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Modern Metal on Metal Articulation for Total Hip Replacements

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

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Metal on metal articulation for total hip replacements began as early as 1938 when Wiles[25] implanted stainless steel prostheses in 6 patients in England. These failed early because of poor fixation and excess wear. During the late 1950s and early 1960s McKee and coworkers[14,15] and Watson-Farrar (as reported by McKee et al) popularized metal on metal articulation with the use of CoCrMo articulating surfaces. Dandy and Theodorou[5] reported a 4.4% revision rate for acetabular loosening between 2 and 10 years with the McKee-Farrar prosthesis. With the metal on metal Stanmore prosthesis Dobbs[6] reported a 4.3% annual revision rate for component loosening, 58% of which had acetabular loosening. These prostheses featured femoral head sizes of 38 to 42 mm and the McKee-Farrar femoral stem had a short, wide neck that promoted impingement of the femoral neck against the socket. These design features have been implicated in the failure of these implants.

Concomitantly in the early 1960s, Charnley[2] introduced low friction arthroplasty using a 22-mm stainless steel head and an all plastic acetabular component. Charnley's technique provided reproducible durable skeletal fixation using methylmethacrylate bone cement, which resulted in cessation of use of the metal on metal prostheses. By the mid 1970s and early 1980s osteolysis associated with cement fragmentation and polyethylene wear debris were being implicated in aseptic loosening in long term patients.[10] In response to this, cementless fixation was introduced. This concept, however, did not resolve the problems of aseptic loosening and osteolysis[11,18,26] attributed to polyethylene debris.

In the late 1980s, Weber in St. Gallen, Switzerland, stimulated the development of a modern metal on metal articulation surface with a CoCr alloy which has been named Metasul®. This articulation surface was designed based on retrieval data of successful metal on metal implants.[19]

This study answers 2 questions regarding modern metal on metal articulation using the Metasul design: will early loosening of acetabular components occur as it had with the early metal on metal designs? Will wear and osteolysis be decreased?

MATERIALS AND METHODS

From 1991 through 1994, 395 primary total hip replacements were performed by the senior author. Seventy of these received metal on metal articulation. These were not performed in a consecutive fashion nor were they randomized. There was a limitation in the number of components that were available and the components were available at random times so that the series could be done only as components became available. Some patients did not desire to participate in the metal on metal series, which further prevented the ability to operate in a consecutive series. The patients who participated agreed to the use of a custom implant and signed the appropriate consent forms.

The acetabular component was the Weber cup (Sulzer Medica, Winterthur, Switzerland) which has a stainless steel outer mesh, a polyethylene substrate, and a 3–mm thick CoCr metal articulation surface molded into the polyethylene (Fig 1). The femoral head was CoCr alloy with a 28–mm diameter and the cup size was 60 mm or above when 32–mm heads were used. The CoCr alloy used was Protasul-21 WF (Sulzer Medica). The clearance between femoral head and socket was proprietary. The frictional moment of this metal on metal design with a 28–mm head was comparable with a metal on polyethylene prosthesis with a 32–mm head.[22]

Twenty-nine femoral stems were uncemented and the components used were 9 APR-II and 20 APR-IIT (Anatomic Porous Replacement, Intermedics Orthopedics, Austin, TX) (Fig 2). The APR-II femoral components for fixation without bone cement were Ti alloy with Ti porous coating on the proximal 25% only.[3] The APR-IIT had circumferential porous coating and a hollowed stem for stiffness relief when the stem size was 15 mm or greater. Twenty-five stems were cemented using the APR stem, which was CoCr alloy and had an anatomic shape, for cement fixation (Fig 2). The indication for cemented fixation was age greater than 75 years, osteoporotic bone, or a cemented stem of a hip replacement present in the opposite hip. All patients who had bilateral hip replacements had the same fixation of the stem in both hips.

Anesthesia was epidural augmented with general anesthetic agents so that the mean arterial blood pressure was maintained between 60 to 80 mm Hg. A posterolateral incision was used.[3] Bone preparation of the acetabulum was accomplished by reaming through the acetabular ridge to the cortical bone of the cotyloid notch. Eight, 1/4 inch drill holes were placed in the acetabulum with 2 rows of 3 holes in the ilium and 1 hole in

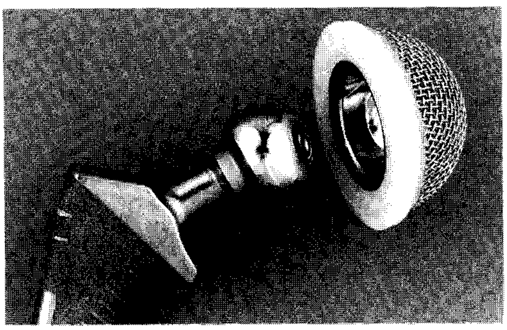

Fig 1. Weber acetabular component with CoCr Metasul articular surface. APR-II stem with Metasul CoCr head.

A

B

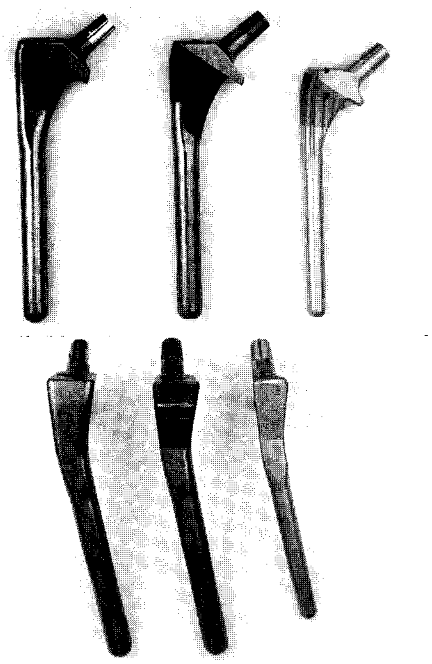

Fig 2A–B. (A) Anatomic Porous Replacement stems used in this study. On the left is the APR-II cementless stem, in the center is the APR-IIT cementless stem, on the right is the APR cemented stem which is CoCr. The cementless stems are Ti alloy with Ti porous coating. (B) Anatomic Porous Replacement stem as seen on the lateral radiograph. All 3 have anatomic shape. The cemented stem has a cobra flange.

the pubis and in the ischium. Simplex cement (Howmedica, Rutherford, NJ) was inserted at 3 to 4 minutes after mixing and pressurized for 2 to 3 minutes using an Asepto bulb (Davol, Incorporated, Cranston, RI). At 6 minutes after mixing, the acetabular component was implanted and malleted into the doughy cement. The desired acetabular position was a 35° to 40° theta angle and 15° anteversion. The noncemented femoral component was malleted into the femur after reaming and broaching. No reaming was done for the cemented femoral component and a distal plastic plug was used. Two packages of bone cement were mixed and cement was inserted with a cement gun at 4 minutes after mixing and manually pressurized using additional cement for 2 minutes. The femoral component was implanted and malleted the final 2 cm into a position of 10° anteversion.

Patients were observed prospectively with clinical evaluations performed preoperatively and postoperatively at 6 months, 1 year, and annually thereafter. Clinical evaluation was measured by Harris hip scores[9] preoperatively and at each clinic visit by the senior author or the arthritis fellow (Table 1). The patient self assessment form HKB21 (Orthographics Inc, Salt Lake City, UT) for pain and functional outcome was completed by each patient at their last followup visit. This form was the Short Form-36 questionnaire for evaluation of orthopaedic results that has been validated.[13]

Serial radiographs were anteroposterior (AP) pelvis views that included the proximal femur (and the entire stem) and 17–inch lateral views of the involved hip that were obtained preoperatively, immediately postoperative, 6 months postoperatively, and annually thereafter. The radiographs were analyzed by 2 observers (KH and ZW) who were not involved with patient care. Interobserver variability was less than 1% and was accurate because of the paucity of radiographic findings. Femoral stem radiolucent lines and osteolysis were measured by Gruen zones on AP and lateral radiographs.[8] Acetabular radiolucent lines or migration and osteolysis were measured using DeLee and Charnley zones on AP and lateral radiographs.[4] Measurements for wear were not successful because no distinction could be made between the edge of the femoral head and the metal articulation surface of the acetabular component (Fig 3).

Synovial fluid was aspirated through an anterior hip joint puncture from 24 patients preoperatively or at 6 to 24 months postoperatively or both. Twenty-one patients had 1 aspiration; 2 patients had 2 aspirations each; and 1 patient had 3 aspirations, each at different time intervals. There

TABLE 1. Harris Hip Scores

Maximum	Preoperative Average	Last Followup Average
Total = 100	49	93
Pain = 44	15.5	40.7
Function = 47	23.7	41.2
Limp* = 11	4.7	10.3

*Limp score is a subset of the function score.

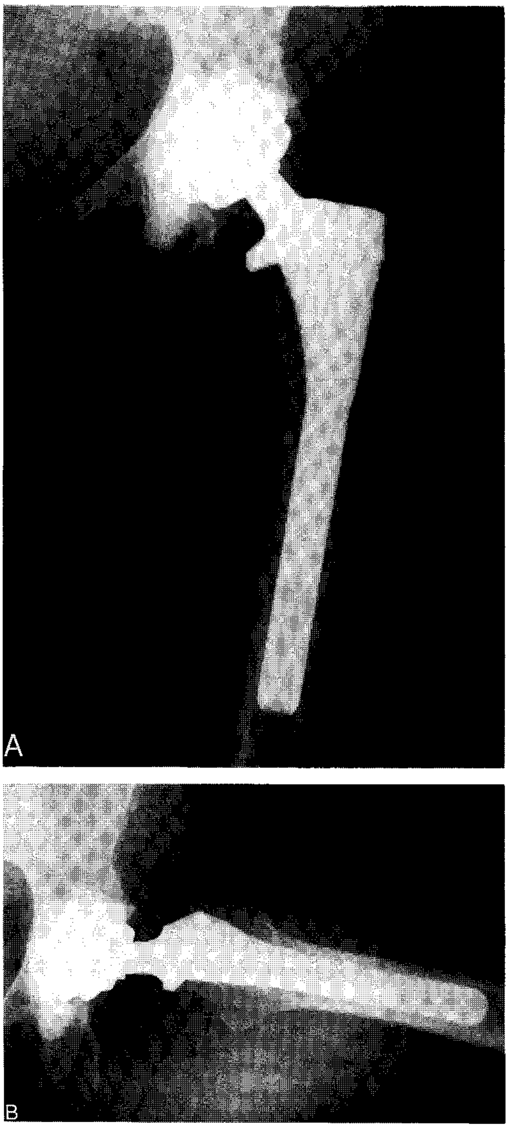

Fig 3A–B. (A) Anteroposterior radiograph of cemented Weber acetabular component and uncemented APR II T femoral component at 2 years postoperative. There is no clear distinction between edge of femoral head and metal articulation surface of acetabular component. (B) Lateral radiograph of metal on metal total hip replacement with cemented acetabular component and uncemented femoral component at 2 years postoperative. There is no clear distinction between the edge of femoral head and metal articulation of the acetabular component.

were 28 samples from 24 hips in 24 patients with metal on metal articulation. Synovial fluid was also obtained from 18 hips in 17 patients with metal on polyethylene hips from 1 to 13 years postoperatively and served as a comparison. Ten of these samples were obtained from hips before surgery and served as controls (Tables 2, 3). In the metal on metal hips there were 22 postoperative samples with 12 having cementless stems and 10 having cemented stems. The fluid was collected into a green top Vacutainer tube (Becton Dickinson, Rutherford, NJ) that had lithium heparin anticoagulant. The fluid was independently analyzed for metal and polyethylene particulate counts by an experienced investigator at the Department of Orthopedics, University of Utah School of Medicine. The particulate counts were graded by a method previously published.[6]

Implant retrieval was available for 2 hips at the time of writing. One implant was obtained at revision surgery for a dislocation and the other was obtained at an autopsy of a patient who died 6 months postoperatively. An unused prosthesis was also analyzed as a control. The metal articulation surface of each of these prostheses was bisected twice to produce quadrants that allowed the specimens to fit in the scanning electron microscope chamber. The images used for 3–dimensional measurements on metal surfaces were generated by a scanning electron microscope (JSM-6100, JEOL Inc, Peabody, MA) equipped with an imaging system (Link-eXL, Oxford Instrument Ltd, England). To do this, each image was captured at a 9 or 10 KV accelerating voltage, aperture diameter of 50 mm, and a filament current of 330 mA. Once an area of interest was found, the stage was tilted to 0° and a photo was taken using the Type 55 Polaroid (Kodak, Rochester, NY) film. The image was then collected by the eXL imaging system. The stage was tilted to +2°. Again, this image was collected by the imaging system to be compared and aligned with the 0° image. The photomicrograph was taken for the +2° image. These 2 photomicrographs were termed steropairs. After obtaining steropairs from the scanning electron microscope and the eXL imaging system, the negatives were viewed using a stereoscope and irregularities were measured using a parallax bar. To make 3–dimensional measurements and to determine heights and depths of any surface irregularities,[1,17] the following equation was used:

TABLE 2. Synovial Fluid Samples From Patients with Metal on Metal Total Hip Replacements

Particulate Grade	Preoperative (N = 6)	6 months (N = 9)	1 year (N = 10)	2 years (N = 3)
Metal 0	6	4	6	2
1+	0	1	2	0
2+	0	0	0	0
3+	0	4	2	1
Polyethylene 0	3	6	7	3
1+	2	1	1	0
2+	1	1	2	0
3+	0	1	0	0

N = number of hips at that time; 0 = no particles observed; 1+ metal = 1 to 25 particles; 2+ metal = 25 to 100 particles; 3+ metal = 101 or more particles; 1+ polyethylene = 1 to 15 extracellular particles and/or 1 to 5 histiocytes containing 1 or more fibers per cell; 2+ polyethylene = 16 to 25 extracellular particles and/or 16 to 25 histiocytes containing 1 or more fibers per cell; 3+ polyethylene = 26 or more extracellular particles and/or 26 or more histiocytes containing 1 or more fibers per cell.

$$h = \frac{P_1 - P_2}{2M\sin\frac{\phi}{2}}$$

where h was the height or depth of the irregularity in millimeters, P_1 and P_2 were the measurements taken from the parallax bar, M was the magnification of the scanning electron microscopy images and theta was the angle spread in radians between the pair of images. Six regions from the surface of each metal cup or head were randomly selected to be viewed. At each region the number of scratches per mm^2 were counted at a magnification greater than ×500. After steropairs were prepared, 3 points on each picture were randomly collected and measured. Ten regions from the surface of each metal cup or head were randomly selected to be viewed. At each region the number of scratches per mm^2 were counted at a magnification of ×1000.

Descriptive statistical analysis was performed to calculate mean and standard deviations for the parameters, including depth of irregularities and number of scratches in each area. No other statis-

TABLE 3. Synovial Fluid From Patients With Metal on Polyethylene Total Hip Replacements

		Postoperative				
Particulate Grade	**Preoperative (N = 4)**	*1 year (N = 3)*	*2 years (N = 4)*	*4 years (N = 5)*	*8 years (N = 1)*	*13 years (N = 1)*
Metal 0	4	3	2	0	1	1
1+	0	0	1	1	0	0
2+	0	0	1	1	0	0
3+	0	0	0	3	0	0
Polyethylene 0	3	0	1	1	1	0
1+	0	0	2	0	0	0
2+	0	0	0	3	0	0
3+	1	3	1	1	0	1

N = number of hips. See Table 2 for grading scale.

tical analyses were performed on the data in this study because no data required comparative analysis.

RESULTS

Sixteen patients were less than 2 years postoperative and were eliminated from this study leaving 54 patients and hips for analysis. The average age was 72 years (range, 35–85 years). There were 31 men and 23 women. In the patients, 46 hips had primary osteoarthritis, 5 had posttraumatic arthritis, 1 had rheumatoid arthritis, 1 had osteonecrosis, and 1 had developmental dysplasia. Twenty of these patients had bilateral total hip replacements with 1 hip being metal on metal and the other metal on polyethylene.

All acetabular components were cemented in place and ranged in size from 49 to 64 mm in outer diameter. Forty-nine of the femoral heads were 28 mm and 5 were 32 mm in diameter. Twenty-five femoral stems were cemented and 29 were uncemented. The average age of patients with cemented stems was 74 years (range, 45–85 years) and of patients with uncemented stems it was 66 years (range, 35–81 years).

Harris hip scores[9] on average improved from 49 preoperatively to 93 at last followup (Table 1). The results of 48 patients (89%) were rated as excellent, 5 (9%) were rated good, and 1 (2%) was rated fair. The average pain score improved from 15.5 preoperatively to 40.7. The average function score improved from 23.7 preoperatively to 41.2, and the average limp score improved from 4.7 preoperatively to 10.3 at last followup.

The patient self assessment form showed 51 patients (94%) thought that they had a good or excellent outcome from their surgery, whereas 3 patients (6%) thought that they had a fair or poor outcome. Each of these 3 patients had a postoperative complication: infection in 1, peroneal nerve palsy in 1, and dislocation in 1. There are 41 patients (76%) who used no walking aids, 8 (15%) who used a cane for walks of 30 minutes or more, 4 (7%) who used a cane full time, and 1 (2%) who used a walker. The patient who used the walker was the patient with a peroneal nerve palsy.

The 20 patients who had bilateral total hip replacements could not determine any difference between their hips regarding pain, function, motion, or stability. They did not favor 1 hip over the other.

Complications from surgery were an infection in 1 patient (2%), a peroneal nerve palsy in 1 patient (2%), a dislocation in 2 patients (4%). One of the patients with a dislocation required revision surgery 3 years after initial implantation for recurrent dislocation. At surgery impingement was evident by a notch in the femoral neck (Fig 4). At the time of revision the tissues were stained black with metal debris. The components were well fixed and there was no evidence of component failure or osteolysis.

No hip had radiographic loosening, progressive radiolucencies, cortical thinning, component subsidence or migration, or osteolysis. Six patients (11%) had radiolucent lines adjacent to the acetabular component, all of which were present immediately postoperatively and were not progressive (Fig 5). Two patients (4%) had radiolucent lines ad-

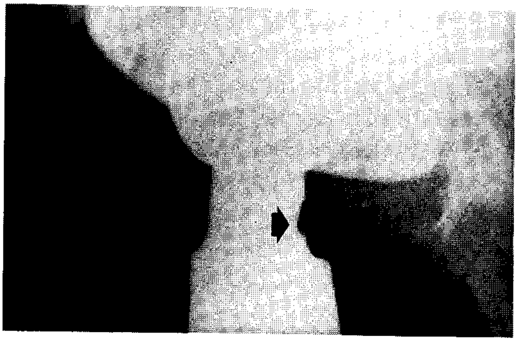

Fig 4. Lateral radiograph of the hip immediately postoperative from revision of acetabular component and head for impingement and recurrent dislocation. Retained femoral component is 3 years postoperative. Arrow identifies notched area of femoral neck secondary to impingement.

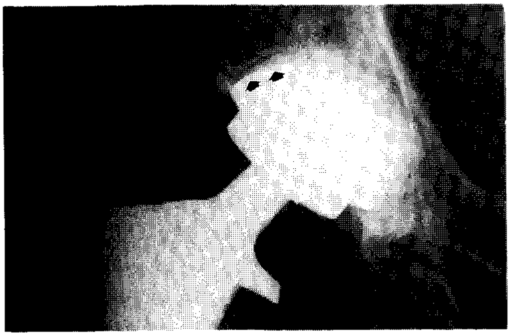

Fig 5. Anteroposterior radiograph of metal on metal total hip replacement at 3 years postoperative with with nonprogressive radiolucent line (arrows) observed immediately postoperatively in Zone 1 of the acetabular component.

jacent to noncemented femoral components, neither of which were progressive. Both patients were asymptomatic. There were no radiolucent lines adjacent to any of the cemented femoral stems. The interobserver error was 0.01% as defined as a difference in measurement of 3 mm or 3° or presence or absence of radiolucent lines.

Preoperative synovial fluid samples had no metallic debris. Polyethylene particulate debris was reported in 4 of 10 preoperative hips (Tables 2, 3). Postoperatively, from 6 to 24 months, the presence of metallic particulate debris, which ranged in size from 0.5 to 10 μm, was reported in 10 of 22 samples (45%). Polyethylene particulate debris, which ranged in size from 50 to 500 μm, was reported in 6 of 22 samples (27%) from metal on metal hips (Table 2). Seven of the hips with metal particles had cementless stems and 3 had cemented stems. Postoperatively, metallic debris was reported in 7 of 14 polyethylene hip samples (50%) and in 11 of 14 polyethylene hip samples (79%) (Table 3). In metal on polyethylene hip particles were rare until the second postoperative year (Table 3).

The depth of the irregularity and the number of scratches on the acetabular metal articulation surface and heads are listed in Tables 4 and 5. There were no statistical differences for the implanted and unused metal surfaces when comparing the depth and frequency of surface irregularities.

DISCUSSION

Contemporary total hip replacement is plagued with periprosthetic osteolysis with polyethylene particulate debris implicated as the main causative factor.[7,11,18,26] This study was performed to investigate the hypothesis that modern metal on metal articulation would reduce early acetabular loosening as compared with earlier metal on metal designs and would reduce wear and osteolysis as compared with metal on polyethylene replacements. The limitation of this study is the selection process of patients. A consecutive series or randomized study would be preferred. This study was compromised by the availability of acetabular components. In this study, the use of bilateral hip replacements performed with a metal on metal articulation and a metal on polyethylene articulation in opposite hips does provide the best method for patient comparison of performance of the different surfaces. Presently, the study of metal on metal articulation has been continued with a Food and Drug Administration investigational device exemption study using a modular insert with this same metal on metal articulation design in a randomized study against a ceramic head polyethylene acetabular articulation couple.

The McKee-Farrar metal on metal hip replacement had 6% revised and 2% with acetabular loosening at 2 to 3 years postoperatively.[15] The Stanmore metal on metal hip replacement had 7% revised and 6% with acetabular loosening at 2 to 3 years postoperatively.[6] In this study using the Metasul® articulation, at 2.7 years postoperatively there were no revisions for loosening and no socket or stem had radiographic evidence of loosening or progressive radiolucent lines or osteolysis. This modern metal on metal articulation design has eliminated the previously reported incidence of early acetabular loos-

TABLE 4. Depth of the Surface Irregularities From the Scanning Electron Microscope Imaging and Stereo Measurements

Hip Component	Measurement Depth (μm)	Z177/94 Control	S32/93R Retrieved	S130/93R Retrieved
Head	Mean ± SD	4.49 ± 2.50	8.11 ± 4.60	10.57 ± 12.76
Head	Range	1.51–11.10	1.23–17.90	0.57–58.45
Cup	Mean ± SD	12.37 ± 10.32	9.88 ± 4.62	5.83 ± 4.41
Cup	Range	1.15–45.32	1.72–17.19	0.41–16.04

SD = standard deviation.

Z177/94, S32/94R, and S130/93R are laboratory identification numbers of specimens.

ening with metal on metal articulation designs implanted during the 1960s.

The clinical results with these modern metal on metal articulation surfaces did not differ from other hip replacements.[16] The Harris hip scores and the patient self assessment results were the same as those reported with metal on polyethylene hips.[16] In this metal on metal series, only 1 patient reported a click with his hip during the first year that then disappeared and no patient reported a feeling of jamming (component impaction) as had been reported with the McKee-Farrar design.[15]

Several factors may contribute to the improved early results with modern metal on metal articulation. The fixation of the components may be better using modern bone cement techniques, which included pressurization of the cement combined with hypotensive anesthesia. Impingement of the femoral neck on the acetabular rim was alleged to have been a cause of loosening with early designs.[14,15] This cause for loosening should be significantly reduced with current femoral prostheses, which have better head to neck ratios than the earlier designs. Impingement can still occur as shown by the patient who underwent revision surgery for a dislocation. When impingement occurs a large volume of metallic debris will be created. Perhaps the best metal on metal articulation will occur with a 32–mm femoral head, which improves the head to neck ratio and also reduces the risk of dislocation. The clearance between the femoral head and acetabular surface in modern metal on metal articulation allows better removal of debris and may decrease the frictional torque as occurred with those metal on metal surfaces that had equatorial contact.[23] Finally, the use of a wire mesh (rather than a solid metal

TABLE 5. Number of Scratches for Each Surface Area (Number/mm²) Measured From the Scanning Electron Microscope Images

Hip Component	Measurement (Number/mm²)	Z177/94 Control	S32/93R Retrieved	S130/93R Retrieved
Head	Mean ± SD	1331 ± 413	1098 ± 382	712 ± 433
Head	Range	309–2321	619–1857	155–1702
Cup	Mean ± SD	944 ± 709	1640 ± 490	1269 ± 363
Cup	Range	0–2166	1083–2475	619–1702

SD = standard deviation.

2177/94, S32/93R, and 5130/93R are laboratory identification numbers of specimens.

backing) and the polyethylene substrate may reduce the stiffness of the acetabular component as compared with earlier all metal components and this may be favorable for more durable fixation.

The hypothesis for this study included the investigation of reduced wear and osteolysis as compared with metal on polyethylene hips. The wear with modern metal on metal articulation surfaces is anticipated to be less than what occurs with metal on polyethylene surfaces. Semlitsch et al[19] reported evidence to suggest that the wear rates of metal on polyethylene pairing surfaces may be as high as 40 times that of metal on metal pairing surfaces. Walker et al[24] reported a more conservative wear rate differential with metal on polyethylene being 10 times that of metal on metal. McCalden et al[12] reported no correlation between time of implantation and the amount of wear in McKee-Farrar prostheses with 9 to 25 years of implantation. In this study wear could not be measured on radiographs because no distinction could be made between the femoral head and the metal articulation surface (Fig 3).

The only data on wear available in this study were obtained from synovial fluid analysis and implant retrievals. Synovial fluid analysis did show polyethylene in the hips with metal on metal articulation. Perhaps some polyethylene particles were produced from behind the molded metal articulation surface or by impingement of the neck on the polyethylene rim. However, the polyethylene measurements may not be accurate. False positive readings may occur as evidenced by polyethylene particulate reported from fluid obtained from hips before surgery. This may be caused by birefringent contaminates that were falsely identified as polyethylene. Shea et al[20,21] reported as much as 47% false positive findings with polarized light microscopic techniques. In this study the incidence of polyethylene was no different in postoperative specimens than in hips without prior surgery, suggesting that polyethylene readings were not accurate.

Metal particles were more common in metal on metal hips. Metal particles were seen in 10 of 22 hips with metal on metal articulation at 6 months to 1 year, whereas no metal particles were seen until 2 years in metal on polyethylene hips. Seven of these 10 metal on metal hips had cementless stems whereas only 1 of the 4 metal on polyethylene hips with particles at 2 years postoperation had cementless stems. In these hips with cementless stems it was not determined if the metal particles were CoCr from the articular surface metal on metal or Ti from the stem. Metal particles at 6 months and 1 year may represent run in wear as reported by Semlitsch et al[19] and Walker et al.[24]

The results of implant retrieval analysis showed no apparent differences between the implanted metal components and the control when comparing depth of surface irregularities (Table 4) and number of scratches (Table 5). The standard deviations showed marked overlap between the retrievals and the control. These results suggest that wear on metal on metal surfaces in the 6 month to 1 year postoperative period (the run in period) was minimal as suggested by Semlitsch et al[19] and Walker et al.[24]

Osteolysis was not evident on radiographs in any hip in either the acetabular or femoral bone. Osteolysis can occur in the first 2 years with cementless and cemented hips.[12] However, osteolysis is more commonly seen at an average of 5 years postoperative. With an average 2.7-year followup in these hips, the followup is still too early to know whether the use of metal on metal articulation has reduced the incidence of osteolysis.

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