

Indications for Use:
The Ultima® Metal-On-Metal Acetabular Cup 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 Ultima Metal-On-Metal Acetabular Cup is intended for use with DePuy S-ROM and PFC 28mm diameter Co-Cr-Mo femoral heads only.

Concurrence of CDRH, Office of Device Evaluation

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K001523

Prescription Use Yes
(Per 21 CFR 801.109)

OR

Over-The Counter Use No

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

April 28, 2009

DEPUY ORTHOPAEDICS, INC.
P.O. BOX 988
WARSAW INDIANA 46581

Re: Premarket Notification Number: K001523

Dear Manufacturer:

The Food and Drug Administration (FDA) is currently in the process of evaluating the classification of class III devices that are currently marketed through clearance of a premarket notification (510(k)) submission. These devices were found to be substantially equivalent to a preamendments class III device type for which no date has yet been established for requiring the submission of a premarket approval application (PMA). (A class III preamendments device type is a device type that was legally on the market before May 28, 1976, and that was subsequently classified into class III.) FDA premarket notification (510(k)) records indicate that you received clearance to market a device belonging to one of the class III device types being evaluated. Accordingly, FDA is requesting that you submit specific information, discussed below, to support these classification efforts. These classification efforts will culminate in a decision either to call for a PMA for these class III devices, or to reclassify these devices into Class II (special controls) or Class I (general controls). FDA will reach this decision based on all available and reviewed information pertaining to each device type. For certain device types, classification panel hearings may be held to assist in these efforts. Any future proposed decisions will apply to the device type as a whole, not solely to your individual device.

As stated, FDA, in accordance with Section 515(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. § 360e(i)), is requiring manufacturers who were marketing, or have clearance to market through a 510(k) substantial equivalence decision, the class III device types referenced above as of April 9, 2009, to submit certain information. The enclosed Federal Register notice details the specific device types, the requested information, and the submission instructions. You are required to submit this information by August 7, 2009, to:

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD, 20852.

Please note that items posted to this docket will be redacted in accordance with the Freedom of Information Act (FOIA) (5 U.S.C. § 552), and posted to the docket. To ensure your posted documents are redacted, prior to posting, please denote submissions uploaded to the docket as such by typing the following words in the top of the *"General Comments"* box: *"CONFIDENTIAL MATERIAL DO NOT POST TO THE WEB AS REQUESTED BY SUBMITTER. STATUS SHOULD BE CONFIDENTIAL."*

If you have information showing that you have received this letter in error, or that our records supporting this letter are inaccurate, such that you are relieved of the obligation to submit the requested information, please send an explanation of the error, noting your 510(k) number, to:

Attn.: 510(k) Staff, 515(i) Submission
Document Mail Center, HFZ-401
Center for Devices and Radiological Health
9200 Corporate Boulevard
Rockville, MD, 20850

Please note that in lieu of submitting the above requested information, you may also petition FDA to reclassify the device type in accordance with Section 513(e) of the act (21 U.S.C. 360c(e)) and our regulations found in 21 CFR Part 860. In general, FDA's review of reclassification petitions can be completed more efficiently when manufacturers collaborate and submit a single reclassification petition that includes all relevant and accurate information for the given device type. This collaboration can be organized by contacting other manufacturers of the pertinent device through either a professional association or other affiliation.

Additional information or inquiries relevant to this classification mandate can be obtained by referencing the FDA Class III website at: http://www.fda.gov/cdrh/classiii.html, or by contacting Sarah K. Morabito at (240) 276-3975.

Sincerely yours,

Donna-Bea Tillman, Ph.D.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 0 2000

Ms. Cheryl Hastings
Director, Regulatory Affairs
DePuy, Inc.
P.O. Box 988
700 Orthopedic Drive
Warsaw, Indiana 46581-0988

Re: K001523
Trade Name: Ultima® Metal-On-Metal Acetabular Cup
Regulatory Class: III
Product Code: KWA
Dated: May 12, 2000
Received: May 16, 2000

Dear Ms. Hastings:

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,

Russell Pyn

for 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) K001523

Device Name DePuy Orthopaedics Ultima® Metal-On-Metal Acetabular Cup

Indications for Use:
The Ultima® Metal-On-Metal Acetabular Cup 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 Ultima Metal-On-Metal Acetabular Cup is intended for use with DePuy S-ROM and PFC 28mm diameter Co-Cr-Mo femoral heads only.

Concurrence of CDRH, Office of Device Evaluation

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K001523

Prescription Use Yes
(Per 21 CFR 801.109)

OR

Over-The Counter Use No

3

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

From: Reviewer(s) - Name(s) Pei Surg

Subject: 510(k) Number K 001523

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: KWA / III

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

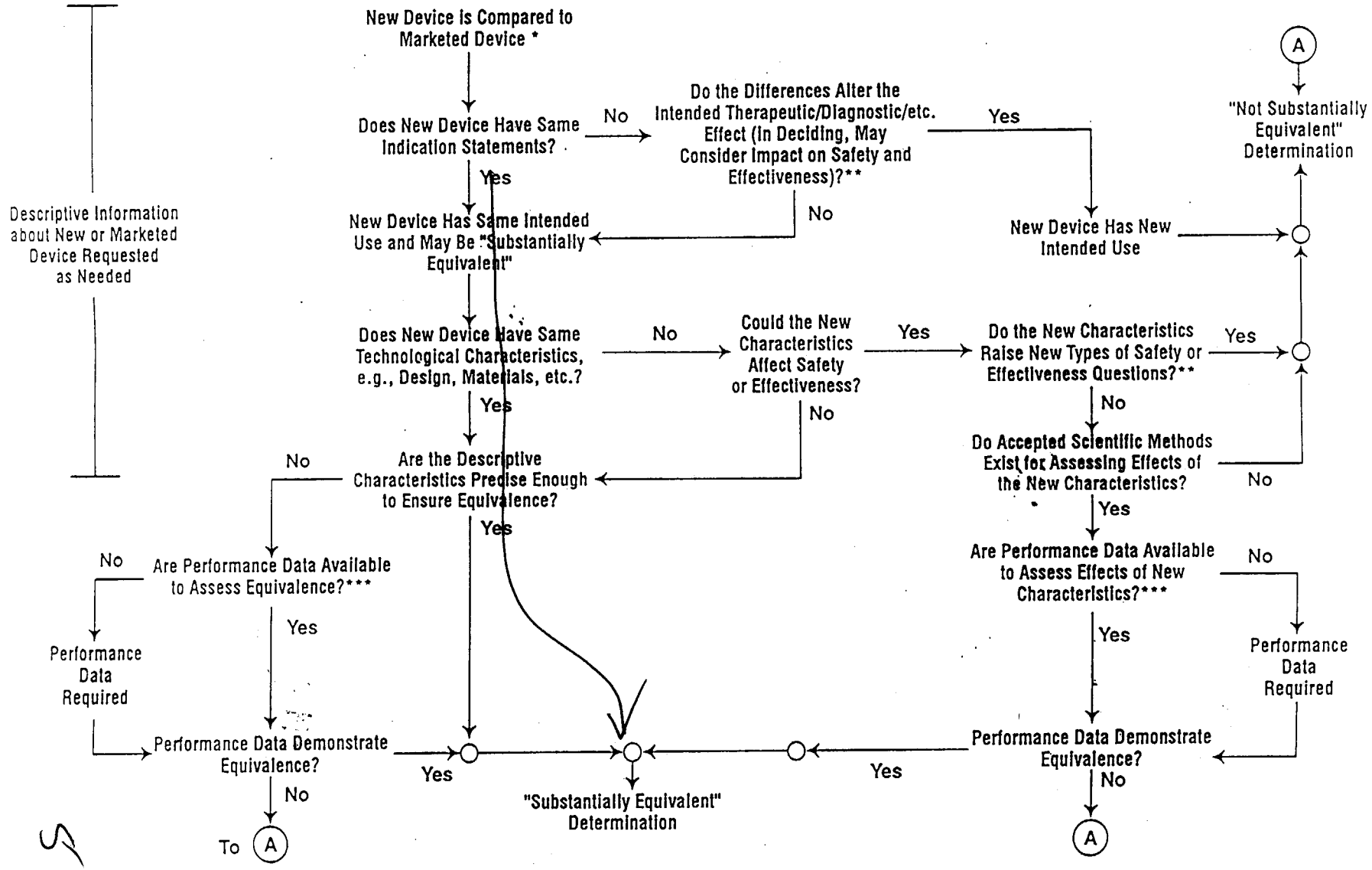
Review: Barbara Zimmerman (Branch Chief) ODB (Branch Code) 8/10/00 (Date)

Final Review: [illegible] for CDRH (Division Director) 8/11/00 (Date)

Revised:8/17//99

4

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



* 510(k) Submissions Compare New Devices to Marketed Devices. FDA Requests Additional [illegible]mation if the Relationship Between Marketed and "Predicate" (Pre-Ame[illegible]its or Reclassified Post-Amendments) Devices is Unclear.

** This Decision is Normally Based on Descriptive Information Alone, But Limite[illegible]sting Information is Sometimes Required.

*** Data [illegible]e in the 510(k), Other 510(k)s, The Center's Classification Files, or the Literature.

Document: K001523
Device Name: Ultima® Metal-On-Metal Acetabular Cup
Classification: III, 87/KWA
Submitted by: Depuy
Date Decision Due: 8/14/00
Reviewed by: Pei Sung, Ph.D. Pei 8/8/00
Date: 7/26/00

Recommendation:

This subject 510(k) notification:

- [x] is substantially equivalent to the marketed devices.
- [ ] requires more data.

Type letter and wording suggested:

- [x] "SE" Letter Attached
- [ ] "AI" Letter Attached
- [ ] "AI" via Telephone and/or FAX
- [ ] "CR" Letter Attached

Summary:

The Ultima® Metal-On-Metal Acetabular Cup is substantially equivalent to the Sulzer Inter-Op Metasul Acetabular System (K974728). Both are metal-on-metal acetabular cup systems, intended for cementless fixation.

The Ultima® Metal-On-Metal Acetabular Cup is also substantially equivalent in basic design and intended use to the pre-amendment, McKee-Farrar hip system, which were implanted in the 1950's through the 1970's and is the forerunners of today's metal-on-metal hip designs.

The clinical study was conducted through G960262. The number of cases with a minimum of 24-month follow-up was 107 for the metal-on-metal group and 59 for the metal-on-polyethylene group. The metal/metal hip total HHS scores and pain HHS scores at two or more years follow-up were significantly greater than those from the control group with metal/polyethylene hip prostheses (94.7 vs. 90.7, p=0.011). HHS pain score for the metal-on-metal cases was also greater (i.e. better) than for the metal-on-polyethylene cases (42.6 vs. 40.4, p=0.045). The radiographic outcomes at two or more years were comparable. Both operative and postoperative surgical site complications in both the metal/metal and metal/polyethylene groups were rare.

It is unlikely that even with increased sample size that the metal/metal group would perform in a manner that would result in the metal/metal group having a mean HHS total score lower than that of the metal/polyethylene group.

Description of the Subject Device(s):

The Ultima Metal-On-Metal (MOM) Acetabular Cup is comprised of a metal shell and a metal liner. The outer acetabular cup is a near hemispherical stepped and porous-coated shell with three dome screw holes, an apical hole used for visualization, and a peripheral female taper. The liner is offered in both standard (neutral) and augmented (10° lip) forms and has a 28mm inner diameter. The MOM liner is mechanically locked with the shell via a taper

junction, and articulates with commercially available DePuy S-ROM and PFC 28mm diameter CoCrMo femoral heads only.

Materials:

- The Ultima MOM acetabular shell is manufactured from Ti-6Al-4V titanium alloy conforming to ASTM F-136.
- The porous coating on the shell is Commercially Pure Titanium conforming to ASTM F-67.
- The metal liner is manufactured from Co-Cr-Mo alloy conforming to ASTM F-1537.

Device dimension:
The size of the Ultima MOM shells ranges from 48mm to 68mm in 2mm increments. The device will articulate with 1) S-Rom, 28mm +0, +6, +12 and 2) PFC, 28mm +0, +5, and +10 femoral heads. Part numbers and descriptions, engineering prints, and photographs are provided in Exhibit 1. A list of ancillary parts is provided in Exhibit 2.

Device testing and results:
A.

(b)(4)

(b)(4)

8

none in the metal-on-polyethylene group. There were four postoperative dislocations/subluxations reported for three metal-on-metal cases.

A complete summary of the clinical data and statistical analysis of the data is provided in Exhibit 5.

Proposed "Indications for Use":

The Ultima® Metal-On-Metal Acetabular Cup 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, *protrusic acetabuli,* slipped capital femoral epiphysis and disability due to previous fusion, where bone stock is inadequate for other reconstruction techniques.

The Ultima Metal-On-Metal Acetabular Cup is intended for use with DePuy 5-ROM and PFC 28mm diameter Co-Cr-Mo femoral heads only.

Sterilization:

This device is intended to be provided sterile and will be sterilized by a minimum 2.5 Mrd gamma radiation and validated to (b)(4) (b)(4) guideline for gamma sterilization.

No claim of "non-pyrogenic" is made. No pyrogen testing is conducted.

Description of the packaging used to maintain sterility is enclosed. Sterile notation reflects on the sample labeling.

The product is for single use only.

Labeling:

Draft package labels and draft package inserts are provided in Exhibit 3.

The draft package insert has been modified slightly from the package inserts approved in G960262. It has been re-written specifically for the Ultima Metal-On-Metal Acetabular Cup and references to investigational devices and investigators have been removed.

Product(s) to Which Compared:

1. K951000, Johnson & Johnson's ZTT II Acetabular Cup System:
   The Ultima Metal-On-Metal Acetabular Cup and the ZTT II Acetabular Cup have the same intended use and the same basic design. The differences between the two designs are that the Ultima MOM Cup has a metal insert and a taper-lock locking mechanism, whereas the ZTT II Cup has a polyethylene insert which locks into the metal shell via polyethylene lugs on the insert that dial into slots in the shell.

   The Clinical data collected from two prospective, multi-center studies showed that at 24(+) month follow-up, mean total Harris Hip Scores and mean pain Harris Hip Scores for the Ultima Metal-On-Metal Acetabular Cup were higher than the ZTT II Acetabular Cup. Mean function scores, radiographic parameters and complication rates between the two groups were similar.

2. K974728, Sulzer's Inter-Op Metasul Acetqbular System:

The Ultima Metal-On-Metal Acetabular Cup is substantially equivalent to the Sulzer Inter-Op Metasul Acetabular System. Both are metal-on-metal acetabular cup systems, intended for cementless fixation. The liner of the Ultima MOM Cup is composed only of wrought Co-Cr-Mo. The liner of the Inter-Op Metasul Cup is composed of polyethylene with a wrought (forged) Co-Cr-Mo inlay. This creates a metal-polyethylene-metal "sandwich" when the liner is assembled with a metal shell.

3. Pre-Amendment McKee Farrar Hip System:
   The Ultima Metal-On-Metal Acetabular Cup is equivalent in basic design and intended use to this pre-amendment metal-on-metal hip system. The McKee-Farrar metal-on-metal hips were implanted in the 1950's through the 1970's with moderate clinical success and are the forerunners of today's metal-on-metal hip designs.

Conclusion:

This subject device system is substantially equivalent to legally marketed device(s), i.e., McKee Farrar (Pre-amendment device) and K974728 in terms of the metal-on-metal design, physical characteristics, and intended use.

Decision Making Documentation

Product to which compared: see review

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

Note: "Yes" responses to questions 4,6,8,11, and every "No" response requires an explanation.

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

Internal Administrative Form

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

Screening Checklist

2. GENERAL INFORMATION:							
Financial Certification or Disclosure Statement for 510(k)s with a Clinical Study 807.87(i)	NA		YES		NO		
	SPECIALS		ABBREVIATED		TRADITIONAL		
	YES	NO	YES	NO	YES	NO	
a) trade name, classification name, establishment registration number, device class					x		
b) OR a statement that the device is not yet classified	(may be a classification request; see coordinator)						
c) identification of legally marketed equivalent device	NA				x		
d) compliance with Section 514 - performance standards	NA						
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)							
j) Description of device (or modification) including diagrams, engineering drawings, photographs, service manuals					x		
k) Proposed Labeling					x		
l) Comparison Information (similarities and differences) to named legally marketed equivalent device (table preferred)					x		
m) If kit, certification							
5. Additional Considerations: (may be covered by Design Controls)							
a) Biocompatibility data for all patient-contacting materials, OR certification of identical material/formulation					x		
b) Sterilization and expiration dating information					x		
c) Software validation & verification							

Passed Screening: Yes Reviewed by: Pei Sung Concurred by: _____

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

May 16, 2000

DEPUY ORTHOPAEDICS, INC.
P.O. BOX 988
WARSAW, IN 46581
ATTN: CHERYL HASTINGS

510(k) Number: K001523
Received: 16-MAY-2000
Product: ULTIMA
METAL-ON-METAL
ACETABULAR CUP

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

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K 001523

DePuy
a Johnson & Johnson company

DePuy Orthopaedics, Inc.

PO Box 988
700 Orthopaedic Drive
Warsaw, Indiana 46581-0988
USA

Tel: +1 (219) 267 8143
Fax: +1 (219) 267 7196

May 12, 2000

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

Subject: DePuy Orthopaedics Ultima® Metal-On-Metal Acetabular Cup

Dear Madam/Sir:

Pursuant to Section 510(k) of the Food, Drug and Cosmetic Act and Title 21 Part 807 of the Code of Federal Regulations, DePuy Inc. submits the enclosed documentation in triplicate, as notification of its intent to market the above-referenced device.

Pursuant to 21 CFR 807.95(c) (3), DePuy considers this 510(k) submission to be confidential commercial information and requests nondisclosure of its existence for 90 days from the date of its receipt.

Questions regarding this submission may be directed to me at (219) 371-4901.

Sincerely,

Cheryl Hastings

Cheryl Hastings
Director, Regulatory Affairs

510\00\MOM

FDA/CDRH/ODE/DMC
16 May 00 10 40
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OR
14 III

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510(k) Number (if known) _____

Device Name DePuy Orthopaedics Ultima® Metal-On-Metal Acetabular Cup

Indications for Use:
The Ultima® Metal-On-Metal Acetabular Cup 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 Ultima Metal-On-Metal Acetabular Cup is intended for use with DePuy S-ROM and PFC 28mm diameter Co-Cr-Mo femoral heads only.

Concurrence of CDRH, Office of Device Evaluation

Prescription Use _____ OR Over-The Counter Use ___ 17
(Per 21 CFR 801.109)

SUMMARY OF SAFETY AND EFFECTIVENESS

NAME OF FIRM:	DePuy Orthopaedics, Inc. 700 Orthopaedic Drive Warsaw, Indiana 46581-0988
510(k) CONTACT:	Cheryl Hastings Director, Regulatory Affairs
TRADE NAME:	Ultima® Metal-On-Metal Acetabular Cup
COMMON NAME:	Total Hip Replacement System
CLASSIFICATION:	888.3330: Hip joint, metal/metal semi-constrained, with an uncemented acetabular component, prosthesis. Class III
DEVICE PRODUCT CODE:	87 JDM
SUBSTANTIALLY EQUIVALENT DEVICES:	♦ ZTT II Acetabular Cup System (K951000) ♦ Sulzer Orthopedics Inc. Inter-Op Metasul Acetabular System (K974728) ♦ McKee-Farrar Metal-On-Metal Hip (pre-amendment) ♦ Ring Metal-On-Metal Hip (pre-amendment)

DEVICE DESCRIPTION AND INTENDED USE:
The Ultima Metal-On-Metal (MOM) Acetabular Cup is comprised of a metal shell and a metal liner. The outer acetabular cup is a near-hemispherical stepped and porous-coated shell with three dome screw holes, an apical hole used for visualization, and a peripheral female taper. The liner is offered in both standard (neutral) and augmented (10° lip) forms and has a 28mm inner diameter. The 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

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and disability due to previous fusion, where bone stock is inadequate for other reconstruction techniques.

The Ultima Metal-On-Metal Acetabular Cup is intended for use with DePuy S-ROM and PFC 28mm diameter Co-Cr-Mo femoral heads only.

BASIS OF SUBSTANTIAL EQUIVALENCE:

The Ultima Metal-On-Metal Acetabular Cup is equivalent to the ZTT II Acetabular Cup in that they have the same intended use and the same basic design. The differences between the two designs are that the Ultima MOM Cup has a metal insert and a taper-lock locking mechanism, whereas the ZTT II Cup has a polyethylene insert which locks into the metal shell via polyethylene lugs on the insert that dial into slots in the shell.

Clinical data collected from two prospective, multi-center studies showed that at 24(+) month follow-up, mean total Harris Hip Scores and mean pain Harris Hip Scores for the metal-on-metal cases (using the Ultima Metal-On-Metal Acetabular Cup) were significantly higher than those for metal-on-polyethylene cases (using the ZTT II Acetabular Cup). Mean function scores, radiographic parameters and complication rates between the two groups were similar.

The Ultima Metal-On-Metal Acetabular Cup is also substantially equivalent to the Sulzer Inter-Op Metasul Acetabular System. Both are metal-on-metal acetabular cup systems, intended for cementless fixation. The liner of the Ultima MOM Cup is composed only of wrought Co-Cr-Mo. The liner of the Inter-Op Metasul Cup is composed of polyethylene with a wrought forged Co-Cr-Mo inlay. This creates a metal-polyethylene-metal "sandwich" when the liner is assembled with a metal shell.

The Ultima Metal-On-Metal Acetabular Cup is also substantially equivalent in basic design and intended use to several pre-amendment metal-on-metal hip systems. Of these, the McKee-Farrar and the Ring are probably the most widely known and documented. The McKee-Farrar and Ring metal-on-metal hips were implanted in the 1950's through the 1970's with moderate clinical success and are the fore-runners of today's metal-on-metal hip designs.

SUMMARY OF SAFETY AND EFFECTIVENESS

NAME OF FIRM:	DePuy Orthopaedics, Inc. 700 Orthopaedic Drive Warsaw, Indiana 46581-0988
510(k) CONTACT:	Cheryl Hastings Director, Regulatory Affairs
TRADE NAME:	Ultima® Metal-On-Metal Acetabular Cup
COMMON NAME:	Total Hip Replacement System
CLASSIFICATION:	888.3330: Hip joint, metal/metal semi-constrained, with an uncemented acetabular component, prosthesis. Class III
DEVICE PRODUCT CODE:	87 JDM
SUBSTANTIALLY EQUIVALENT DEVICES:	♦ ZTT II Acetabular Cup System (K951000) ♦ Sulzer Orthopedics Inc. Inter-Op Metasul Acetabular System (K974728) ♦ McKee-Farrar Metal-On-Metal Hip (pre-amendment) ♦ Ring Metal-On-Metal Hip (pre-amendment)

DEVICE DESCRIPTION AND INTENDED USE:
The Ultima Metal-On-Metal (MOM) Acetabular Cup is comprised of a metal shell and a metal liner. The outer acetabular cup is a near-hemispherical stepped and porous-coated shell with three dome screw holes, an apical hole used for visualization, and a peripheral female taper. The liner is offered in both standard (neutral) and augmented (10° lip) forms and has a 28mm inner diameter. The 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 Ultima Metal-On-Metal Acetabular Cup is intended for use with DePuy S-ROM and PFC 28mm diameter Co-Cr-Mo femoral heads only.

BASIS OF SUBSTANTIAL EQUIVALENCE:

The Ultima Metal-On-Metal Acetabular Cup is equivalent to the ZTT II Acetabular Cup in that they have the same intended use and the same basic design. The differences between the two designs are that the Ultima MOM Cup has a metal insert and a taper-lock locking mechanism, whereas the ZTT II Cup has a polyethylene insert which locks into the metal shell via polyethylene lugs on the insert that dial into slots in the shell.

Clinical data collected from two prospective, multi-center studies showed that at 24(+) month follow-up, mean total Harris Hip Scores and mean pain Harris Hip Scores for the metal-on-metal cases (using the Ultima Metal-On-Metal Acetabular Cup) were significantly higher than those for metal-on-polyethylene cases (using the ZTT II Acetabular Cup). Mean function scores, radiographic parameters and complication rates between the two groups were similar.

The Ultima Metal-On-Metal Acetabular Cup is also substantially equivalent to the Sulzer Inter-Op Metasul Acetabular System. Both are metal-on-metal acetabular cup systems, intended for cementless fixation. The liner of the Ultima MOM Cup is composed only of wrought Co-Cr-Mo. The liner of the Inter-Op Metasul Cup is composed of polyethylene with a wrought forged Co-Cr-Mo inlay. This creates a metal-polyethylene-metal "sandwich" when the liner is assembled with a metal shell.

The Ultima Metal-On-Metal Acetabular Cup is also substantially equivalent in basic design and intended use to several pre-amendment metal-on-metal hip systems. Of these, the McKee-Farrar and the Ring are probably the most widely known and documented. The McKee-Farrar and Ring metal-on-metal hips were implanted in the 1950's through the 1970's with moderate clinical success and are the fore-runners of today's metal-on-metal hip designs.

DePuy
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USA

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Fax: +1 (219) 267 7196

May 12, 2000

PREMARKET NOTIFICATION
CLASS III CERTIFICATION AND SUMMARY
(As Required by 21 CFR 807.94)

I certify that, in my capacity as Director of Regulatory Affairs at DePuy Orthopaedics, Inc., a Johnson & Johnson company that I have conducted a reasonable search of all information known or otherwise available about the types and causes of safety or effectiveness problems that have been reported for metal-on-metal total hip systems. I further certify that I am aware of the types of problems to which metal-on-metal total hip systems are susceptible and that, to the best of my knowledge, the following summary of the types and causes of safety or effectiveness problems is complete and accurate.

Cheryl Hastings
(Signature)

Cheryl K. Hastings
(Name)

May 12, 2000
Date

(Premarket Notification [510(k)] Number)

DePuy Ultima Metal-On-Metal Acetabular Cup

SUMMARY OF THE TYPES AND CAUSES OF SAFETY OR EFFECTIVENESS PROBLEMS

METAL-ON-METAL TOTAL HIP SYSTEMS

Based on the literature summary provided in G960262, the most significant complications associated with historical metal-on-metal total hip replacement systems include:

- Loosening, possibly related to surgical technique, poor fixation, sub-optimal bearing design resulting in high frictional torque and/or bearing seizure, or sub-optimal range of motion in early designs;
- Pain, possibly related to loosening;
- Calcar resorption, possibly related to poor early stem designs and not the metal-on-metal articulation;

Other potential complications which could be associated with metal-on-metal hip replacement, but have not been conclusively documented clinically include:

- Local and systemic reactions to increased metal ion release and metal wear debris, especially a higher incidence of certain site specific cancers;
- Fretting and corrosion of the implant due to galvanic corrosion between dissimilar metals;

Other types of safety and effectiveness problems which are associated with metal-on-metal hip replacement are those which are associated with all total joint replacements. These include: infection, dislocation, cardiovascular disorders (including venous thrombosis, pulmonary embolism, and myocardial infarction), pneumonia, atelectasis, hematoma, nerve damage, delayed wound healing, reaction to bone cement, metal sensitivity, bone fracture, soft tissue imbalance, failure to relieve pain, failure to restore range of motion and deformity of the joint.

In order to reduce the chance of complications with a metal-on-metal hip replacement device, the following conditions, which tend to adversely affect safety and/or effectiveness of any total joint arthroplasty, should be reduced or eliminated: marked osteoporosis with poor bone stock and danger of impaired abutment of implants, systemic and metabolic disorders leading to progressive deterioration of solid bone support for the implant (e.g. cortisone therapies, immunosuppressive therapies), history of general infectious disease (e.g. erysipelas) or local infectious disease, severe deformities leading to impaired anchorage or improper positioning of the implant, tumors of the supporting bone structure, allergic reactions to the implant materials, and tissue reactions to corrosion or wear products.

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May 12, 2000

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

Pursuant to 21 CFR 807.87(j), I, Cheryl Hastings, certify that to the best of my knowledge and belief and based upon the data and information submitted to me in the course of my responsibilities as Director of Regulatory Affairs of DePuy Orthopaedics, Inc., and in reliance thereupon, the data and information submitted in this premarket notification are truthful and accurate and that no facts material for a review of the substantial equivalence of this device have been knowingly omitted from this submission.

Cheryl Hastings

Cheryl Hastings
Director, Regulatory Affairs
DePuy Orthopaedics, Inc.

DePuy Ultima® Metal-On-Metal Acetabular Cup

510(k) NOTIFICATION

Pursuant to Section 510(k) of the Federal Food, Drug, and Cosmetic Act and in accordance with subpart E of Part 807 of Title 21 of the Code of Federal Regulations; DePuy Orthopaedics Inc., P.O. Box 988, Warsaw IN, 46581-0988, hereby submits the following information as premarket notification for the DePuy Orthopaedics Ultima® Metal-On-Metal (MOM) Acetabular Cup. ***This same device was approved for investigational use in G960262. Conditional approval was received on January 24, 1997 and final approval was received on September 3, 1997.***

I. ADMINISTRATIVE INFORMATION

A. SPONSOR OF THE 510(k) SUBMISSION

DePuy Orthopaedics, Inc.
P.O. Box 988
Warsaw, IN 46581-0988
Establishment Registration Number: 1818910

B. MANUFACTURER

DePuy International Ltd.
St. Anthony's Road
Leeds LS11 8DT
England
Tel: +44 (113) 270 0461
Fax: +44 (113) 272 4101

C. CONTRACT STERILIZER

(b)(4)

D. CONTACT PERSON

Cheryl Hastings
Director, Regulatory Affairs
DePuy Orthopaedics, Inc.
(219) 371-4901
FAX (219) 371-4940

II. DEVICE IDENTIFICATION

A. PROPRIETARY NAME
Ultima® Metal-On-Metal Acetabular Cup

B. COMMON NAME
Total Hip Replacement System

C. CLASSIFICATION NAME AND REFERENCE
888.3330: Hip joint, metal/metal semi-constrained, with an uncemented acetabular component, prosthesis. Class III

D. DEVICE PRODUCT CODE
87 JDM

III. COMPLIANCE WITH SPECIAL CONTROLS

Sections 513 and 514 of the FD&C Act, as amended under the Safe Medical Devices Act of 1990, do apply to this type of device, but a performance standard has not yet been promulgated. DePuy Orthopaedics, Inc. is not aware of any requirements for postmarket surveillance or other special controls for this device.

IV. STERILITY AND PACKAGING

The Ultima MOM Acetabular Cup is supplied packaged and sterile by exposure to Cobalt-60 Gamma Radiation at a minimum dose of 25 kilogray. The metal shells and metal liners are packaged and sold separately.

- The sterilization method has been validated (b)(4)
  (b)(4)
- (b)(4)
-
-

V. DEVICE DESCRIPTIVE INFORMATION

A. MATERIALS
- The Ultima MOM acetabular shell is manufactured from Ti-6Al-4V titanium alloy conforming to ASTM F-136.
- The porous coating on the shell is Commercially Pure Titanium conforming to ASTM F-67.

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- The metal liner is manufactured from Co-Cr-Mo alloy conforming to ASTM F-1537.

B. INTENDED USE

The Ultima® Metal-On-Metal Acetabular Cup 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 Ultima Metal-On-Metal Acetabular Cup is intended for use with DePuy S-ROM and PFC 28mm diameter Co-Cr-Mo femoral heads only.

C. DEVICE DESCRIPTION

The subject device is identical to the Ultima Metal-On-Metal Acetabular Cup that was approved for investigational use in G960262.

The Ultima Metal-On-Metal (MOM) Acetabular Cup is comprised of a metal shell and a metal liner. The outer acetabular cup is a near-hemispherical stepped and porous-coated shell with three dome screw holes, an apical hole used for visualization, and a peripheral female taper. The liner is offered in both standard (neutral) and augmented (10° lip) forms and has a 28mm inner diameter. The MOM liner is mechanically locked with the shell via a taper junction, and articulates with commercially available prosthetic femoral heads.

Part numbers and descriptions, engineering prints and photographs are provided in Exhibit 1. A list of ancillary parts is provided in Exhibit 2.

D. LABELING AND ADVERTISING

Draft package labels and a draft package insert are provided in Exhibit 3. The draft package insert has been modified slightly from the package inserts approved in G960262. It has been re-written specifically for the Ultima Metal-On-Metal Acetabular Cup and references to investigational devices and investigators have been removed.

VI. TESTING

A. HIP SIMULATOR TESTING

(b)(4)

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09

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(b)(4)

A complete summary of the clinical data and statistical analysis of the data is provided in Exhibit 5.

VIII. SUBSTANTIALLY EQUIVALENT DEVICES (Exhibit 6)

Johnson & Johnson (now DePuy) ZTT II Acetabular Cup System (K951000)

Sulzer Orthopedics Inc. Inter-Op Metasul Acetabular System (K974728)

McKee-Farrar Metal-On-Metal Hip (pre-amendment)

Ring Metal-On-Metal Hip (pre-amendment)

IX. BASIS OF SUBSTANTIAL EQUIVALENCY

The Ultima Metal-On-Metal Acetabular Cup is equivalent to the ZTT II Acetabular Cup in that they have the same intended use and the same basic

31

design. The differences between the two designs are that the Ultima MOM Cup has a metal insert and a taper-lock locking mechanism, whereas the ZTT II Cup has a polyethylene insert which locks into the metal shell via polyethylene lugs on the insert that dial into slots in the shell.

The Ultima MOM Acetabular Cup is available in outer diameters ranging from 48 to 68mm and an inner diameter of 28mm. The ZTT II Cup is available in outer diameters ranging from 48 to 66mm and inner diameters of 28 and 32mm.

Clinical data collected from two prospective, multi-center studies showed that at 24(+) month follow-up, mean total Harris Hip Scores and mean pain Harris Hip Scores for the metal-on-metal cases (using the Ultima Metal-On-Metal Acetabular Cup) were significantly higher than those for metal-on-polyethylene cases (using the ZTT II Acetabular Cup). Mean function scores, radiographic parameters and complication rates between the two groups were similar.

The Ultima Metal-On-Metal Acetabular Cup is also substantially equivalent to the Sulzer Inter-Op Metasul Acetabular System. Both are metal-on-metal acetabular cup systems, intended for cementless fixation. The liner of the Ultima MOM Cup is composed only of wrought Co-Cr-Mo. The liner of the Inter-Op Metasul Cup is composed of polyethylene with a wrought forged Co-Cr-Mo inlay. This creates a metal-polyethylene-metal "sandwich" when the liner is assembled with a metal shell. The Inter-Op Metasul Cup is available in outer diameters ranging from 49mm to 81mm and has a 28mm inner diameter.

The Ultima Metal-On-Metal Acetabular Cup is also substantially equivalent in basic design and intended use to several pre-amendment metal-on-metal hip systems. Of these, the McKee-Farrar and the Ring are probably the most widely known and documented. The McKee-Farrar and Ring metal-on-metal hips were implanted in the 1950's through the 1970's with moderate clinical success and are the fore-runners of today's metal-on-metal hip designs. Since that time much improvement has been made in metal-on-metal devices as demonstrated in the "Wear and Lubrication of Metal-on-Metal Hip Implants" by Chan et al. This article is included at the end of Exhibit 6.

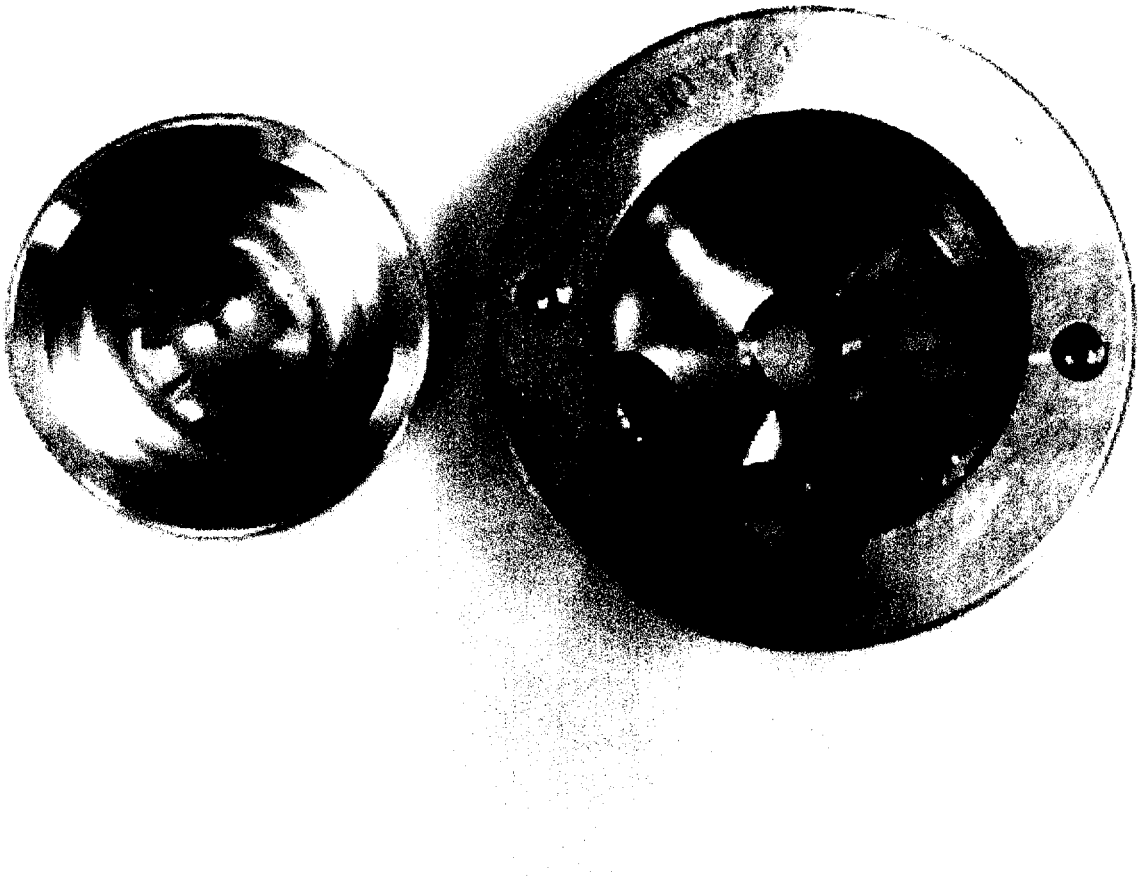
In conclusion, DePuy feels that the Ultima Metal-On-Metal Acetabular Cup is substantially equivalent to the above metal-on-metal and metal-on-polyethylene predicate acetabular cup systems, which are either pre-amendment or have been cleared by FDA through the pre-market notification process.

EXHIBIT 1

Ultima Metal-On-Metal Acetabular Cup

Part Numbers and Descriptions

85-9834	Ultima MOM Shell, 48mm
85-9835	Ultima MOM Shell, 50mm
85-9836	Ultima MOM Shell, 52mm
85-9837	Ultima MOM Shell, 54mm
85-9838	Ultima MOM Shell, 56mm
85-9839	Ultima MOM Shell, 58mm
85-9840	Ultima MOM Shell, 60mm
85-9841	Ultima MOM Shell, 62mm
85-9842	Ultima MOM Shell, 64mm
85-9843	Ultima MOM Shell, 66mm
85-9844	Ultima MOM Shell, 68mm
85-9845	Ultima MOM Insert, Standard
85-9846	Ultima MOM Insert, Augmented



Ultima Standard Metal Insert (left) and Metal Shell (right)

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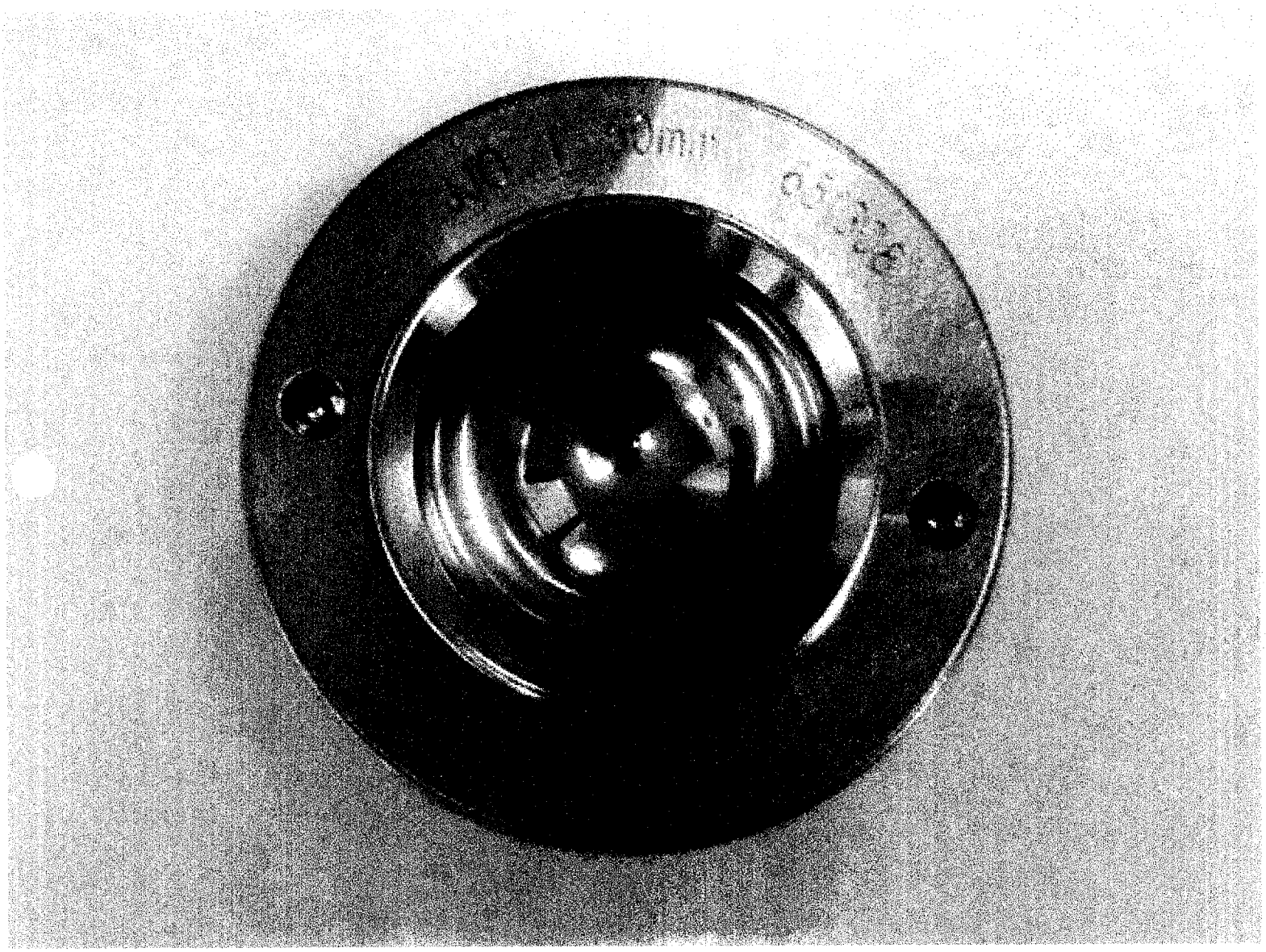

35

Ultima Metal-On-Metal Acetabular Cup, Assembled

Pages 45 through 48 redacted for the following reasons:
- -
Exemption 4: Pages 45-48 contain proprietary schematic drawings.

EXHIBIT 2

Ancillary Components

The following components are intended for use with the Ultima MOM Acetabular Cup:

Part Number	Description	Cleared In:
85-9913	S-ROM 28mm +0 Femoral Head	K851422
85-9915	S-ROM 28mm +6 Femoral Head	K851422
85-9916	S-ROM 28mm +12 Femoral Head	K851422
85-9847	PFC 28mm +0 Femoral Head	K893872
85-9848	PFC 28mm +5 Femoral Head	K893872
85-9849	PFC 28mm +10 Femoral Head	K893872
85-1410	PFC Apical Hole Plug	K944769
55-6070	6.5mm Bone Screw, 15mm Length	K951000
55-6071	6.5mm Bone Screw, 20mm Length	K951000
55-6072	6.5mm Bone Screw, 25mm Length	K951000
55-6073	6.5mm Bone Screw, 30mm Length	K951000
55-6074	6.5mm Bone Screw, 35mm Length	K951000
55-6075	6.5mm Bone Screw, 40mm Length	K951000
55-6076	6.5mm Bone Screw, 45mm Length	K951000
55-6077	6.5mm Bone Screw, 50mm Length	K951000
55-6078	6.5mm Bone Screw, 55mm Length	K951000
55-6079	6.5mm Bone Screw, 60mm Length	K951000

EXHIBIT 3

DRAFT LABELS

Metal Shell:

REF: XX-XXXX

DePuy International Ltd.

Ultima Metal-On-Metal Shell

Size X

Ti-6Al-4V

Lot: XXXXX
ID#

Sterile Unless Damaged or Opened

Rx Only.

Distributed in the USA by:
DePuy Orthopaedics, Inc.
700 Orthopaedic Drive
Warsaw, IN 46580

Metal Insert:

REF: XX-XXXX

DePuy International Ltd.

Ultima Metal-On-Metal Insert

Size X

Co-Cr-Mo

Lot: XXXXX
ID#

Sterile Unless Damaged or Opened

Rx Only.

Distributed in the USA by:
DePuy Orthopaedics, Inc.
700 Orthopaedic Drive
Warsaw, IN 46580

000029

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EXHIBIT 3

DRAFT PACKAGE INSERT

ULTIMA® Metal-On-Metal Acetabular Cup

Manufactured by

DePuy International Ltd.
St. Anthony's Road
Leeds LS11 8DT
England
Tel: +44 (113) 270 0461
Fax: +44 (113) 272 4101

Distributed in the USA by:

DePuy Orthopaedics, Inc.
700 Orthopaedic Drive
Warsaw, IN 46580
USA
Tel: +1 (800) 366 8143
Fax: +1 (219) 267 7196

Ultima Metal-On-Metal Acetabular Cup

Rx Only

Description
The Ultima Metal-On-Metal (MOM) Acetabular Cup is comprised of a metal shell and a metal liner. The outer acetabular cup is a near-hemispherical stepped and porous-coated shell with three dome screw holes, an apical hole used for visualization, and a peripheral female taper. The liner is offered in both standard (neutral) and augmented (10° lip) forms and has a 28mm inner diameter. The MOM liner is mechanically locked with the shell via a taper junction, and articulates with commercially available prosthetic femoral heads.

Indications
The Ultima Metal-On-Metal Acetabular Cup 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 Ultima Metal-On-Metal Acetabular Cup is intended for use with DePuy S-ROM and PFC 28mm diameter Co-Cr-Mo femoral heads only.

Information for Use
An instrumentation system, as well as a system of trial components, is available to assure proper fit and alignment of the prosthesis. Correct fit and alignment will reduce stresses at interface surfaces to enhance implant fixation. The surgeon should refer to the appropriate surgical technique manual on use of the instrument system and implantation of the prosthesis. A special instrument is provided to enable the surgeon to remove the insert once it has been fitted in place. It is recommended that a reamer of the same size designation as the shell is used since this will provide a 1.5mm diametral press fit.

Contraindications
Use is contraindicated in cases with active or recent joint sepsis, insufficient bone stock, marked atrophy or deformity in the upper femur, skeletal immaturity, or where loss of musculature or neuromuscular disease would render the procedure unjustifiable.

Warnings
Improper prosthesis selection or alignment, inadequate fixation, use where contraindicated or in patients whose medical, physical, mental or occupational

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conditions will likely result in extreme stresses to the implant may result in premature failure due to loosening, fracture or wear. Postoperative care is extremely important. The patient should be instructed on the limitations of the device and should be cautioned regarding load bearing, ranges of motion and activity levels permissable. Early motion and load bearing should be carefully monitored.

Use of other manufacturers' components with this implant is not advised. Use of components other than those recommended could lead to loosening, wear, fracture during assembly and premature failure. Use the Ultima Metal-On-Metal shell only with the Ultima Metal-On-Metal insert.

The inner diameter of the Ultima Metal-On-Metal insert must correspond to the hip head size. Use of an insert with a non-matching hip head size (e.g. 28mm inner diameter insert with a 22mm head) will result in accelerated wear and early failure. Use only with DePuy S-ROM and PFC 28mm diameter Co-Cr-Mo femoral heads.

Precautions

To prevent contamination of this prosthesis, keep free of lint and powders. Do not open the package until surgery. Do not place the implant in contact with prepared bone surface before the final decision to implant has been made.

An implant should never be re-used. Any implant, once used, should be discarded. Even though it appears undamaged, it may have small defects and internal stress patterns that may lead to failure.

Likewise, a new implant should be handled carefully to avoid damage that could compromise the mechanical integrity of the device and cause early failure or loosening.

The wear rate of prosthesis contact surfaces is greatly accelerated if loose fragments of bone cement become detached and act as an abrasive in the bearing surfaces. When using bone cement, care should be taken to remove all excess cement from the periphery of the implant.

The highly polished bore of the insert should not come into contact with abrasive surfaces, as this may damage the bore and affect performance. In addition, all mating surfaces should be clean before assembly to ensure proper seating. If the insert is not properly seated into the metal on metal shell it may become loose.

Adverse Effects

Peripheral neuropathy, deep wound infection, and heterotopic bone formation have been reported following hip replacments. Subclinical nerve damage has also been reported more frequently, often associated with surgical trauma. Dislocation and subluxation resulting from improper positioning and/or muscle and fibrous tissue

laxity may also occur, as may loosening and subsequent failure of the total hip prosthesis.

Histological reactions have been reported as an apparent response to exposure to a foreign material. The actual clinical significance of these reactions is unknown.

Implanted metal alloys release metallic ions into the body. In situations where bone cement is not used, higher ion release due to increased surface area of a porous coated prosthesis is possible.

There have been reports of failure of bone to grow into porous surfaces and fix components. Shedding or fragmentation of the porous surface has been reported, with potential for release of metallic debris into the joint space. Radiolucencies of bone adjacent to porous surfaces have been noted, although the clinical significance of this observation is uncertain in many cases.

Serious adverse effects may necessitate surgical intervention.

Sterility and Handling
The components of the Ultima Metal-On-Metal Acetabular Cup are supplied sterile by exposure to gamma irradiation.

DO NOT RESTERILIZE and DO NOT USE if the package is damaged or broken and sterility may be compromised.

Components may not be resterilized by the hospital because of the possibility of damaging the articulating and interfacing surfaces of the implant and/or damaging or contaminating the porous surface.

The care and handling of porous coated implants demands greater attention because of the increased potential for particulate and microbiological contamination. Body fluids, tissues and particulate matter adhere to the beaded surface. Therefore, it is critical to minimize handling of the prosthesis.

The package should be opened only after the correct size has been determined, as opened packages may not be returned for credit.

Johnson & Johnson
PROFESSIONAL, INC.

RESEARCH REPORT COVER SHEET

TEST OF FINAL DESIGN OF METAL ON METAL: HIP SIMULATOR STUDY

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Johnson & Johnson
PROFESSIONAL, INC.

RESEARCH REPORT

TEST OF FINAL DESIGN OF METAL ON METAL: HIP SIMULATOR STUDY

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TEST OF FINAL DESIGN OF METAL ON METAL: HIP SIMULATOR STUDY

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A Novel Low Wearing Differential Hardness, Ceramic on Metal Hip Joint Prosthesis

*P.J.Firkins, **J.L. Tipper, **E. Ingham,*** M.H. Stone, ****R. Farrar, *J. Fisher.
*MBE, School of Mechanical Engineering, Leeds University, Leeds, LS2 9JT, UK. menpjf@leeds.ac.uk.

Introduction.

Osteolysis and loosening of artificial joints caused by polyethylene wear debris has prompted a renewed interest in alternative materials for hip prosthesis designs. Metal on metal (MOM) and ceramic on ceramic prostheses are already in clinical use. This study investigated the low wear properties and debris morphology of a novel hip prosthesis design using differential hardness, ceramic on metal (COM) articulating surfaces.

Materials and Methods.

Six 28 mm femoral heads were manufactured; three from medical grade alumina (ISO 6474) and three from medical grade low carbon (< 0.07%) wrought cobalt chrome alloy (ASTM F1537). These were coupled with six 28 mm acetabular cups manufactured from medical grade high carbon (< 0.2%) wrought cobalt chrome alloy (ASTM F1537). The diametral clearance was 60 μm and initial surface roughness R_a values < 0.01 μm. The implants were tested in the anatomical position in a hip simulator with two axes of motion and one axis of loading [1]. Articulations and loading patterns were applied similar to Paul type curves [2] with an open elliptical wear track. Bovine serum (25%) was used as the lubricant. The implants were tested for 5 million cycles. Interruptions were made at various intervals for lubricant collection for wear debris analysis and gravimetric wear and surface analysis. Wear debris was isolated from the serum using methods devised by Firkins et al [3]. Characterisation was carried out using TEM and digital image analysis techniques. Surface analysis was carried using contacting and non-contacting profilometry. Linear regression analysis of the cumulative volumetric wear was performed. Ninety five percent confidence limits were derived from the regression analysis of the slopes (wear rates) in the first million and from 1 to 5 million cycles.

Results.

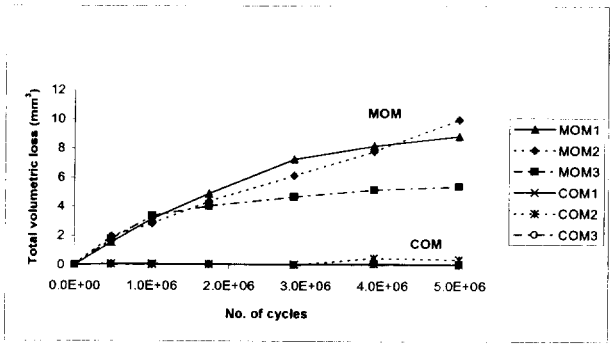

Figure 1. Volume change for COM versus MOM.

Figure 1 shows the volumetric wear for each pairing. The COM showed approximately 100 times less wear than MOM. The MOM pairings showed a high "bedding in" wear rate (3.09 ± 0.46 $mm^3/10^6$ Cycles) in the first million cycles which then settled to a lower steady state wear rate (1.23 ± 0.50 $mm^3/10^6$ Cycles). Very low wear was detected on the COM components, however an accurate measurement of the volumetric wear was difficult to obtain due to material transfer on the components and the accuracy of the balance (± 10 μg). The wear of the COM throughout the whole test was approximately 0.02 mm^3/million cycles. The wear scar on all cups and heads was localised to the superior quadrant. Surface analysis of the ceramic heads showed no signs of wear. However metal transfer (<100 nm thick) and calcium phosphate deposits were present at the edge of the contact area. The metal cups also showed deposits of calcium phosphate at the edge of the contact areas. Fine scratches were present in the contact areas of the cups. Profilometry revealed these scratches to be less than 100 nm deep, and the overall surface roughness showed no significant change to that of the non-contacting surface. The MOM components revealed much larger contact areas, which were covered over by a thin film of phosphate transfer on each component. The low carbon heads had worn down in the contact area to give a similar radius to that of the high carbon cups.

Only metal particles were clearly identified when isolating the COM debris from the serum. The mean particle sizes were 18 ± 1.37 nm for the COM and 30 ± 2.25 nm for the MOM. The majority of the particles were oval to round. The smaller metal particles in the COM bearing were consistent with less severe wear and smoother cup surface finish than MOM.

Discussion.

MOM hip prostheses are currently in clinical use and have shown to have lower wear than polyethylene cup prostheses. The wear rates for MOM prostheses from this present study are similar to those in clinical use. This study has shown that the use of differential hardness pairings of ceramic on metal has drastically reduced the wear rate compared to that of the MOM pairings tested. The exact amount of wear on the COM components was hard to accurately measure due to its very low level of wear, transfer films and the accuracy of the balance, it was however approximately 0.02 mm^3/million cycles over the whole test. Previous studies of ceramic on ceramic hip prostheses in the same type of simulator have shown an average wear rate of 0.08 mm^3/million cycles [4]. Surface analysis of each component revealed little if any surface damage. It could be hypothesised that if a scratch was produced on the metal cup due to abrasive wear, the scratch lips [5] and even the scratch itself would be polished away by the harder ceramic head which also had a better initial surface finish than its metal counterpart, thus reducing any acceleration in wear which would occur if the bearing surface was damaged. The metal transfer on the ceramic heads did not appear to accelerate the wear on the metal cup. The deposits of calcium phosphate only appeared at the edge of the contact area thus having no effect on wear on the articulating surfaces.

The size of MOM particles isolated and characterised were similar to those obtained from a study using a full physiological anatomical hip simulator, and were clinically relevant [3,6]. The metal particles from the COM pairings were statistically smaller and this may be due to the less harsh abrasive action occurring as well as the presence of a better lubricating regime which might be achieved (full fluid film lubrication) [7]. The extremely low wearing differential hardness bearings presented here may contribute to a reduction in osteolysis and other adverse biological reactions and therefore ultimately a further improvement in the long-term survivorship of total hip replacements *in vivo*.

References.

1. Barbour PSM et al, *Proc Instn Mech Engnrs, Part H*, **213**, 1999, IN PRESS; **2.** Paul JP, *Proc Instn Mech Engnrs.* **23**, 8-15, 1967; **3.** Firkins PJ et al. *Trans ORS*, **45**, 49, 1999; **4.** Nevelos J et al, *Trans ORS*, **45**, 857, 1999; **5.** Mc Nie CM, *Trans ORS*, **45**, 241, 1999; **6.** Doorn P, *Trans EORS*, **8**, O61, 1998; **7.** Jin ZM et al *Proc Instn Mech Engrs Part H*, **211**, 247-56, 1997.

Acknowledgements.

This study was supported by DePuy International, a Johnson & Johnson company & EPSRC.

Additional affiliations.

**Dept of Microbiology, University of Leeds, Leeds, UK.
***Dept of Orthopaedic Surgery, Leeds General Infirmary, Leeds, UK.
**** DePuy International, a Johnson & Johnson company, Leeds, UK.

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Pages 73 through 158 redacted for the following reasons:
- -
Exemption 4: Pages 73-158 contain proprietary clinical trial data.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20856

APR 14

Mr. Kevin J. Crossen
Vice President, Regulatory Affairs
and Quality Functions
Joint Medical Products Corporation
860 Canal Street
Stamford, Connecticut 06902

RECEIVED
APR 19 1995
K.J. CROSSEN

Re: K951000
ZTT™ I and II Acetabular Cup of
the S-ROM® Total Hip System
Regulatory Class: II
Product Code: LPH
Dated: March 2, 1995
Received: March 3, 1995

FILE COPY

Dear Mr. Crossen:

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 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 practices, 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 (CFR), Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practices (GMP) for Medical Devices: General GMP regulation (21 CFR Part 820) and that, through periodic GMP 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.

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This letter immediately will allow you to begin marketing your device as described in your 510(k) premarket notification. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market, but it does not mean that FDA approves your device. Therefore, you may not promote or in any way represent your device or its labeling as being approved by FDA. If you desire specific advice regarding labeling for your device in accordance with 21 CFR Part 801, promotion, or advertising please contact the Office of Compliance, Promotion and Advertising Policy Staff (HFZ-302) at (301) 594-4639. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,

Ann C Torrence for

Paul R. Beninger, M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

AUG -3 1999

K974728

510(k) SUMMARY

In accordance with the Food and Drug Administration Interim Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807, this is to serve as a 510(k) summary for the Sulzer Orthopedics Inc. Inter-Op Metasul Acetabular System.

Submitter:	Sulzer Orthopedics Inc. 9900 Spectrum Drive Austin, TX 78717 (512)432-9900
Contact Person:	Jacquelyn Hughes Manager, Regulatory Affairs
Classification Name:	CFR 888.3330 - Hip joint metal/metal semiconstrained, with an uncemented acetabular component, prosthesis
Common/Usual Name:	Acetabular insert and head component of a total hip replacement
Trade/Proprietary Name:	Inter-Op Metasul Acetabular System

PRODUCT DESCRIPTION:

The Inter-Op Acetabular System is comprised of two components: (1) a polyethylene acetabular insert with an integral Metasul metal inlay (inner diameter), and (2) a Metasul femoral head.

Inter-Op Metasul Acetabular Insert

The Inter-Op Metasul Acetabular Insert is a hemispherical polyethylene component manufactured from UHMWPE (ASTM F648). The outer diameter of the insert is machined with locking features that mate with one of the previously cleared Inter-Op metallic acetabular shells.

The inner diameter which forms the bearing surface of the insert features a metallic Metasul inlay that is integrally locked to the polyethylene insert. The metal inlay is manufactured from Protasul®-21WF, a wrought forged CoCrMo alloy (ISO 5832). This inlay is polished to a mirror-finish and hot-pressed into the UHMWPE backing. Just prior to hot-pressing, two Protasul-10 (CoCr alloy, ASTM F562) pins are press fit into the design of the inlay to help provide added rotational stability. The Metasul inlay is designed for use only with the Metasul head component.

The Inter-Op Metasul Acetabular Insert component is available with outside diameters of 49mm to 81mm (in 2mm increments) with an inner diameter of 28mm.

Metasul Femoral Head

The Metasul Femoral Heads are manufactured from the same Protasul-21WF (CoCr, ISO 5832) material as the metal inlay of the acetabular component. The design incorporates a 12/14 morse type female taper with beveled face for ease of reduction intraoperatively. The female taper matches the 12/14 male taper used on Sulzer Orthopedics femoral stems.

The Metasul femoral heads are designed specifically to articulate with the Metasul inlay of the acetabular component. High precision manufacturing allows for optimal articulating surface

geometry (e.g., clearance between the Metasul head and the Metasul inlay). These devices are manufactured within tight tolerances because the success of the system is dependent on optimal performance at this articulating interface

The Metasul heads are available in 28mm diameter with four neck lengths: short (-4mm), medium (neutral), long (+4mm) and extra long (+8mm).

SPECIFIC DIAGNOSTIC INDICATIONS:

The Inter-Op Metasul Acetabular System is intended for use in cases of total hip replacement for treatment of the following:

1. Patient conditions of non-inflammatory degenerative joint disease (NIDJD), e.g., osteoarthritis, post traumatic arthritis or avascular necrosis and inflammatory degenerative joint disease (IJD), e.g., rheumatoid arthritis.

2. Those patients with failed previous surgery where pain, deformity or dysfunction persists.

3. Revision of previously failed hip arthroplasty.

SUBSTANTIAL EQUIVALENCE:

Substantial equivalence determination is based on comparison of the Inter-Op Metasul Acetabular System to the following preamendments predicate devices:

- McKee-Farrar Total Hip
- Ring Total Hip
- Sivash Total Hip

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 3 1999

Mitchell A. Dhority, RAC
Sr. Regulatory Affairs Specialist
Sulzer Orthopedics, Inc.
9900 Spectrum Drive
Austin, Texas 78717

Re: K974728
Trade Name: Inter-Op™ Metasul® Acetabular System
Regulatory Class: III
Product Code: KWA
Dated: May 20, 1999
Received: May 21, 1999

Dear Mr. Dhority:

We have reviewed your Section 510(k) notification of intent to market the device referenced above, and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general 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. Furthermore, for questions regarding the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification (21 CFR 807.97)." Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

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

Enclosure

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510(k) Number (if known): K974728

Device Name: Inter-Op Metasul Acetabular System

Indications for Use:

The Inter-Op Metasul Acetabular System is intended for use in cases of total hip replacement for treatment of the following:

1. Patient conditions of non-inflammatory degenerative joint disease (NIDJD), e.g., osteoarthritis, post traumatic arthritis or avascular necrosis and inflammatory degenerative joint disease (IJD), e.g., rheumatoid arthritis.

2. Those patients with failed previous surgery where pain, deformity or dysfunction persists.

3. Revision of previously failed hip arthroplasty.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K974728

Prescription Use ✓ **OR** **Over-the Counter Use** ____

(Optional Format 1-2-96)

2. Literature Review

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THE AWARD PAPERS

The Otto Aufranc Award

Wear and Lubrication of Metal-on-Metal Hip Implants

Frank W. Chan, PhD,‡; J. Dennis Bobyn, PhD*,**,‡; John B. Medley, PhD†; Jan J. Krygier, CET‡; and Michael Tanzer, MD**,‡*

The implication of polyethylene wear particles as the dominant cause of periprosthetic osteolysis has created a resurgence of interest in metal-on-metal implants for total hip arthroplasty because of their potential for improved wear performance. Twenty-two cobalt chromium molybdenum metal-on-metal implants were custom-manufactured and tested in a hip simulator. Accelerated wear occurred within the first million cycles followed by a marked decrease in wear rate to low steady-state values. The volumetric wear at 3 million cycles was very small, ranging from 0.15 to 2.56 mm^3 for all implants tested. Larger head-cup clearance and increased surface roughness were associated with increased wear. Independent effects on wear of material processing (wrought, cast) and carbon content were not identified. Implant wear decreased with increasing lambda ratio, a parameter used to relate lubricant film thickness to surface roughness, suggesting some degree of fluid film lubrication during testing. This study provided important insight into the design and engineering parameters that affect the wear behavior of metal-on-metal hip implants and indicated that high quality manufacturing can reproducibly lead to very low wear.

From the *Department of Biomedical Engineering, McGill University; the **Department of Surgery, McGill University; the †Department of Mechanical Engineering, University of Waterloo, Waterloo, Ontario, Canada; and the ‡Jo Miller Orthopaedic Research Laboratory, Montreal General Hospital, Montreal, Quebec, Canada.

Funding for this study was provided by the Medical Research Council (MRC) of Canada and Fonds pour la Formation de Chercheurs et l'Aide à la Recherche (FCAR) of Quebec.

Reprint requests to Frank W. Chan, PhD, DePuy Orthopaedics Inc, a Johnson & Johnson Company, PO Box 988, 700 Orthopaedic Drive, Warsaw, Indiana 46581-0988.

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

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

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

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

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

MATERIALS AND METHODS

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

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

TABLE 1. Cobalt Chromium Molybdenum Hip Implants Tested

Material	Carbon Content (%)	Process	Grain Size (μm)	Number of Implants
F1537-94	Low (< 0.05)	Wrought	< 10	8
F1537-94	High (> 0.20)	Wrought	< 10	6
F75-92	High (> 0.20)	Cast	30 to 1000	8

TABLE 2. Specifications of CoCrMo Hip Implants

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

CLA = centerline average; SD = standard deviation.

*Test numbers correspond to those from Chan.[5]

Number of Implants	Average CLA Surface Roughness (Head) (nm)
8	5.3
	6.0
	8.0
	7.8
	9.4
	9.2
	13.5
	5.7
	8.1 ± 2.7
6	19.8
	10.0
	6.0
	4.6
	2.1
	3.0
	7.6 ± 6.6
8	7.2
	5.8
	7.3
	6.4
	12.7
	6.8
	5.0
	7.6
	7.4 ± 2.3

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

Wear testing was performed using a model EW08 MMED hip simulator (Matco, La Canada, CA) (Fig 1) that has been used extensively for the testing of metal-on-polyethylene implants and verified to produce wear particles and wear rates that compare favorably with those in vivo.[15–17] Furthermore, the kinematics of the simulator have been examined by Medley et al[20] who reported that although the simulator was a simple approximation of in vivo hip motion, it did include appropriate load angle and magnitude and a multidirectional sliding action that has been shown to be important for realistic hip simulation with polyethylene cups.[3] The hip simulator involved mounting the components in a nonanatomic configuration (cups below the heads) in chambers oriented at 23° to the horizontal plane and subjecting the implants to a biaxial rocking motion at a frequency of 1.13 Hz. A load simulating normal gait[23] with a peak of approximately 2100 N (three times body weight) was applied vertically to the femoral head. These conditions also were similar to what commonly has been applied in metal-on-polyethylene testing.[15–17]

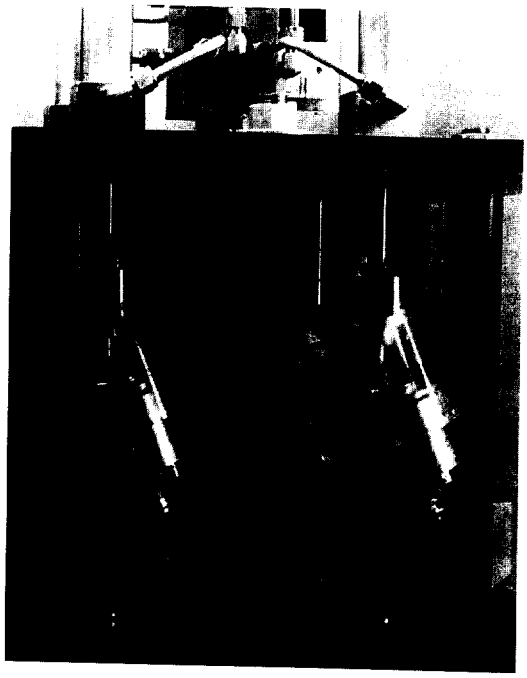

Fig 1. Photograph of two wear test stations of EW08 MMED hip simulator.

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

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

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

The progressive gravimetric data were converted to volumetric wear using a value of 8.3 mg/mm^3 for the density of CoCrMo. Statistical analyses were performed using SPSS version 7.5 (SPSS Inc, Chicago, IL). Each group of data used in comparisons was analyzed for normality using the Kolmogorov-Smirnov test and equality of variances using Levene's test. Based on the normality and equality of variances of the data, the appropriate test of comparison was used. For parametric data with either equal or unequal variances, the independent samples two-tailed Student's t test was used, whereas the two-tailed Mann-Whitney test for independent samples was used for nonparametric data. The significance of differences in average wear for implants tested in bovine serum with and without ethylenediaminetetraacetic acid and for implants of different material processing (wrought and cast) and C content (low and high) was determined. Univariate one-way analysis of variance (ANOVA) or the Kruskal-Wallis test (non-parametric) was used to determine the significance of differences in volumetric wear and wear rates between the three groups of CoCrMo (low C wrought, high C wrought, cast). The Bonferroni method (equal variances) or the Tamhane test (unequal variances) was the post hoc procedure used to identify specifically the differences that were significant. To determine steady-state wear rates, linear regression analysis using a least squares fit was performed on the data. For all statistical comparisons in this study, $\alpha = 0.05$ was used as the level of significance.

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

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

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

The wear data also were linked to theoretical predictions of the type of lubrication that occurred with each implant. Following an approach initiated by Medley et al,[20] a numerical analysis was developed by Chan[5] and Chan et al[8] that estimated the time-varying thickness (during the gait cycle) of the lubricant film at the center of the head-cup contact area for the simulator-tested hip implants. The ratio between this theoretical lubricant film thickness, typically in the 20 to 70 nm range, and the measured surface roughness (head and cup combined) is known as the parameter lambda that quantified the extent of direct surface interaction in the contact area.[5,8] In general terms, lambda values less than approximately one suggest direct surface contact at the asperity tips, whereas lambda values greater than approximately three suggest surface separation by a continuous lubricant film.[11,35] Lambda values between one and three indicate a combination of direct contact and continuous film lubrication (Fig 2). Chan[5] and Chan et al[8] showed that a remarkably good estimation of the minimum film thickness during the gait cycle was provided by a steady-state formula (for film thickness) using the average applied load. This approach was used to obtain a unique minimum lambda value for each implant tested. The minimum lambda value was plotted against total volumetric wear to examine the influence of lubrication on simulator wear of the metal-on-metal hip implants. Regression analysis was used to quantify the correlation between wear and lambda, and a univariate one-way ANOVA or the Kruskal-Wallis test was used to determine the significance of differences between wear for lambda values less than one, between one and three, and greater than three.

RESULTS

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

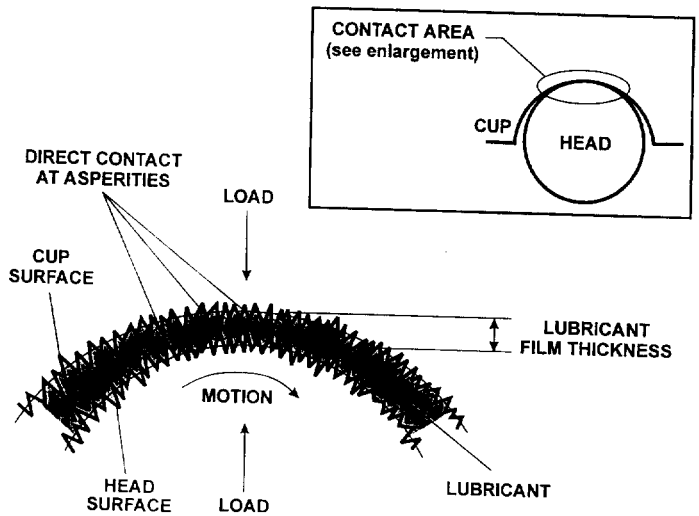

Fig 2. Schematic indicating the head-cup contact area with combination of direct surface interaction and separation by a continuous lubricant film (lambda values between one and three).

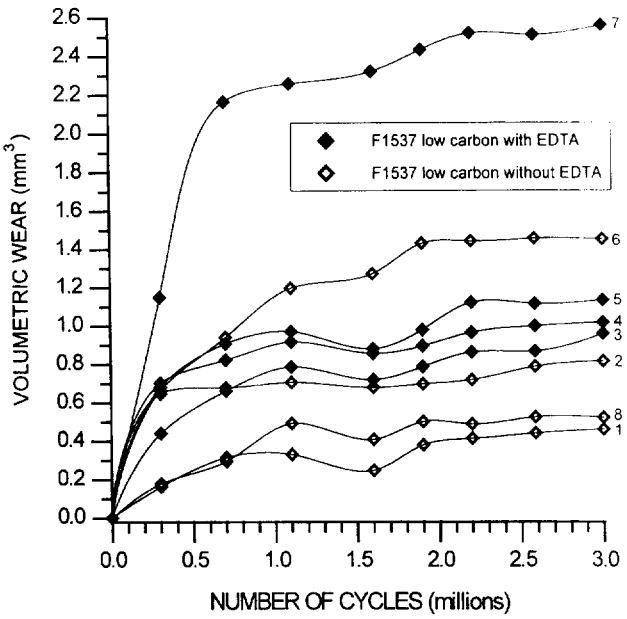

Fig 3. Total volumetric wear of low C wrought F1537-94 implants plotted against the number of cycles. Numbers in the graphs represent implant labels in Tables 2 and 3. EDTA = ethylenediaminetetraacetic acid.

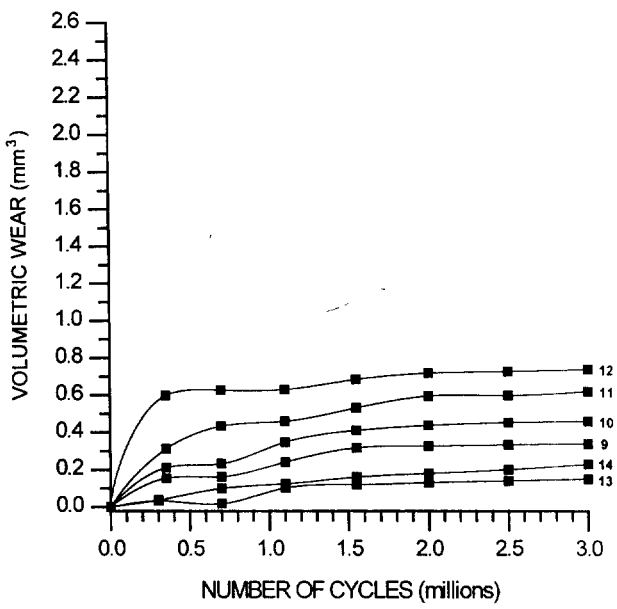

Fig 4. Total volumetric wear of high C wrought F1537-94 implants plotted against the number of cycles. Numbers in the graphs represent implant labels in Tables 2 and 3.

plants experienced a characteristic period of accelerated run-in wear within the first 1 million cycles. This was followed by a substantial decrease in wear rate tending toward low, steady-state values. In the following analyses, initial and total wear were defined as the wear at 1 million and 3 million cycles, respectively, and steady-state wear rate was defined by the best-fit regression line from 1 to 3 million cycles.

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

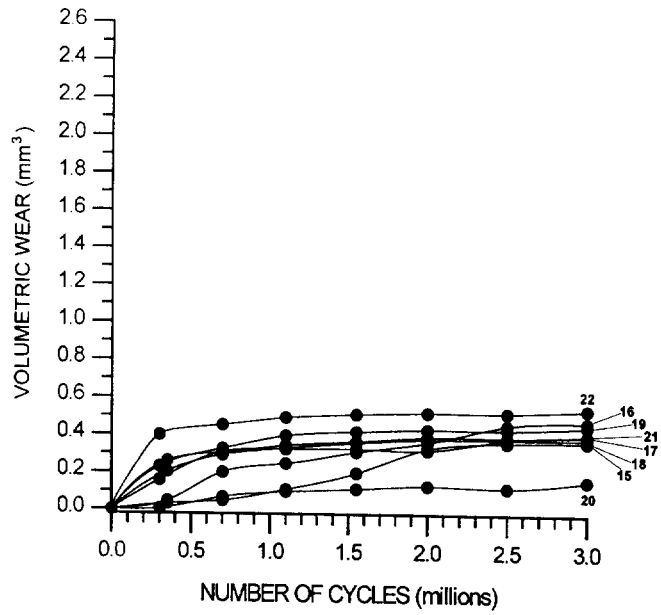

Fig 5. Total volumetric wear of high C cast F75-92 implants plotted against the number of cycles. Numbers in the graphs represent implant labels in Tables 2 and 3.

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

An inspection of the surface of the components by a high-powered stereomicroscope indicated that those tested within serum containing ethylenediaminetetraacetic acid either possessed minute traces of deposits or generally were free of deposits and maintained the same mirror surface finish as the original untested surfaces. Those tested in lubricant without ethylenediaminetetraacetic acid had varying degrees of deposit development from moderate to severe in the form of circular regions about the centers of the heads and cups. To minimize the possible influence on implant wear of these strongly adherent deposits and to facilitate accurate wear measurements, ethylenediaminetetraacetic acid was used for all other tests.

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

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

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TABLE 3. Wear of CoCrMo Hip Implants

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

SD = standard deviation.

*Implants tested without ethylenediaminetetraacetic acid additive.

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

The average total volumetric wear after 3 million cycles of 1.11 ± 0.67 mm^3 for the low C wrought implants was significantly greater ($p = 0.022$, ANOVA and Bonferroni) than the 0.42 ± 0.23 mm^3 for the high C wrought pairings and 0.40 ± 0.11 mm^3 for the high C cast components ($p = 0.010$, ANOVA and Bonferroni) (Table 3). There was also no significant difference between the wear of the high C wrought and cast components ($p = 0.999$, ANOVA and Bonferroni). Although these statistical comparisons suggest higher wear for the low C implants, they do not account for variations in parameters, such as clearance and roughness, within each group.

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

To show the independent effect of C content on wear, the average total wear of groups of low and high C implants with clearance and roughness values within 75 to 105 μm and 5 to 10 nm,

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

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

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

The ANCOVA was performed with results for all implants, excluding implant Number 7 to avoid possible confounding effects of an outlier. The analysis indicated a weak material effect on wear ($p = 0.818$), whereas evidence existed for clearance and roughness effects ($p = 0.245$ and $p = 0.260$, respectively). These results supported the previous analyses in which the independent effects of various parameters were analyzed by judicious grouping of the data. However, the ANCOVA also identified an effect of C content ($p = 0.081$), a result that differed from the analysis of the wrought data with clearance and roughness accounted for by selective implant groups.

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

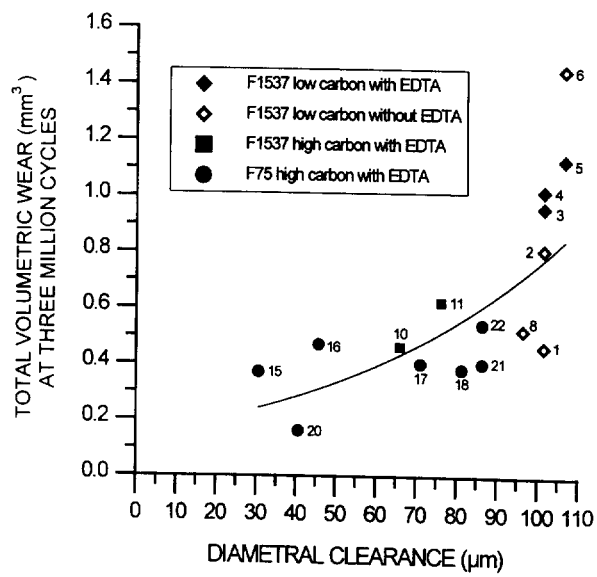

Fig 6. Total volumetric wear after 3 million cycles of wrought F1537-94 and cast F75-92 implants with average centerline-average surface roughness values within 5 to 10 nm plotted against head-cup diametral clearance. A quadratic curve ($R^2 = 0.65$, $p = 0.001$) was fitted to the data and indicated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

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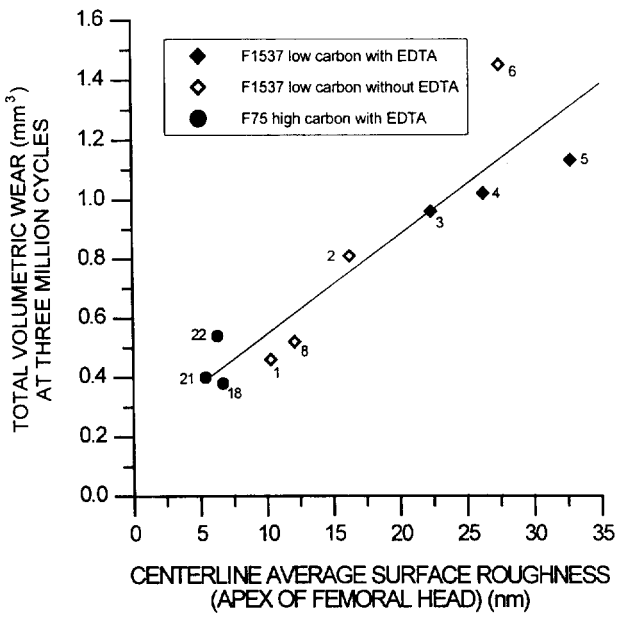

Fig 7. Total volumetric wear after 3 million cycles of wrought F1537-94 and cast F75-92 implants with diametral clearances between 81 and 107 μm plotted against the centerline-average surface roughness measured at the apex of the femoral head. A best-fit linear regression line (R^2 = 0.85, p = 0.001)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

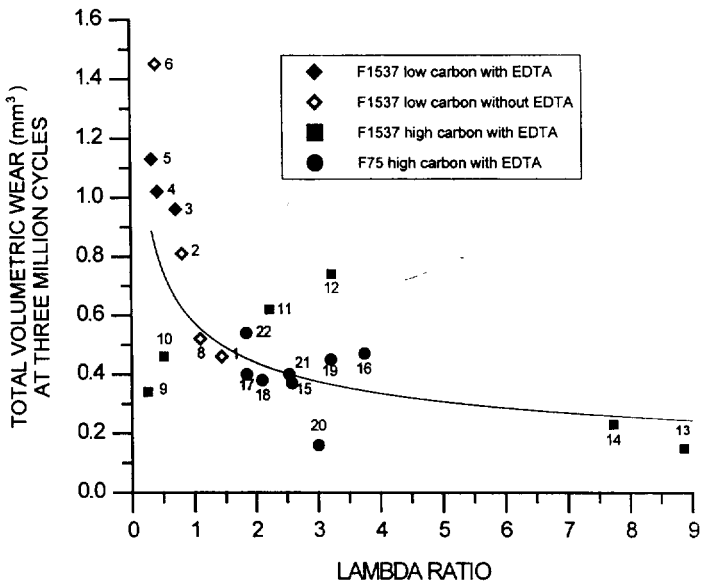

Fig 8. Total volumetric wear after 3 million cycles of wrought F1537-94 and cast F75-92 implants plotted against lambda ratio. An exponential curve (R^2 = 0.48, p = 0.001) was fitted to the data and indicated that wear decreased as the lambda ratio of the implant increased. Numbers in the graphs represent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

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

DISCUSSION

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

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

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

Despite surface analyses indicating some qualitative differences in implants tested with and without ethylenediaminetetraacetic acid, the comparison of average wear for implants tested with and without ethylenediaminetetraacetic acid indicated a difference that was not significant. Although surface deposits have been found to varying degrees on retrieved metal-on-metal implants,[12,18] ethylenediaminetetraacetic acid was used in all subsequent tests to suppress deposit formation, because their presence on in vitro components was a potential confounding factor in the wear analysis. It also has been suggested that these deposits may act as effective boundary lubricants that would shear in preference to the articulating metal surfaces themselves, thereby protecting the head and cup from wear to some extent.[19] If this were the case, by using ethylenediaminetetraacetic acid the wear results generated in this study would represent a worst case test scenario or a conservative estimate of wear performance.

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

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

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

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

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

The results of the ANCOVA and the roughness analysis where clearance was held relatively constant identified an effect of surface roughness on wear. The centerline-average surface roughness values were those measured before tests were begun. Wear depends on the initial surface roughness, because early surface damage may continue to influence the course of subsequent wear. However, surface roughness changes as tests proceed and the instantaneous rate of wear also depends, to some extent, on the instantaneous surface roughness. In particular, the fact that wear rates reached a steady state may be because of the achievement of some constant value of surface roughness after the head-cup articulation has run in or perhaps to an increase in asperity tip radii (as asperity tips become dull). Determination of surface roughness and the evaluation of changes in asperity tip radii after testing would be necessary to determine the correlation between steady-state wear rate and final surface roughness.

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

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

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

The current study, in which parametric changes were limited and more strictly controlled, provided for the determination of the individual effect on wear of different design variables. In general, head-cup diametral clearance and surface roughness of the components were identified as design parameters affecting the wear of metal-on-metal bearings with increased clearance and increased surface roughness resulting in the increased wear. Because all implants evaluated in the current study were finished to uniformly low surface roughness values, the effect on wear of material processing and C content, in which there were large differences in grain and carbide size, was not apparent in the results. The low wear of the implants may have resulted from fluid film lubrication at the head-cup interface. Overall, the high quality manufacturing of the experimental metal-on-metal implants evaluated in the present study resulted consistently in substantial improvement in wear performance over conventional metal-on-polyethylene articulations. Given that wear particle-induced osteolysis may be dose-dependent, the data suggest that metal-on-metal articulations may mitigate the problems associated with wear-related osteolysis. The results from the authors' laboratory and theoretical studies on wear and lubrication coupled with positive information from past and recent clinical studies justify the continued development of this alternative bearing technology.

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