Metal-on-Metal Hybrid Surface Arthroplasty: Two to Six Year Follow-up.

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Abstracted from manuscript accepted for publication and now in press for The Journal of Bone & Joint Surgery which analyzes the results of Dr. Amstutz's initial cohort of 355 patients(400hips) who underwent surface arthroplasty using the Conserve® Plus total surface replacement device. This report represents the first comprehensive analysis of patients undergoing M/M surface arthroplasty anywhere in the world.

Introduction

Although total hip arthroplasty is quite predictable and durable in older patients, young and active patients have higher revision rates [1,2,3,4,5] and these rates are increased when the etiology is osteonecrosis [6,7]. Because there was no satisfactory biological or prosthetic solution for advanced arthritis in the young and active patient, we began to investigate metal-on-metal surface arthroplasty in the early 1990's**.**

Our concept of applying metal-on-metal bearings to surface arthroplasty followed the re-introduction of metal-on-metal bearings to total hip arthroplasty in Europe in 1988 [8,9]. The measured wear of first generation metal-on-metal retrievals of these implants has been reported to be only a few microns per year [10,11]. Unlike the adverse effects of increased volumetric wear of polyethylene as a function of increased head size, the wear is minimally affected by increasing the head size in metal-on-metal components [10,12]. For these reasons, we, as well as others, began to implant metal-on-metal surface arthroplasties. Although the Conserve® Plus design began in 1992, initially we used the fully cemented McMinn [13] and a small number of a complex cementless Wagner [14] design. However, we observed short-term loosening of the acetabular component and inconsistent manufactured tolerances in the McMinn Design and the overall results were disappointing and 6-9 year results are in press[15]. The purpose of this study was to evaluate the clinical and radiographic performance of this implant in the first consecutive 400 hips of the Conserve® Plus design.

Methods and Materials

Patient Cohort

Between November 1996 and November 2000, the first 400 Conserve® Plus (Wright Medical Technology, Arlington, Tennessee) surface arthroplasties were performed in 355

patients. The study was approved by the hospital Institutional Review Board. The most common indications for the procedure included patients of a young age, and or high activity level. In some older patients with abnormal proximal femoral morphology, we also chose to perform surface arthroplasty. Many of our young patients had been advised to defer surgery and had extremely severe degenerative changes but we did not exclude any who met the above criteria because of severe femoral head cysts or osteopenia. The demographics and etiology of the arthritis of the patients who underwent hip resurfacing (average age 48.2 years, range fifteen to seventy-seven) are shown in Table 1.

Table 1. Patient demographics (mean, standard deviation and range)

N = 400	**Mean**	**SD**	**Range**
Age at surgery (years)	48.2	10.9	15-77
Weight (Kg) Females/Males	68.6/88.6	12.7/16.4	45-107/57-164
Height (cm) Females/Males	165.2/178.4	6.8/7.2	148-183/157-198
BMI Females/Males	25.1/27.8	4.3/4.5	17.5-42.3/19.2-46.4
Male Patients	73%	-	-
Female Patients	27%	-	-
Charnley class A	49%	-	-
Charnley class B	44%	-	-
Charnley class C	7%	-	-

Etiologies	**Percent**
Osteoarthritis	65.6%
Osteonecrosis (14% ON Ficat III and 86% ON Ficat IV)	9.0%
Developmental dysplasia (77% Crowe class I 23% Crowe class II)	10.8%
Post-traumatic arthritis	7.8%
Legg Calve Perthes	2.5%
Slipped capital femoral epiphysis	1.8%
Ankylosing spondylitis	1.0%
Juvenile rheumatoid arthritis	0.8%
Rheumatoid arthritis	0.8%
Melorheostosis	0.3%
Previous surgeries	6.3%
Failed osteotomy	6
Failed coring	10
Failed hemisurface arthroplasty	2

Failed pinning	5
Failed Judet graft	1
Failed acetabular reconstruction	1

Thirty-two patients had bilateral arthroplasty at the same operation, and thirteen patients had sequential bilateral procedures between 2.5 and 34 months after the first side.

The Implant

The Conserve® Plus acetabular shell is nearly hemispherical (170^{o}). Its exterior surface has sintered beads ranging from 50 μm to 150 μm in diameter for cementless fixation. The one-piece acetabular shell is five millimeters in thickness. Insertion is press-fit by under reaming one millimeter[16].

The femoral component has the same design as the Conserve® hemi-resurfacing (Wright Medical Technology, Arlington, Tennessee) which was approved by the FDA in 1995. This component has a short metaphyseal stem to facilitate accurate component alignment and permits a cement mantle that averages 1.25mm around the femoral head. The femoral component is greater than a hemisphere (208° degrees), which in most instances, enables coverage of all of the reamed bone by the component, and maintains length of the femoral head and neck. The surface finish is approximately 0.008 μm (0.3 microinches). The specifications for roundness are strict to permit adequate diametrical clearances for lubrication and to minimize wear. There are ten femoral and acetabular component sizes are in two-millimeter increments: the acetabulum 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. Although the device is classified by the Food and Drug Administration as investigational, the initial multi-center investigational device exemption trial has been completed and the manufacturer has

submitted an application for a PMA (pre–market approval). Implantations are now being performed in ten centers under "extended enrollment" pending final approval.

Surgical Technique and Hospital Course

A detailed description of the technique and instrumentation has been published [15,17]. Most of the modifications of the surgical technique for this cohort were made during the first 100 hips operated but the technique continues to be refined with new instrumentation to facilitate the procedure . Initially we used a standard posterior approach but changed to a hockey stick incision over time because of the musculature of our many active patients. The incision length has been minimized and depends on the size of the patient. The acetabulum is reamed to one millimeter under size and checked carefully for depth and roundness with gauges and placing the acetabular component at 25° to 30° of anteversion and 45° of abduction [17].

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 prosthesis. [17] The target angle for the femoral component is now 140° with the femoral shaft[17,18]. 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 additional holes are placed in the dome and chamfered area to improve fixation. 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 blood prior to fixation with acrylic cement. All femoral components were cemented but only a small number of metaphyseal stems were cemented. Early in the series, the stem was cemented in fifteen hips because of severe neck osteopenia or large defects. In thirty-nine of the last forty-four cases of 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.

Prior to closure a range of motion is performed and impinging bone is removed from the acetabular walls and occasionally the posterior trochanteric ridge which enables patients to regain and in occasional instances exceed preexisting range of motion of the hip.

Post-operative Management

All patients have prophylactic antibiotics, adjusted low dose Warfarin, Indomethacin or 700 rads of radiation pre operatively to prevent sepsis thromboembolic phenomona and heteroptic bone formation. Ambulation begins on the first postoperative day, allowing weight bearing as tolerated, using crutches for 4-5 weeks. A cane is occasionally used for an additional 2-3 weeks. Sports are generally permitted at 3-6 months post-operatively[17].

Outcome Evaluation

The average follow-up is 3.5 years (range 2.8 - 6.8). Follow-up visits including hip range of motion and radiographic examination were scheduled preoperatively and postoperatively at three to four months, one year and at yearly intervals in which all patients were followed prospectively to evaluate pain, walking, function, and activity according to the UCLA hip scores [19], SF-12 [20], and Harris hip score [21]. Leg length discrepancy was assessed using blocks of different thickness placed under the patient's foot until the pelvis leveled. This measurement was performed preoperatively and at each visit after surgery. The majority (91%) of the patients 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 at the prescribed follow-up intervals and 8% of patients were clinically evaluated by local orthopedists who sent us radiographs for review. The patients were then contacted by phone to discuss their progress. Two patients (three hips) died at twenty-one and twenty-three months postoperatively of causes unrelated to the surgery. Only three patients (0.75%) have been lost to clinical follow-up.

All of the patients had antero-posterior, modified table-down lateral, and Johnson cross-table lateral radiographs[23] of the pelvis taken preoperatively and, where possible, during each follow-up. An independent reviewer (T.G.) evaluated the radiographic series on an annual basis.

Results

Clinical results

The average duration of follow-up was three and a half years (range, 2.2 to 6.2 years). Clinical results (UCLA hip score, Harris hip score and SF-12 scores) are summarized below.

Table 2. Summary of the clinical results from UCLA hip scores, SF-12, and Harris hip scores (HHS). Average scores and (ranges)

		Preoperative scores	Last Follow-up scores	P values
UCLA	Pain	3.5 (1 to 8)	9.5 (2 to10)	$p < 0.0001$
	Walking	6.0 (2 to10)	9.6 (3 to10)	$p < 0.0001$
	Function	5.7 (1 to10)	9.4 (3 to10)	$p < 0.0001$
	Activity	4.5 (1 to10)	7.7 (2 to10)	$p < 0.0001$
SF-12	Physical	31.2 (16.8 to 54.8)	50.0 (17.6 to 62.7)	$p < 0.0001$
	Mental	46.8 (4.0 to 68.5)	53.1 (10.5 to 67.1)	$p < 0.0001$
HHS		-	93.5 (41 to 100)	N/A

The average Harris hip score was 93.5 . Charnley class and Harris hip scores were associated with 95.2 average (range 61 to 100) for Charnley class A and 93.3 (range 66 to 100) for Charnley class B ($p = 0.008$). The average Harris hip score was 80.7 (range 41 to 100) for Charnley class C, which was inferior to both Charnley A and B ($p=0.001$). Postoperative SF-12 scores did not differ significantly from the average score of the general United States population matched for age (Physical = 50.01 ± 9.69 and Mental = 53.10 ± 9.40 [20]). The range of motion improved from a mean 85.5° (range 5° to150°) in flexion, 30.5° (range 0° to 90°) in abduction–adduction measured in extension, and 18.5° (range 0° to 85°) rotation arc measured in extension, to 122.0° (range 55° to 170°), 69.8° (range 25° to 130°) and 73.7° (range 10° to 125°), respectively.

Leg length discrepancy

Seventy-eight patients had leg length discrepancies preoperatively. Fifty-three were <1cm, sixteen were 1 to 2 cm, eight were 2 to 3 cm, and one was > 3cm. After surgery, only

twenty-five patients had a leg length discrepancy: twenty-two had leg length discrepancies that were <1cm and three patients had a discrepancy of 1 to 2 cm but all were less than their preoperative levels.

Radiographic Results

Heterotopic Ossification

One hundred and six hips had some heterotopic bone (36% of the males and 12% of the females). The average pain score for this group was 9.4 (range 2 to 10), which did not differ statistically from the rest of the patient group. Brooker Grade III and IV bone was observed in twenty-eight hips, all in male patients (7% of the whole group, 9.5% of male patients). As a group these cases showed a decreased range of motion in flexion arc (mean 109.5 degrees (range 55 to140) vs. 121.9 degrees (range 85 to155) for the rest of the male patients, $p = 0.001$). All of the patients had a functional arc of rotation and abduction-adduction arc. After implementation of our radiation protocol for one stage bilateral patients, our overall rate of heterotopic ossification Brooker grade III or IV declined to 5.3% (three Brooker grade III cases in 56 hips).

Hip Biomechanics

The stem shaft angle increased (more valgus) significantly ($p=0.001$) between the first 100 (average 131.1 degrees, range 110 to 150) and the subsequent operations (average 137.8 degrees, range 111 to 153). The stem-shaft angle was significantly ($p=0.0255$) lower (more varus) for the patients revised for femoral loosening (average129 degrees, range 110 to 148) compared to the rest of the cohort (average 136 degrees, range 111 to 163). The stem-shaft angle was negatively correlated ($r=-0.374$, $p<0.001$) to the abductor moment arm.

In Charnley class A patients, normal hip abductor mechanics were restored as denoted by a hip ratio that was similar between the operated side (average 0.584, range 0.40 to 0.83) and the contralateral, unoperated side (average 0.571, range 0.40 to 0.78) ($p=0.193$).

Acetabular Radiolucencies

Two hundred and sixty-one hips (67%) had no radiolucencies and 122 (32%) had radiolucencies in one or two zones. There have been no progressive radiolucencies in Delee and Charnley zones I or II.

Metaphyseal Stem Radiolucencies

According to our rating scheme, sixteen hips (4.2%) that have not been revised have femoral metaphyseal stem radiolucencies score of ≥ 7. The average pain and activity scores of the group with a radiolucency score of ≥ 7 were not statistically different from the rest of the cohort. Several factors correlated with femoral fixation scores and the relationship of the main clinical factors associated with the presence of radiolucencies is summarized below.

Table 3. Clinical variables in relationship with femoral radiolucencies greater or equal to 7 based on Cox multivariate proportional hazard model (n=384). Hazard ratio represents the increase in risk of apparition of a femoral radiolucency between the mentioned group and its counterpart for comparison between groups, and between one level and the next increment for continous variables. For example, females are 3.1 times more at risk of early development of a radiolucencythan males and, in males, patients 10kg lighter than others are 1.56 times more at risk.

	Hazard ratio	**p value**	**95% confidence interval**
Whole group			
Females	3.1	0.005	1.4 – 6.3
Cysts > 1cm	2.6	0.029	1.1 – 6.3
SARI > 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 BMI*	2.63	0.062	0.95 – 7.14

***** For continuous variables, increments were the following: 10cm for height, 2mm for component size, 10Kg for weight, and 5 points for BMI.
SARI = surface arthroplasty risk index

Patients were at increased risk of radiolucency if they had a large cyst formation (p=0.029), 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 59 cemented metaphyseal stems showed any radiolucency at last review, even in cases with less than optimal bone quality.

Conversions to Total Hip Replacement

There were twelve conversions to total hip replacement (3.0%). Seven conversions were secondary to femoral loosening (Table 4) and three to femoral neck fracture.

Table 4. Occurrence of femoral loosening by subsections of 100 cases.

	# of conversions to THR for femoral loosening	**Average Follow-up (months)**
1st 100	4	62
2nd100	2	45
3rd 100	1	38
4th 100	0	32

Two neck fractures occurred within the first six weeks postoperatively and the third fracture happened at twenty months. One hip was revised to total hip replacement for recurrent subluxations. One rheumatoid patient developed a late hematogenous sepsis which was not promptly treated and required conversion to total hip replacement (direct exchange) at thirty-six months and is now sepsis free.

The demographics of the seven femoral loosenings were not different from those of the overall group. However the component stem shaft angle was 128.3° (range, 110° to148°) and was significantly different from the rest of the population (136.2°, range, 111° to 163°, p=0.0255). The time to first observed radiolucency was twenty months (range, 12.5 to 36 months) and the time to first symptoms was twenty-seven months (range, sixteen to fifty-one months). The time to revision was thirty-five months (range, twenty-three to sixty-one months). All but one of the femoral

failures were revised to total hip replacement using a unipolar head size-matched to the inside diameter of the already existing well-fixed socket.

In five of the patients who were revised to total hip replacement for femoral loosening, there was large cystic degeneration of the head and remaining bony defects after bone preparation that diminished the surface area 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. The activity levels were high and soon after surgery in four patients. (Activity score 8 in two, and 9 in two).

Discussion

The predictability of the results with total hip arthroplasty has been shown to be excellent in older age groups, but for patients forty-years-old or younger, the failure rates range from 21% to 28% at five years [1,3,29,30]. The concept of surface arthroplasty for the treatment of young and active patients has many attractive features because of its ability to preserve femoral bone.

Our early clinical results are very promising. The major factors related to femoral radiolucency are female gender and large femoral head cysts. These reflect the importance of femoral fixation, a factor that we consider crucial to long-term durability. The most significant factor determining 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) were at greater risk than those with larger head sizes. In recognition of the higher risk for this group, we cement in the femoral stem and using additional drill holes into the meticulously prepared femoral head to increase fixation area. Fixation area in the cemented femoral surface arthroplasty is, in turn, related to the quality of the bone and it is apparent that

more and or larger cyst size and a smaller femoral head adversely affect the area available for fixation.

Patient selection is critical to the success of any given procedure. By acknowledging that certain types of patients will do better than others with this procedure, at least as performed currently, we can minimize early failures. For the higher risk group there are two approaches. 1. Use alternate therapies such as THR and this is desirable for the inexperienced surgeon or 2. Improve the quality of fixation and minimize impact activities. 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%) and has been essentially eliminated in our most recent series, probably reflecting surgeon experience and optimized surgical technique. It is important to avoid or at least 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 cylindrical reaming at the recommended angle of 140° to stop reaming before the reamer touches the lateral cortex. The large osteophyte, which usually forms anteriorly, contains bone that replaces the anterior cortex and is to be removed only if there is a significant impingement in 90° of flexion and internal rotation.

The hips that sustained aseptic loosening and required revision appear to have several risk factors, which are enumerated in Table 5. Four of the hips were among the first 100 resurfaced before additional fixation holes were added to the chamfered area and the femoral suction tip was developed. Our current femoral component has a short metaphyseal stem that serves as an "antenna" and we believe this provides an early indication of the quality of fixation at the femoral bone-cement-implant interfaces. We believe that radiolucencies of magnitude 7 on our rating system are substantial and likely to progress to component loosening in time.

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 this time we do not have definitive contraindications to the surgery but those patients who have compromised bone stock, particularly large head cysts and small femoral heads, warrant special consideration and techniques for fixation. Patients also should be informed that, even though not statistically significant at this time, high activity levels (especially impact sports) may shorten the life of the implant.

The incidence of Brooker grade III & IV of 7% in the overall group is comparable to 5.8% reported by Dorn (40% males) who advocated indomethacin prophylaxis for four days [32]. We anticipated some increase in incidence of heterotopic ossification due to the additional stretching of muscles because of the technical challenges presented to preform surface arthroplasty working around the head and neck as opposed to THR and to obtain access to the acetabulum. After the first of thirty-two simultaneous bilateral arthroplasties formed Brooker grade III and IV heterotopic bone, we changed our protocol when operating on both hips at the same operation, to provide radiation using a single preoperative dose of 700 rads. This protocol has proven to be effective with only 5.3% (3 out of 56) cases of heterotopic ossification Brooker grade III or IV in this category of patients. Indomethacin remains our prophylactic recommendation for unilateral cases.

Despite the lack of clear evidence linking metal-on-metal total hips 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 from failed metal-on-metal stem-type total hips [33,34] prompted us to investigate the presence of such features in the tissues from failed Conserve® Plus cases and they were found to be present in approximately one third of the failed cases[35]. At this 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 50 patients with Conserve® Plus implants are being monitored over time and the results to date are comparable or less than those from conventional total hips with metal-on-metal bearings. [36]

Also at this time there is no associated cause and effect relationship between metal-on-metal implants and cancer that were first implanted in the 1960's [37].

In summary the clinical results have been excellent and continue to improve by critically analyzing the results and making appropriate technique changes. Survivorship comparisons of the present series with other implants should take into account the high activity levels (average 7.7) of these patients. Fifty-four percent of the patients have activity levels above a UCLA score of 8 the hightest yet recorded of any group of arthroplasty patients. Continued close follow-up of our patients is needed to better define the results and indications for this procedure. We are very encouraged by excellent clinical results and absence of any potentially negative radiographic findings of the most recent cohort of 200 Hips.

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