

METAL-ON-METAL HYBRID SURFACE ARTHROPLASTY: TWO TO SIX-YEAR FOLLOW-UP STUDY

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Background: Following the reintroduction of metal-on-metal articulating surfaces for total hip arthroplasty in Europe in 1988, we developed a surface arthroplasty prosthetic system using a metal-on-metal articulation. The present study describes the clinical and radiographic results of the first 400 hips treated with metal-on-metal hybrid surface arthroplasties at an average follow-up of three and a half years.

Methods: Between November 1996 and November 2000, 400 metal-on-metal hybrid surface arthroplasties were performed in 355 patients. All femoral head components were cemented, but only fifty-nine of the short metaphyseal stems were cemented. The patients had an average age of forty-eight years, 73% were men, and 66% had a diagnosis of osteoarthritis. Clinical and radiographic follow-up were performed at three months postoperatively and yearly thereafter.

Results: The majority of the patients returned to a high level of activity, including sports, and 54% had activity scores of >7 on the University of California at Los Angeles activity assessment system. Kaplan-Meier survivorship curves demonstrated that the rate of survival of the components at four years was 94.4%. For patients with a surface arthroplasty risk index score of >3, the rate of survival of the components at four years was 89% compared with a rate of 97% for those with a score of ≤3. The patients with a higher risk index were 4.2 times more likely to undergo revision to a total hip replacement at four years. Twelve hips (3%) had a revision to a total hip replacement. Seven of the twelve hips were revised because of loosening of the femoral component, and three were revised because of a femoral neck fracture. Substantial radiolucencies were seen around sixteen uncemented metaphyseal femoral stems. No femoral radiolucencies were observed among the hips in which the metaphyseal stem was cemented. The most important risk factors for femoral component loosening and substantial stem radiolucencies were large femoral head cysts ($p = 0.029$), patient height ($p = 0.032$), female gender ($p = 0.005$), and smaller component size in male patients ($p = 0.005$).

Conclusions: The preliminary experience with this hybrid metal-on-metal bearing is encouraging. Optimal femoral bone preparation and component fixation are critical to improving durability. The metal-on-metal hybrid surface arthroplasty is easily revised to a standard femoral component if necessary.

Level of Evidence: Therapeutic study, Level IV (case series [no, or historical, control group]). See Instructions to Authors for a complete description of levels of evidence.

Although total hip arthroplasty is quite predictable and durable in older patients, young and active patients have higher rates of revision¹⁻⁵ and these rates are increased when the etiology is osteonecrosis^{6,7}. Because, in our

view, there was no satisfactory biological or prosthetic solution for the treatment of advanced arthritis in young and active patients, we began to investigate metal-on-metal surface arthroplasty in the early 1990s.

Our concept of applying metal-on-metal bearings to surface replacements followed the reintroduction of metal-on-metal bearings to total hip replacement in Europe in 1988^{8,9}. The measured wear of first-generation retrievals of these implants has been reported to be only a few micrometers per year^{10,11}. Unlike the adverse effects of increased volumetric wear of polyethylene as a function of increased head size, the



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A commentary is available with the electronic versions of this article, on our web site (www.jbjs.org) and on our quarterly CD-ROM (call our subscription department, at 781-449-9780, to order the CD-ROM).

TABLE I Demographic Data on the 355 Patients (400 Hips)

Characteristic	Value
Age at time of surgery* (yr)	48.2 ± 10.9 (15-77)
Weight* (kg)	
Female patients	68.6 ± 12.7 (45-107)
Male patients	88.6 ± 16.4 (57-164)
Height* (cm)	
Female patients	165.2 ± 6.8 (148-183)
Male patients	178.4 ± 7.2 (157-198)
Body mass index*	
Female patients	25.1 ± 4.3 (17.5-42.3)
Male patients	27.8 ± 4.5 (19.2-46.4)
No. of male patients	259 (73%)
No. of female patients	96 (27%)
Charnley classification (no. of hips)	
Class A	196 (49%)
Class B	176 (44%)
Class C	28 (7%)

*The values are given as the mean and the standard deviation, with the range in parentheses.

effect on wear by increasing the head size in metal-on-metal components is minimal^{10,12}. For these reasons, we began to implant metal-on-metal surface replacements. Initially we used the fully cemented McMinn¹³ and fully cementless Wagner¹⁴ designs. However, loosening of the acetabular component in the McMinn design in the short term (less than two years postoperatively)¹⁵ and the complexity of the insertion of the Wagner prosthesis led us to adopt a new design. The purpose of the present study was to evaluate the clinical and radiographic performance of this implant in the first 400 hips.

Methods and Materials

Patient Cohort

Between November 1996 and November 2000, the first 400 surface arthroplasties with a Conserve Plus prosthesis (Wright Medical Technology, Arlington, Tennessee) were performed in 355 patients. The study was approved by the hospital institutional review board. The most common indications for the procedure included a young age and/or a high level of activity. In some patients, abnormal proximal femoral morphology was also an indication for the surface arthroplasty. No patients who met these criteria were excluded because of severe femoral head cysts or osteopenia. All operations were performed by the senior author (H.C.A.) who, during that time, also performed sixty-nine primary conventional total hip arthroplasties. The patients who had the primary arthroplasties were older (average age, 62.2 years; range, twenty to ninety-two years) or had important limb-length discrepancies (five had Crowe class-III developmental dysplasia of the hip¹⁶ and one had a proximal femoral focal deficiency). One

patient had a nonunion of the femoral neck that did not allow resurfacing, two patients had Gaucher disease, and two patients had severe juvenile rheumatoid arthritis.

The demographic characteristics of the patients who underwent hip resurfacing are shown in Table I, and the etiology of the disease is shown in Table II. The average age of the patients who had resurfacing was 48.2 years (range, fifteen to seventy-seven years). Thirty-two patients had a bilateral arthroplasty at the same operation, and thirteen patients had sequential bilateral procedures between 2.5 and thirty-four months after the first side. Fifteen patients had a subsequent surface arthroplasty of the contralateral hip, but only the first hip resurfacing, which had the minimum two-year follow-up, is included in this study.

The Implant

The Conserve Plus acetabular shell is nearly hemispherical (170°). Its exterior surface has sintered beads ranging from 50 to 150 µm in diameter for cementless fixation. The one-piece acetabular shell is 5 mm in thickness. We recommend press-fit insertion by underreaming by 1 mm¹⁷.

The femoral component has the same design as the Conserve hemiresurfacing implant (Wright Medical Technology), which was approved by the Food and Drug Administration in 1995. This component has a short metaphyseal stem to facilitate accurate component alignment, and it permits a cement mantle with an average thickness of 1.25 mm around the

TABLE II Data on the 400 Hips

Etiology of the Disease	No. of Hips
Osteoarthritis	262 (65.6%)
Osteonecrosis (14% were Ficat stage III and 86% were Ficat stage IV)	36 (9.0%)
Developmental dysplasia (77% were Crowe class I and 23% Crowe class II)	43 (10.8%)
Posttraumatic arthritis	31 (7.8%)
Legg-Calvé-Perthes disease	10 (2.5%)
Slipped capital femoral epiphysis	7 (1.8%)
Ankylosing spondylitis	4 (1.0%)
Juvenile rheumatoid arthritis	3 (0.8%)
Rheumatoid arthritis	3 (0.8%)
Melorheostosis	1 (0.3%)
Previous operations	25 (6.3%)
Osteotomy	6
Coring	10
Hemisurface arthroplasty	2
Pinning	5
Judet graft	1
Acetabular reconstruction	1

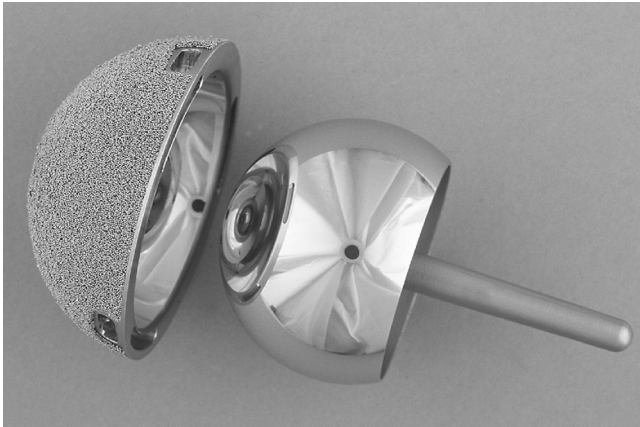


Fig. 1
The hybrid metal-on-metal surface replacement prosthesis (Conserve Plus; Wright Medical Technology, Arlington, Tennessee).

femoral head. The femoral component is greater than a hemisphere (208°), which, in most instances, enables coverage of all of the reamed bone by the component and maintains the length of the femoral head and neck (Fig. 1). The surface finish is approximately $0.008 \mu\text{m}$ (0.3 microinch). The specifications for roundness are substantially more strict for this design compared with those for the currently available hemisurface replacement because of the importance of maintaining adequate diametral clearances for lubrication and for minimizing wear. There are ten component sizes in 2-mm increments: the acetabular sizes are 46 to 64 mm and the femoral head sizes are 36 to 54 mm. All components are made of cast F-75 cobalt-chromium molybdenum alloy that is heat treated and solution annealed. The initial multicenter investigational device exemption trial has been completed, and the device is classified by the Food and Drug Administration as investigational. Implantations are currently being performed in ten centers under "continued access" pending final approval.

Surgical Technique and Hospital Course

A detailed description of the technique and instrumentation has been published^{15,18}. Some modifications of the surgical technique were made during the first 100 operations, but the technique has been essentially unchanged since then. Initially, we used a standard posterior approach but over time changed to a hockey-stick-shaped incision. We have performed only three trochanteric osteotomies to improve exposure. After a total capsulectomy is performed, the acetabulum is reamed to 1-mm under size and is checked carefully for depth and roundness with gauges. The socket is then impacted into the cavity until it is fully seated. Radiographs were made during the procedure for the first 100 hips, and, as a result, additional impaction of the acetabular component was done in three of those hips. After the initial 100 hips, no further intraoperative radiographs were made to assess the position of the acetabular component. Currently, we recommend placing the acetabular component at 25° to 30° of anteversion and 45° of abduction¹⁸.

The femoral component is aligned with the anatomic main axis of the femoral neck to avoid notching the neck, especially laterally, and to cover all of the reamed bone with the femoral prosthesis¹⁸. The target angle for the femoral component is 140° with the femoral shaft^{18,19}. Once the head is cylindrically reamed to size, the dome is removed with an oscillating saw, a tower alignment guide is applied to ream for the tapered stem, and the head is chamfered. The bone is meticulously prepared by removing all soft tissue from cysts, and numerous 0.125-in (0.32-cm) drill-holes are placed in the dome and chamfered areas. After jet lavage to clean the head, a femoral suction tip of the same dimensions as the metaphyseal stem is inserted into the head to suction out the marrow prior to fixation with acrylic cement.

In this series, all femoral head components were cemented but only a small number of metaphyseal stems were cemented. Early in the series, the stem was cemented in twenty hips because of severe osteopenia or large bone defects of the femoral neck. In thirty-nine of the last forty-four hips in this series, the stem was routinely cemented to better evaluate the effects of cementation to improve initial fixation and to evaluate any possible negative consequences such as stress-shielding. Twelve hips had grafting of the femoral head with bone paste only and/or with cancellous chips (six hips). Prior to closure, the hip should be moved through a range of motion and impinging bone should be removed from the acetabular walls and occasionally from the posterior trochanteric ridge.

Postoperative Management

All patients were managed with prophylactic antibiotics for two days, adjusted low-dose warfarin for three weeks, an indomethacin suppository (100 mg) immediately postoperatively, and 25 mg of indomethacin three times a day for five days. Currently, we give 50 mg of indomethacin preoperatively and 25 mg of indomethacin three times a day postoperatively for four days. Beginning with the forty-ninth patient in the series, patients undergoing simultaneous bilateral surgery were given 700 rads of single-dose radiation preoperatively and indomethacin. Walking was begun on the first postoperative day, with weight-bearing allowed as tolerated. Crutches were used for four to six weeks, and a cane was occasionally used for an additional two to three weeks. Sports were generally permitted at four months postoperatively¹⁸.

Outcome Evaluation

The average duration of follow-up was 3.5 years (range, 2.2 to 6.2 years). Follow-up visits to measure the range of motion of the hip and to have radiographs made were scheduled postoperatively at three to four months, at one year, and then at yearly intervals. All patients were followed prospectively, and pain, walking, function, and activity were evaluated with use of the University of California at Los Angeles (UCLA) hip-rating system²⁰, the Short Form-12 (SF-12) questionnaire²¹, and the Harris hip-rating system²². The Harris hip scores were not collected preoperatively for the first 100 patients in the study.

Limb-length discrepancy was assessed with use of blocks

of different thickness that were placed under the patient's foot until the pelvis leveled. This measurement was performed preoperatively and at each follow-up visit after surgery. Most patients (91%) were examined by the senior author in the Los Angeles clinic or in one of fifteen special clinics held annually in other cities in the United States. Online self-evaluation forms were submitted by 8% of the patients who were clinically evaluated by local orthopaedists who sent us radiographs for review. These patients were then contacted by telephone to discuss their progress. Two patients (three hips) died of causes unrelated to the surgery at twenty-one and twenty-three months postoperatively. Three patients were lost to follow-up. Fifteen patients (sixteen hips; 4%) failed to provide radiographs at two years; thus, our radiographic analysis was based on 384 hips. In 350 hips, intraoperative photographs of the femoral head were made prior to bone-cement fixation and were used to record the quality of the bone in the femoral head and to measure the size of bone defects. The size of the defects in the remaining fifty hips was estimated from preoperative radiographs that were corrected for magnification.

Surface Arthroplasty Risk Index

Beaulé et al. previously developed a risk index for surface arthroplasty in patients who were forty years of age or less²³. This index was calculated for all patients, with a maximum of 6 points representing the highest possible score; the higher the score, the higher the risk of failure. Two points were given for femoral head cysts of >1 cm; 2 points, for a weight of <82 kg; 1 point was given for previous surgery; and 1 point, for an activity level of ≥ 7 , according to the UCLA rating system, at one to two years postoperatively.

Radiographic Analysis

All patients had anteroposterior, modified table-down lateral, and Johnson cross-table lateral radiographs²⁴ of the pelvis made preoperatively and, when possible, during each follow-up visit. An independent reviewer evaluated all radiographs. A new system was devised to analyze femoral fixation with use of a scoring system of 0 to 9 points, indicating the presence or absence of radiolucencies in three zones around the short metaphyseal stem (Fig. 2, A). Acetabular radiolucencies were identified in three zones as previously described (Fig. 2, B)^{25,26}.

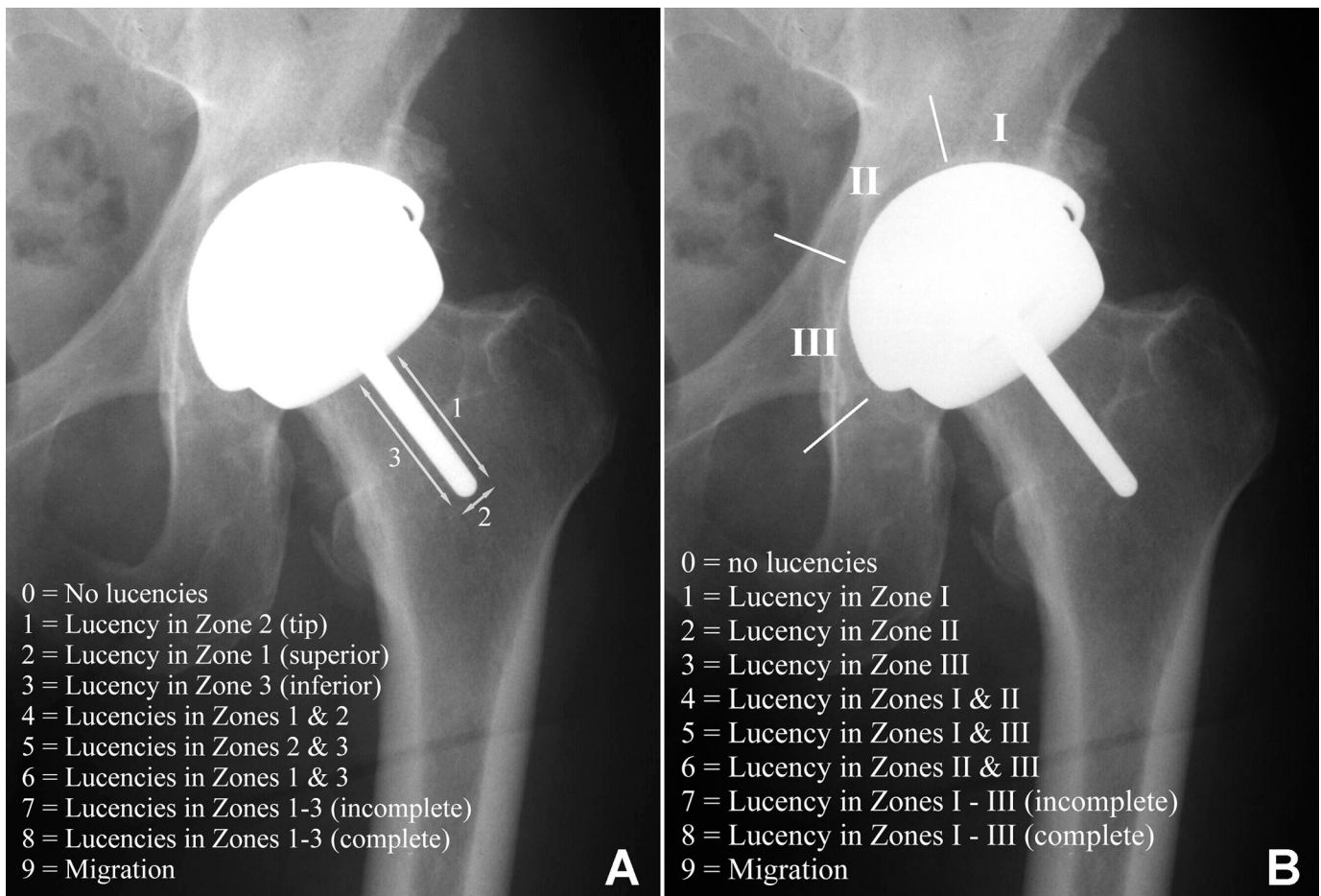


Fig. 2

A: The femoral zones around the metaphyseal stem and the related fixation assessment scores. B: The acetabular zones and the related fixation assessment scores.

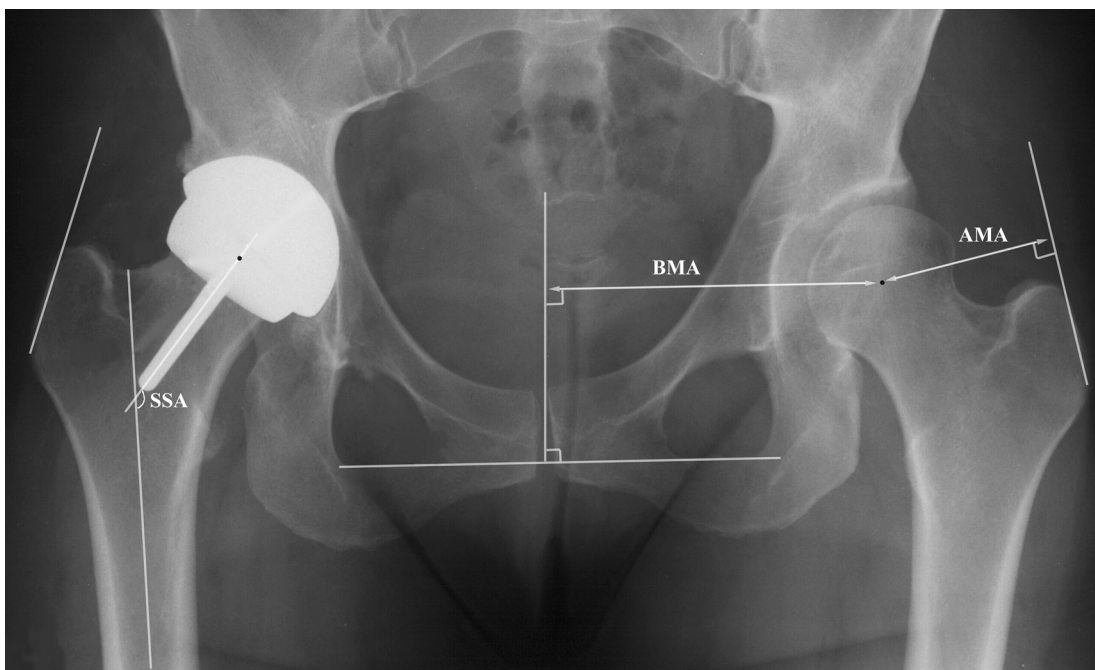


Fig. 3

The biomechanical constructs used in the present study to assess the stem-shaft angle (SSA) and the hip ratio (abductor moment arm [AMA] divided by body moment arm [BMA]). The hip ratio represents the relationship between the force exerted by the abductor muscles (AMA) and the body weight (BMA) to maintain equilibrium in the one-leg stance. The greater the ratio, the smaller the magnitude of the hip joint reaction force.

Heterotopic ossification was graded according to the Brooker classification²⁷.

Component Position and Biomechanical Analyses

The preoperative femoral neck-shaft angle was compared with the postoperative stem-shaft angle on the anteroposterior radiograph. Valgus was defined as a stem-shaft angle that was greater than the neck-shaft angle by more than 5°, and varus was defined as a stem-shaft angle that was less than the neck-shaft angle by >5°. The orientation of the stem in the sagittal plane was assessed from the Johnson cross-table lateral radiographs²⁴. A deviation of ≥10° of the stem axis from the main axis of the neck was designated as “anterior” or “posterior.” It was designated as neutral when the deviation was <10°. The hip ratio (the abductor moment arm²⁸ divided by the body moment arm) of the resurfaced hip was compared with that of the normal hip in patients with Charnley class-A involvement²⁹ to assess the accuracy of the biomechanical reconstruction (Fig. 3).

Statistical Analysis

Two different end points were used for the calculation of the Kaplan-Meier survivorship curves: (1) the time from surgery to the conversion to a total hip replacement and (2) the time from surgery to the first appearance of a stem radiolucency in hips with eventual failure of the femoral component or when the metaphyseal stem radiolucency score was ≥7.

The log-rank test was used for comparing Kaplan-Meier survivorship curves. The Cox multivariate proportional-hazards model was used to determine the prognostic factors associated with the time to aseptic revision or the appearance of stem radiolucencies.

Results

Clinical Results

The average duration of follow-up was 3.5 years (range, 2.2 to 6.2 years). Kaplan-Meier survivorship analysis demonstrated that the overall survival rate of the component at four years was 94.4% (95% confidence interval, 91% to 98%). The clinical results (the UCLA hip score, Harris hip score, and SF-12 scores) are summarized in Table III. Only two patients had a UCLA pain score of <7. In one patient, who had osteonecrosis and lymphoma, the pain was reduced but was not completely eliminated. The other patient was a candidate for revision because of femoral component loosening but was lost to follow-up. The average Harris hip score was 93.5 points (range, 41 to 100 points). Nine hips (one in a patient with Charnley class-A involvement, one in a patient with Charnley class-B involvement, and seven in patients with Charnley class-C involvement) had a Harris hip score of <70 points. An association was found between the Charnley class and the Harris hip scores. The average Harris hip score was 95.2 points (range, 61 to 100 points) for hips in patients with Charnley class-A involvement and 93.3 points (range, 66 to 100 points) for hips in patients with Charnley class-B involvement ($p =$

0.008). The average Harris hip score for patients with Charnley class-C involvement was 80.7 points (range, 41 to 100 points), which was inferior to that for both patients with Charnley class-A and those with class-B involvement ($p = 0.001$). Postoperatively, the average scores (and standard deviation) on the SF-12 (50.01 ± 9.69 for the physical component and 53.10 ± 9.40 for the mental component) did not differ significantly from those of the general population of the United States matched for age²⁹. The range of motion improved from an average of 85.5° (range, 5° to 150°) of flexion, 30.5° (range, 0° to 90°) of abduction-adduction measured in extension, and 18.5° (range, 0° to 85°) in rotation arc measured in extension to an average of 122.0° (range, 55° to 170°), 69.8° (range, 25° to 130°), and 73.7° (range, 10° to 125°), respectively.

Limb-Length Discrepancy

Seventy-eight patients had a limb-length discrepancy preoperatively. The discrepancy was <1 cm in fifty-three patients, 1 to 2 cm in sixteen patients, 2 to 3 cm in eight patients, and >3 cm in one patient. Postoperatively, only twenty-five patients had a limb-length discrepancy: twenty-two had a discrepancy of <1 cm and three had a discrepancy of 1 to 2 cm, but all discrepancies were less than the preoperative measurement.

Radiographic Results

Heterotopic Ossification

One hundred and six hips (36% of the male patients and 12% of the female patients) had some heterotopic bone. The average UCLA pain score for this group was 9.4 points (range, 2 to 10 points), which was not significantly different from that for the rest of the patients. Brooker class-III or IV heterotopic bone was observed in twenty-eight hips (7%; twenty-six patients) all of which were in men (10% of the male patients). As a group, these hips showed a decreased range of motion in the arc of flexion (mean, 109.5° ; range, 55° to 140°) compared with that for the rest of the male patients (121.9° ; range, 85° to 155°) ($p = 0.001$). All of the patients had functional arcs of rotation and abduction-adduction. After implementation of our radiation protocol for patients who had one-stage bilateral arthroplasty, the overall rate of Brooker class-III or IV heterotopic ossification was 5.4% (three of fifty-six hips).

Hip Biomechanics

The stem-shaft angle in the first 100 hips (average, 131.1° ; range, 110° to 150°) was significantly more valgus than that in the subsequent hips (average, 137.8° ; range, 111° to 153°) ($p =$

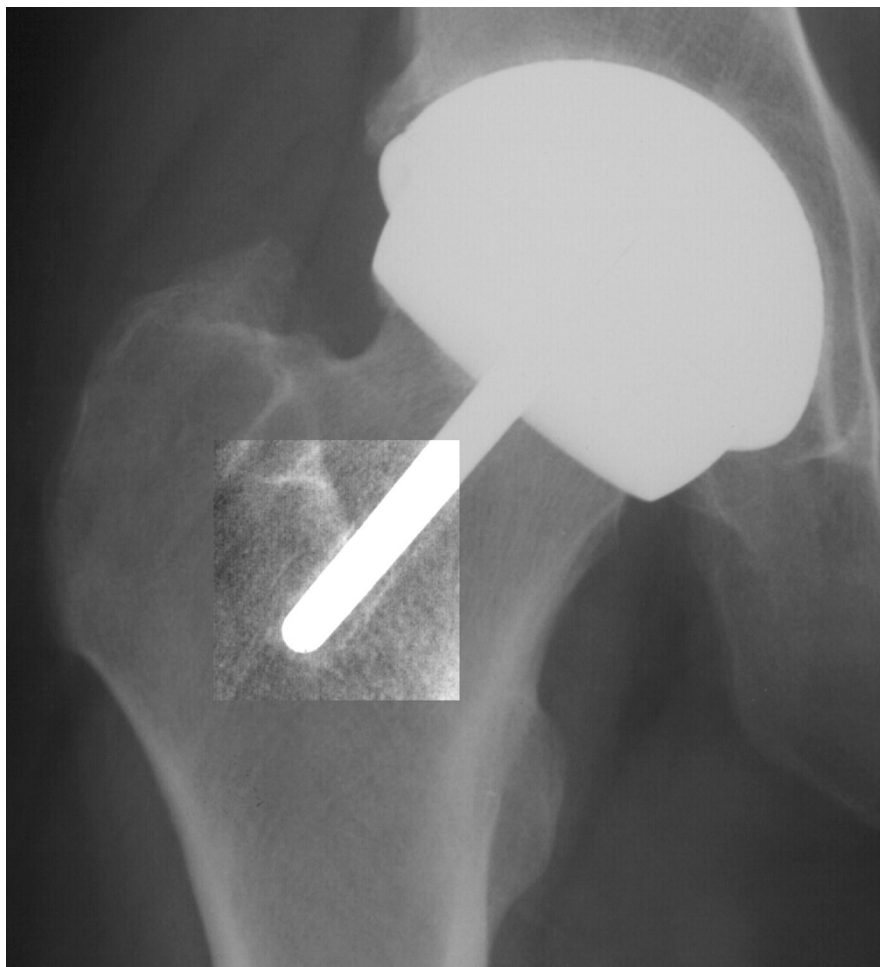


Fig. 4

Radiograph of the hip of a twenty-eight-year-old man, made 3.5 years after metal-on-metal surface arthroplasty, showing femoral radiolucency in all three zones around the metaphyseal stem. The patient stated that he had no pain at the last follow-up examination and remained very active (UCLA activity score of 10).

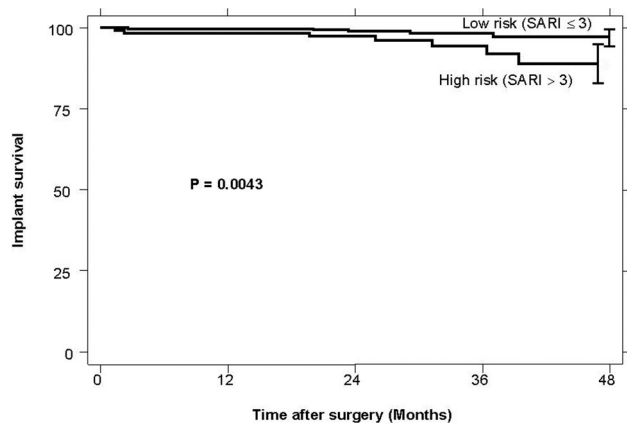


Fig. 5-A

Fig. 5-A Kaplan-Meier survivorship curves comparing the time to conversion to a total hip replacement for patients with a high risk (an index score of >3 points) and those with a low risk (an index score <3 points). SAKI = surface arthroplasty risk index. **Fig. 5-B** Kaplan-Meier survivorship curves comparing the time to femoral radiolucency or failure for patients with a high risk (an index score of >3 points) and those with a low risk (an index score of <3 points). SAKI = surface arthroplasty risk index.

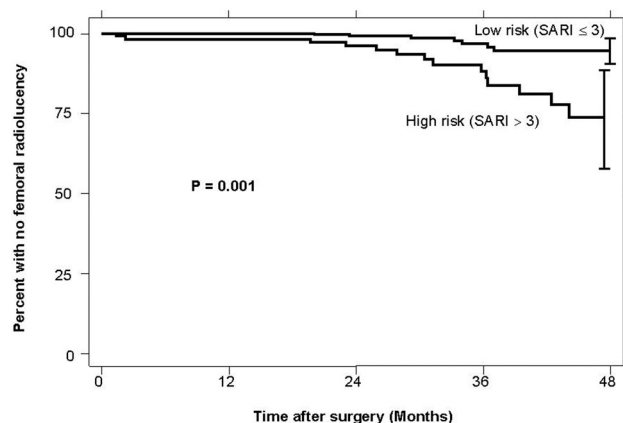


Fig. 5-B

0.001). The stem-shaft angle in the hips that were revised because of femoral loosening (average, 129°; range, 110° to 148°) was significantly lower (more varus) than that in the rest of the cohort (average, 136°; range, 111° to 163°) ($p = 0.0255$). The stem-shaft angle was negatively correlated ($r = -0.374$, $p < 0.001$) to the abductor moment arm.

In patients with Charnley class-A involvement, the normal hip abductor mechanics were restored, as denoted by a similar hip ratio on the involved side (average, 0.584; range, 0.40 to 0.83) and the contralateral, uninvolved side (average, 0.571; range, 0.40 to 0.78) ($p = 0.193$).

Acetabular Radiolucencies

Acetabular radiolucencies are reported in Table IV. Two hundred and sixty-one hips (68%) had no radiolucencies and 122 hips (32%) had radiolucencies in one or two zones. Cup protrusion occurred immediately postoperatively in one hip,

and the component was revised to a polyethylene bearing. There were no progressive radiolucencies in zones I or II.

Metaphyseal Stem Radiolucencies

According to our rating scheme (Fig. 2, A), sixteen hips (4.2%) that had not been revised had a femoral metaphyseal stem radiolucency score of ≥ 7 (Fig. 4). Only one of these patients was symptomatic at the time of latest follow-up. The first appearance of these radiolucencies occurred at an average of twenty-three months (range, ten to fifty months) postoperatively. The average pain and activity scores of the group with a radiolucency score of ≥ 7 were not significantly different from those of the rest of the cohort. Several factors correlated with femoral fixation scores. The main clinical factors associated with the presence of radiolucencies are summarized in Table V. In addition, patients were at increased risk of having a radiolucency if they had large femoral-head cysts ($p = 0.029$),

TABLE III Summary of the Clinical Results

Rating System	Score*			P Value
	Preoperative	Latest Follow-up		
UCLA hip score				
Pain	3.5 (1 to 8)	9.5 (2 to 10)		<0.0001
Walking	6.0 (2 to 10)	9.6 (3 to 10)		<0.0001
Function	5.7 (1 to 10)	9.4 (3 to 10)		<0.0001
Activity	4.5 (1 to 10)	7.7 (2 to 10)		<0.0001
SF-12				
Physical component	31.2 (16.8 to 54.8)	50.0 (17.6 to 62.7)		<0.0001
Mental component	46.8 (4.0 to 68.5)	53.1 (10.5 to 67.1)		<0.0001
Harris hip score	NA	93.5 (41 to 100)		NA

*The values are given as the mean, with the range in parentheses. UCLA = University of California at Los Angeles. SF-12 = Short Form-12. NA = not available.

TABLE IV Summary of Observed Acetabular and Femoral Radiolucencies in 384 Hips*

	Acetabular Fixation Score	No. (%) of Hips	Femoral Fixation Score	No. (%) of Hips†
No radiolucency	0	261 (67.9)	0	266 (69.3)
1 zone	1, 2, or 3	99 (25.8)	1, 2, or 3	81 (21.1)
2 zones	4, 5, or 6	23 (6)	4, 5, or 6	11 (2.9)
3 zones and incomplete	7	0	7	6 (1.6)
3 zones and complete	8	0	8	5 (1.3)
Migration	9	1‡ (0.3)	9	12§ (3.9)

*Data on sixteen hips that did not have radiographs available and on three femoral neck fractures were excluded †Sixteen hips that had femoral radiolucencies with a score of 7, 8, or 9 were not converted to total hip replacement. ‡Cup protrusion occurred immediately postoperatively, and the component was revised to a polyethylene bearing. §Seven hips were converted to total hip replacement, four were asymptomatic, and one was symptomatic and lost to follow-up).

were female ($p = 0.005$), or were of lesser height ($p = 0.032$). Smaller component size was significantly ($p = 0.005$) associated with femoral radiolucencies in male patients only. None of the fifty-nine cemented metaphyseal stems, even those with less than optimal bone quality, showed any radiolucency at the time of the last review. However, this group had had a much shorter duration of follow-up than the rest of the cohort, and we were not able to detect a significant relationship ($p = 0.206$) with use of the log-rank test for Kaplan-Meier survivorship analysis.

Surface Arthroplasty Risk Index

The average surface arthroplasty risk index (and standard deviation) for the whole group was 2.73 ± 1.55 (range, 0 to 6). When conversion to total hip replacement was used as the end point, a surface arthroplasty risk index of >3 points was significantly associated ($p = 0.004$) with an earlier time to revision (Fig. 5-A). The rate of survival of the implants at four years was 97% (95% confidence interval, 94% to 100%) for patients with a low risk of revision (surface arthroplasty risk

index of ≤ 3 points) compared with 88.8% (95% confidence interval, 80.0% to 97.6%) for patients with a high risk (surface arthroplasty risk index of >3 points). The average surface arthroplasty risk index was 3.77 ± 1.45 points (range, 0 to 6 points) for the group with metaphyseal stem radiolucencies compared with 2.66 ± 1.53 points (range, 0 to 6 points) for the remaining hips ($p = 0.0004$). For patients with a surface arthroplasty risk index of >3 points, the chance that a femoral radiolucency would develop was 4.2 times greater than that for patients with a risk index of ≤ 3 points. Figure 5-B shows the survivorship curves at four years with the first appearance of a radiolucency around the metaphyseal stem used as the end point. No femoral stem radiolucency was seen at four years in 73.8% (95% confidence interval, 60.2% to 87.3%) of the high-risk group and 94.5% (95% confidence interval, 90.2% to 98.8%) of the low-risk group ($p = 0.001$).

Femoral Cyst and Bone Defect Assessments

The bone defects of the femoral heads were categorized according to the size of the largest defect and whether they were

TABLE V Clinical Variables Associated with a Femoral Fixation Score of ≥ 7 According to the Cox Multivariate Proportional-Hazards Model (N = 384)

	Hazard Ratio	P Value	95% Confidence Interval
Entire group			
Females	3.1	0.005	1.4-6.3
Cysts of >1 cm	2.6	0.029	1.1-6.3
Surface arthroplasty risk index of >3	4.2	0.001	1.9-9.4
Lesser height*	1.56	0.032	1.04-2.32
Males only			
Smaller component size*	1.31	0.005	1.09-1.59
Lighter weight*	1.56	0.073	0.96-2.5
Smaller body-mass index*	2.63	0.062	0.95-7.14

*For continuous variables, the following increments were used: 10 cm for height, 2 mm for component size, 10 kg for weight, and 5 points for body-mass index.

TABLE VI Distribution of Femoral Cysts and Bone Defects

Type and Size	Total No. of Hips	No. (%) of Hips Revised or in Need of Revision Because of Failure of Femoral Component*	No. (%) of Hips (Including Revisions) with Radiolucencies Around Stem
No defect	121	1 (0.8)	4 (3.3)
Single defect of <1 cm	37	0	1 (2.7)
Multiple defects of <1 cm	38	1 (2.6)	1 (2.6)
Single defect of 1 to 2 cm	20	1 (5)	0
Multiple defects of 1 to 2 cm	125	4 (3.2)	13 (10.4)
Single defect of >2 cm	5	2 (40)	2 (40)
Multiple defects of >2 cm	54	1 (1.9)	2 (3.7)

*Three hips (one revised because of infection, one revised because of subluxation due to impingement, and one revised because of acetabular shell protrusion postoperatively) are not included.

single or multiple. The various categories are summarized in Table VI, which illustrates the association between the size of the defects and the clinical or radiographic results.

Conversion to Total Hip Replacement

Twelve hips (3%) were converted to total hip replacement. Seven revisions were done because of loosening of the femoral component and three, because of a fracture of the femoral neck. Two fractures of the femoral neck occurred within the first six weeks postoperatively, and the third occurred at twenty months. One hip was revised to a total hip replacement because of recurrent subluxations. In one patient with rheumatoid arthritis, a late hematogenous infection developed and the surface replacement was converted to a total hip replacement (a direct exchange) at thirty-six months. The patient was free of infection at eighteen months after the revision.

The demographic characteristics of the seven patients who had loosening of the femoral component were not different from those of the overall group. However, the component stem-shaft angle was 128.3° (range, 110° to 148°), which was significantly different from that of the rest of the patients (136.2°; range, 111° to 163°) ($p = 0.0255$). The time to first observation of the metaphyseal stem radiolucency was twenty months (range, 12.5 to thirty-six months), and the time to the first symptoms was twenty-seven months (range, sixteen to fifty-one months). The time to the revision was thirty-five months (range, twenty-three to sixty-one months). All but one of the failed femoral components were revised to a total hip replacement with use of a unipolar head that was size-matched to the inside diameter of the existing well-fixed socket.

In five of the patients who had a revision to a total hip replacement because of loosening of the femoral component, large areas of cystic degeneration of the head and remaining osseous defects were seen even after bone preparation that diminished the surface area available for fixation. In three hips, the components were "proud," as suggested by a thick mantle of cement in the dome area, and the surrounding bone was sclerotic. Four patients had a high activity level (an activity score of 8 and 9 in two each).

In addition to the twelve hips that had a conversion to a total hip replacement, one hip in a patient who had had a bilateral surface arthroplasty had an isolated revision of the acetabular component on the right side after the shell acutely protruded into the medial acetabular wall on the second postoperative day when the patient had been walking with a four-point gait. An infection subsequently developed in the hip, and an isolated direct socket exchange was performed with use of a cup inserted with bone cement containing antibiotics.

Other Complications

Four hips required a reoperation, including a cup exchange because of component mismatch, removal of heterotopic bone from two hips in one patient, and wire removal in a hip with trochanteric bursitis. The prevalence of dislocation was 0.75% (three of 400). Two hips had an early postoperative dislocation, and one had recurrent dislocation. The latter hip was in a patient with hip dysplasia who had undergone multiple osteotomies and had abnormal femoral geometry (coxa valga of 160°). This hip was eventually converted to a total hip replacement, as mentioned in the previous section. The other two dislocations required closed reduction, but the hips were stable at the time of the most recent follow-up.

Femoral Component Size and Interface Bone-Cement Area

The distribution of the femoral components according to size in the male and female patients is shown in the Appendix. The contact areas between bone and cement, calculated from the inside dimensions of the component by adding the cylindrically reamed area, chamfered reamed area, resected dome area, and approximated area of the drilled holes, also appear in the Appendix.

Discussion

The results of total hip arthroplasty have been excellent in older age-groups; however, for patients who are forty years of age or younger, the failure rates have ranged from 21% to 28% at five years^{1,3,30,31}. The concept of surface arthro-

plasty for the treatment of advanced arthritis of the hip in young and active patients has many attractive features because of its ability to preserve femoral bone.

Although our early clinical results are promising, thirteen hips needed a revision, suggesting that all patients may not be suitable candidates for this procedure. The appearance of femoral stem radiolucencies is of concern, although only one patient was symptomatic. At the present time, the major factors related to femoral stem radiolucency are female gender and the presence of large cysts in the femoral head. These reflect the importance of femoral fixation, a factor that we consider crucial to long-term durability. The most important factor that determines good fixation appears to be the area available for cement fixation. Individuals with smaller reamed femoral heads and small component sizes (which includes most female and lighter male patients) had more loosening and radiolucencies than did those with larger head sizes. These observations are consistent with previous findings with the Tharies (total hip articular replacement with internal eccentric shells) surface replacement, which demonstrated a lower rate of survival for the smaller femoral components (39%) compared with the larger sizes (59%) at eleven years of follow-up³². In recognition of the higher risk for this group, we now recommend insertion of the femoral stem with cement and use of additional drill-holes in the prepared femoral head to increase the fixation area, especially for women and in the presence of extensive cysts. The area available for fixation in a femoral surface arthroplasty with cement is related to the quality of the bone, and it is apparent that more cysts and/or larger cyst size and a smaller femoral head adversely affect the area available for fixation.

Careful patient selection is critical to the success of any given procedure. By acknowledging that certain types of patients do better with this procedure, at least as it is currently performed, than others do, we can minimize early failures. There are two main modes of femoral failure following surface arthroplasty: neck fracture and aseptic loosening. The occurrence of early femoral neck fracture in this series was very low (0.75%), probably reflecting the experience of the surgeon and the surgical technique. It is important to avoid or at least to minimize notching the neck and to cover all of the reamed bone with the component. If the component is not fully seated, the uncovered reamed area behaves as a circumferential stress-riser. Special care must be taken, when reaming cylindrically at the recommended angle of 140°, to stop the reaming before the reamer touches the lateral cortex. A large osteophyte, which usually forms anteriorly on the femoral neck, should be removed only if there is a substantial impingement of the range of motion at 90° of flexion and internal rotation.

The hips that had aseptic loosening of the femoral component and required revision appear to have had several risk factors, which are enumerated in Table VI. Four of the hips were among the first 100 that were resurfaced before additional fixation holes were added to the chamfered area and the femoral suction tip technique was developed. Our cur-

rent femoral component has a short metaphyseal stem that serves as an “antenna,” and we believe that this provides an early indication of the quality of fixation at the femoral bone-cement-implant interfaces. We believe that a radiolucency score of ≥ 7 on our rating system is substantial and that the radiolucency is likely to progress to component loosening over time.

To improve patient selection, Beaulé et al.²³ reviewed the early clinical results after metal-on-metal surface arthroplasty in patients who were forty years of age or younger. This group is considered a target population for the procedure and has the most to gain from a more conservative prosthetic solution. In that series, the surface arthroplasty risk index was significantly higher (4.7 points, $p < 0.001$) for the thirteen hips with a complication (those converted to total hip replacement or those with femoral lucencies) compared with 2.6 points for the group of eighty-one hips that did not have a complication. In patients with an index of >3 points, the relative risk of early problems was twelve times greater than that in patients with an index of ≤ 3 points. In the present series, patients with an index of >3 points had a relative risk of early problems that was 4.2 times greater than that in patients with an index of ≤ 3 points. The surface arthroplasty risk index appears to be a useful tool in determining which patients can safely benefit from metal-on-metal surface arthroplasty.

Ultimately, the control of postoperative factors is up to the patients, but it is the duty of the surgeon to properly inform them of the potential risks. At the present time, we do not have definitive contraindications to the surgery, but patients who have compromised bone stock, particularly large femoral head cysts and small femoral heads, warrant special scrutiny as candidates for the procedure. Patients also should be informed that high activity levels (especially impact sports), although they have not been found to be significant at this time, are likely to shorten the life of the implant in a manner similar to the way in which those activities affect a total hip replacement.


The prevalence of Brooker class-III and IV heterotopic ossification of 10% in the male patients seemed high; however, the prevalence of 7% in the overall group was comparable with the prevalence of 5.8% reported by Dorn et al., in a study in which 40% of the patients were male and the authors advocated the use of indomethacin for four days as prophylaxis against heterotopic ossification³³. We anticipated some increase in the frequency of heterotopic ossification because of the additional stretching of the muscles required for surface arthroplasty to facilitate work around the head and neck and to obtain access to the acetabulum. After the first of thirty-two patients (sixty-four hips) managed with simultaneous bilateral arthroplasty had formation of Brooker class-III or IV heterotopic bone, we changed our protocol when operating on both hips at the same operation and provided radiation at a single preoperative dose of 700 rads. This protocol proved to be effective, as Brooker class-III or IV heterotopic ossification developed in only 5.4% (three) of the fifty-six hips (twenty-eight patients) treated with radiation. Prophylaxis with indomethacin remains our recommenda-

tion for patients who have a unilateral procedure.

Despite the lack of clear evidence linking metal-on-metal total hip arthroplasty with long-term problems, there are lingering concerns over the local and possible systemic effects of metal wear products, including ions. Recent reports of unusual lymphocytic aggregates in the tissues around failed metal-on-metal stem-type total hip replacements^{34,35} prompted us to investigate the tissues around the failed components in our study, and we found that such features were present in approximately one-third of the hips³⁶. At the present time, there does not appear to be an association between these lymphocytic aggregates and clinical outcome, but this is the subject of ongoing research. The levels of metal ions in the blood and urine of approximately fifty patients with the Conserve Plus implants are being monitored over time, and the results to date are comparable with those from conventional total hip replacements with metal-on-metal bearings³⁷. Finally, at the present time, there is no defined cause-and-effect relationship between the metal-on-metal implants that were first implanted in the 1960s and cancer³⁸.

Comparisons of the rate of survival of the implants in the present series and that of other implants should take into account the high activity levels (average score, 7.7) of these patients. For 54% of the patients, the score for activity level on the UCLA rating system was >7. Continued close follow-up is needed to better define the results and indications for this procedure.

Appendix

 A table showing the area of bone-cement interface for the various component sizes and a graph showing the distribution of the component sizes by gender in this series are available with the electronic versions of this article, on our web site at www.jbjs.org (go to the article citation and click on "Supplementary Material") and on our quarterly CD-ROM (call our subscription department, at 781-449-9780, to order the CD-ROM). ■

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