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Metal-on-Metal: Articulations for the New Millennium

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Abstract

Implants with metal-on-metal articulations (Metasul, Sulzer Medica, Winterthur, Switzerland [now Zimmer, Warsaw, IN]) have been used in nearly 300,000 total hip replacements. In three different clinical studies, clinical success has been demonstrated using this implant as measured by Harris hip scores, patient self-assessment, and assessment of mechanical complications. Of a study group of 924 patients who received this implant, the only reported complications were mechanical, including two cup loosenings (0.2%) and 36 dislocations (4.0%). In a randomized study, clinical results for the group that received implants with metal-on-metal articulation were comparable to those of the ceramic-on-polyethylene (control) group. Reports assessing retrieved implants with metal-on-metal articulation demonstrate low annual linear wear rates and no consequences of elevated cobalt ion levels at follow-up from 4 years to 26 years. In light of these data, the continued use of metal-on-metal articulations is recommended for any patient who does not have compromised renal function.

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Implants with metal-on-metal articulations have been used for 40 years for total hip replacement (THR) with no complications other than those experienced by patients who have undergone metal-on-polyethylene articulated THR. Initially, rapid loosening of the metal McKee-Farrar cup because of impingement of the femoral neck against the acetabular rim discouraged the continued use of this design after the early 1970s. Dandy and Theodorou[1] reported aseptic loosening in 739 THRs, with 4.4% for the acetabular component and 3.1% for the femoral component. Impingement was a primary cause of loosening. Dobbs[2] compared 273 metal-on-metal Stanmore THRs with 248 metal-on-polyethylene Stanmore THRs and reported a survivorship rate of 53% at 11 years for metal-on-metal implants compared with 88% at 8 years with metal-on-polyethylene implants. **(DVD-16.1)**

Despite concerns that biologic complications such as cancer or hypersensitivity would occur,[3,4] none of these complications has been reported clinically in the past 40 years. In one series, metal-on-metal implants had a survivorship rate of 20 years, which was comparable to that of the Charnley prosthesis.[5] Clearly, in that series the early failures of McKee-Farrar hip implants were balanced by later failures of the Charnley hip implants. For those THRs that did not have early loosening, the McKee-Farrar metal articulated hip implants could survive a long time.[5,6]

Since 1988, metal-on-metal articulation implants have been in clinical use. The manufacturer of the Metasul implant reports that approximately 300,000 of these devices have been implanted to date. Metasul implants differ from McKee-Farrar metal-on-metal articulation implants in that they are made from a smaller carbide phase in the cobalt-chromium metal, they have a standardized clearance of approximately 90 mm, and they have the ability to predictably reproduce the surface geometry and clearance using computerized tools.[7] Again, no biologic complications are known to have occurred because of an implanted Metasul implant; any complications that have occurred have been mechanical.[7] Metasul implants do not have the unusual rate of loosening of the cup (or stems) in the first 4 to 7 years as did the McKee-Farrar implant used in the 1960s and 1970s.[7-9] Design improvements including a smaller femoral neck and improved head-neck ratio decreased the incidence of component impingement.

Wear with the original McKee-Farrar and Metasul implants has been as low as anticipated. Because wear cannot be measured radiographically, it must be assessed on retrieval of the implants, and autopsy retrievals typically provide the best information. Jantsch and associates[10] found an annual linear wear rate of 1 μm/yr for

three McKee-Farrar implants retrieved 14 years after implantation. Schmalzried and associates[11] reported a combined annual linear wear of the cup and the head of 4.2 mm/yr after 20 years of implantation in five McKee-Farrar implants. In a study by Zahiri and associates[6] of 15 McKee-Farrar THR implants that were still in place at 21- to 26-year follow-up, only 4 (25%) had some osteolysis. Sieber and associates[12] reported the level of wear on 118 retrieved implants with Metasul articulation couples as less than 5 mm/yr. These measured wear levels of metal-on-metal articulations are all well below an annual linear wear level of 0.1 mm (100 μm), which is considered to be the threshold for osteolysis.[4,13,14]

To determine whether the continued use of metal-on-metal implant articulations is justified, data from the authors' clinical experience as well as data from the medical literature will be reviewed. The authors'only experience with metal-on-metal implant articulations, however, has been with the Metasul implant, and the only published data within the past 4 years are with this particular articulation couple. Therefore, data on the Metasul implant comprise the focus of this discussion.

Studies Assessing Metal-on-Metal Articulating Implants

The authors of this chapter have participated in three clinical studies of implants with metal-on-metal articulations, the clinical results of which are summarized below.

Study 1

Seventy patients (70 hips) underwent primary THR with a cemented Weber Metasul cup and an Anatomic Porous Replacement (APR) stem (Zimmer).[7] At 4- to 7-year follow-up, 16 patients had died. Two patients were contacted who reported neither pain nor revision, and they would not return for follow-up radiographs. Three patients underwent revision. At 7- to 11-year follow-up, 49 patients (49 hips) who had not undergone revision were examined clinically with radiographs. These findings were combined with those of 43 patients (47 hips) at 5- to 7-year follow-up who had a modular APR noncemented metal cup and modular Metasul insert with APR stems. This resulted in a pool of 92 patients (96 hips) who were available for follow up. The mean patient age for the overall group was 72 years (age range, 20 to 84 years). All patients were age 55 years or older at the time of the surgery, except for one patient who was 20 years old at the time of the surgery and died 1 year after surgery because of a drug overdose. Four patients (four hips) underwent previous revision because of loosening (one patient), dislocation (two patients with cemented Weber cups), or disassembly of the Metasul modular insert in the APR cups (one patient).

Clinical evaluations were performed at each follow-up visit and Harris hip scores were obtained.[15] The patient self-assessment form (modified Short Form-36, Orthographics, Salt Lake City, UT) was either completed by the patient during office visits and/or mailed to the patient for completion. Activity was graded by the classification of unlimited ambulation (can do any activity), active community ambulation (can walk at least eight blocks), limited community ambulation (can walk two blocks), household ambulation (ambulation basically limited to the house), or wheelchair bound.[16]

An AP pelvic radiograph that included the proximal femur and the entire stem as well as a 17-inch modified Löwenstein lateral radiograph (an iliac oblique view) of the involved hips were obtained. All measurements on the radiographs were corrected for magnification using the diameter of the femoral head. The immediate postoperative and all subsequent radiographs were reviewed, and any presence of osteolysis was recorded. Measurements for wear were not made from radiographs because it was impossible to radiographically distinguish between the edge of the femoral head and metal articulation surface of the acetabular components. Radiographic data regarding the presence and extent of osteolysis were classified by zones[17,18] regardless of whether cement had been used. No osteolysis, except calcar resorption, was observed in any of the patients. Calcar resorption was a focal radiolucent area that was seen immediately underneath the collar of the stem, and it was identified by its location between the calcar cortical bone and the medial stem.

Fixation by radiolucent lines on the AP and lateral radiographs was characterized using the zones described by DeLee and Charnley.[17] Femoral radiolucent lines on the AP and lateral radiographs were recorded in each of the 14 zones described by Gruen and associates.[18] Progression of a radiolucent line was defined as an increase in the number of zones occupied by and/or an increase in the width of a radiolucent line after 2 years. Loosening was defined by a circumferential radiolucent line of 1 mm in width, migration (> 2 mm of horizontal or vertical change or a change in inclination of > 5°), appearance of a radiolucent line after 2 years, or progression of radiolucent lines after 2 years.[19]

The mean Harris hip score for the 92 patients (96 hips) was 92.5, with a mean pain score of 40, and a mean limp score of 10.4. Clinical results by patient self-assessment reveal that 67 patients (70%) scored themselves as excellent, 22 (23%) scored themselves as good, 4 (4%) scored themselves as fair, and 3 (3%) scored themselves as poor. Activity levels were identified as unlimited ambulation and activities in 61 patients (63%), community ambulation of eight blocks in 14 patients (15%), limited community ambulation of two blocks in 13 patients (14%), and household ambulation in 8 patients (8%).

No focal or linear acetabular osteoly-

sis was measured in any of the 96 hips with the cemented or noncemented cups. This finding was limited to plain radiographs. Only the radiographs that were available (AP pelvis and lateral with iliac oblique) were measured. No CT scans were done.

No evidence of focal or linear osteolysis was identified in any of the 96 femurs. Six hips had calcar resorption (Figures 1 and 2). Five hips had noncemented stems and one had a cemented stem. The maximum size of calcar resorption was 5 × 5 mm. No new revisions or impending failures were reported. The only revisions were the three in the cemented cup group described previously (one as a result of loosening of one of the Weber cups and two as a result of dislocation).[7] A fourth revision occurred as a result of a disassembly of the Metasul modular insert in the APR cups. Three dislocations occurred in patients with Weber cemented cups, two of which were revised; no dislocations occurred in patients with APR noncemented cups.

On radiographic assessment, no acetabular components were determined to be loose, nor was there any evidence of migration or progressive radiolucent lines. Additionally, no femoral components were determined to be loose. Radiolucent lines, however, were observed in 16 of 96 femoral components in at least one zone, but in none was it determined to be significant enough to indicate implant loosening.

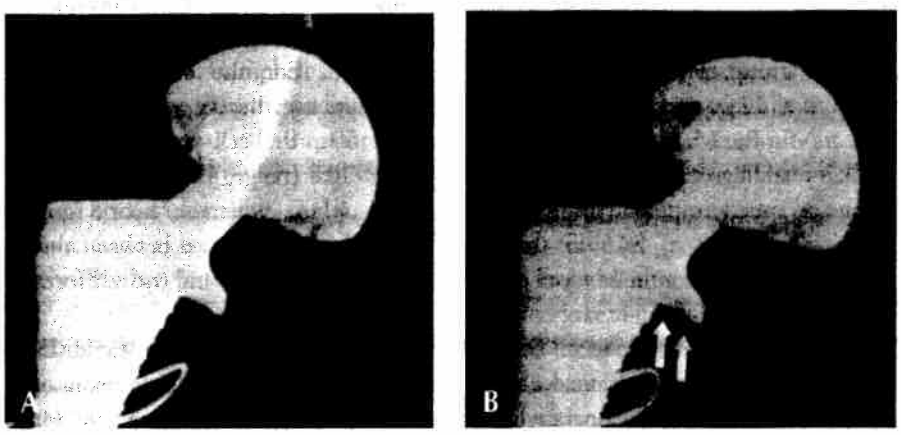

Figure 1 Radiographs demonstrating 5 of 96 hips (5%) that developed a radiolucency, 1 × 1 mm to 2 × 2 mm in size, directly beneath the collar devoid of porous coating *(arrows)*. **A**, Postoperative radiograph. **B**, Radiograph obtained at 6-year follow-up.

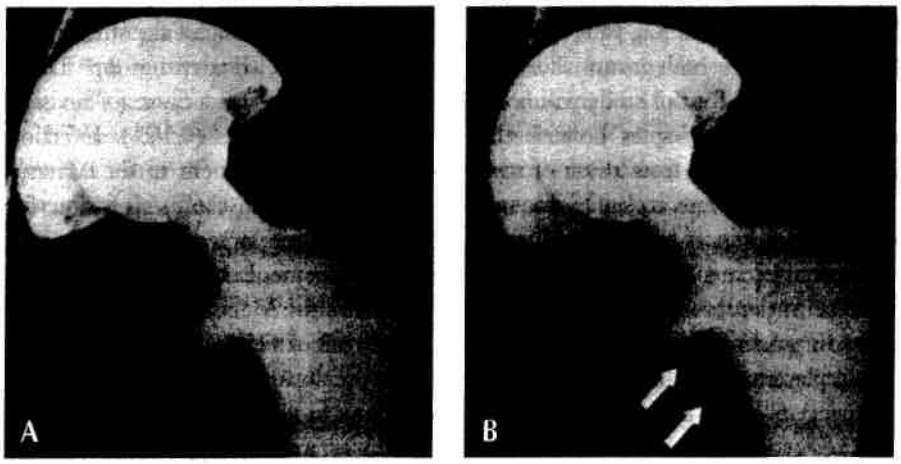

Figure 2 Radiographs demonstrating 1 of 96 hips (1%) that had a radiolucency 1 × 1 mm in size, beneath the collar, at 1-year follow-up. This radiolucency increased to 10 × 20 mm in size at 5-year follow-up *(arrows)*. **A**, Postoperative radiograph. **B**, Radiograph obtained at 5-year follow-up.

Study 2

Six hundred fifteen patients were enrolled in a multicenter investigational device exemption (IDE) randomized controlled study by the Food and Drug Administration. Patients were randomized to receive either Metasul articulation couples or ceramic (zirconia) on polyethylene couples. The metal shell used for the modular liners was the APR shell with or without screws; this is a titanium alloy metal with cancellous structured titanium porous coating. Patients who received noncemented implants also received the Natural hip stem (Sulzer Medica Zimmer, Warsaw, IN), and patients who received cemented implants also received the APR stem.

The cemented group had a total of 301 patients, with 153 receiving Metasul articulation couples and 148 receiving ceramic (zirconia) on polyethylene couples. There were 73 men and 80 women in the Metasul group and 58 men and 90 women in the ceramic group. The mean patient age was 68.9 ± 11.5 years (age range, 27 to 89 years) for the Metasul group and 68.6 ± 10.3 years (age range, 38 to 84 years) for the ceramic group. The mean patient weight was 176.3 ± 36.5 lb (weight range, 105 to 286 lb) for the Metasul group and 167.7 ± 33.3 lb (weight range, 104 to 250 lb) for the ceramic group. There were 314 patients who had cementless stems, of which 158 received Metasul articulation couples and 156 received ceramic (zirconia) on polyethylene couples. There were 111 men

and 47 women in the Metasul group and 98 men and 58 women in the ceramic (control) group. The mean patient age was 50.7 ± 12.2 years (age range, 18 to 76 years) for the Metasul group and 52.4 ± 11.7 years (age range, 19 to 86 years) for the ceramic group. The mean patient weight was 192.9 ± 38.5 lb (weight range, 95 to 308 lb) for the Metasul group and 192.5 ± 39.8 lb (weight range, 105 to 298 lb) for the ceramic group.

Clinically, the patients were evaluated using Harris hip scores preoperatively, at 3 and 6 months postoperatively, and annually thereafter. In this chapter, the preoperative 1- and 5-year postoperative Harris hip scores will be discussed. Complications were recorded for loosening, infection, dislocation, pain, and other complications for both groups. The radiographic results for this study will not be discussed in this chapter because they show no difference from those of study group 1. There were no significant radiographic differences between the noncemented and cemented stem groups.

The mean preoperative Harris hip score for patients who received a hybrid hip replacement (cemented stem) and the Metasul articulation couple was 48.4 ± 13.8 (range, 4 to 83) compared with the preoperative mean of 50.1 ± 12.7 (range, 26 to 86) for patients who received ceramic on polyethylene implants. At 1 year, the mean Harris hip score was 92.9 ± 10.5 (range, 45 to 100), and at 5 years it was 92.0 ± 11.9 (range, 36 to 100). For the patients with zirconia components at 1 year the mean score was 93.7 ± 8.9 (range, 57 to 100) and at 5 years it was 92.5 ± 10.8 (range, 48 to 100). There was no change in the 1- and 5-year mean score for either group. For the 314 patients who had cementless stems and cups, the preoperative mean score for the Metasul implant group was 47.1 ± 12.1 (range, 19 to 78) compared with 47.0 ± 13.2 (range, 17 to 85) for the ceramic group. For the Metasul implant group, the mean score was 93.8 ± 8.6 (range, 51 to 100) at 1-year follow-up and 95.2 ± 12.2 (range, 14 to 100) at 5-year follow-up. For the ceramic implant group, the mean score was 92.4 ± 10.3 (range, 50 to 100) at 1-year follow-up and 93.7 ± 10.8 (range, 41 to 100) at 5-year follow-up. As with the hybrid group, there was no difference between the 1- and 5-year scores and no difference between the groups.

The main complication was dislocation. There were 12 dislocations in each group, a total of 24 of 615 patients (4%). Two patients in the ceramic implant group and three patients in the control group (five patients) required revision because of dislocation. The other revision surgeries required included one revision for loosening of the stem in the Metasul cemented stem group. Loosening, therefore, was a cause for revision in 1 of 615 patients (0.16%). Infection occurred in one patient in the Metasul cemented group (0.16%). Revision for pain was done in one patient in the ceramic cemented group and two patients in the Metasul cemented group, a total of 3 of 615 patients (0.5%). Nine other revisions were done for other reasons (not listed), four of which occurred in the ceramic group and five in the Metasul group. The total number of revisions was 18 of 615 patients (3.0%).

Study 3

Since August 1999, the authors have selectively implanted 253 metal-on-metal articulations, 40 of which were eliminated because of failed (recalled) Inter-Op acetabular cups (Sulzer Medica). The prevalence of complications (the incidence of dislocations, infection, painful hip replacement, intraoperative fractures, and loosening of implants) for 213 metal-on-metal Metasul hip implants was tabulated from prospective data to determine whether it was different than that of the other two studies. The number of revisions that were performed were also tabulated.

No loosening of either acetabular or femoral components of these 213 total hip replacements using Metasul articulation couples occurred. There were nine dislocations (4.0%), four of which were treated with closed reduction and five with revision surgery. There was one infection (0.5%). There were three intraoperative fractures (1.4%) identified on postoperative radiographs, none of which required additional surgery. Two patients (1%) underwent revision surgery because of persistent, unexplained hip pain. These patients had a preoperative diagnosis of hypersensitivity because there was no other obvious cause of the pain. Tissue and blood serum samples from these two patients were sent to the laboratory for examination; one patient had histologic evidence of a hypersensitivity reaction in one of seven samples, and the other patient had evidence of perivascular lymphocytes in four of five samples. The exchange of the articulation surface (from Metasul to ceramic-on-polyethylene) did not result in an elimination of hip pain in either patient.

Summary

The clinical results of these three studies are consistent with those studies assessing metal-on-polyethylene articulations with these same implants.[20,21] The complications observed are all mechanical in origin, with no observed biologic complications from metal particles or ions, and no confirmed cases of metal allergy. The suggestion that patients with metal-on-metal articulating implants may have more pain because of hypersensitivity could not be confirmed by these studies. In the randomized IDE study, mean Harris hip scores did not differ significantly, and revision surgery to treat pain was done for only three patients (one with a metal-on-metal articulations and two with ceramic-on-polyethylene articulations). The data from these three studies demonstrate that the outcomes and mechanical complications for metal-

on-polyethylene and ceramic-on-polyethylene implants are comparable and that there is no evidence of abnormal early fixation loss or osteolysis in either type of implant.

There was no significant difference in the dislocation rate when comparing patients who received the metal-on-metal and ceramic-on-polyethylene implants. Although the 12 dislocations encountered by the authors in the multicenter IDE study occurred in both the metal-on-metal and ceramic-on-polyethylene implant groups, the rate of dislocations with metal-on-metal implants was higher than that reported for the APR implant with metal-on-polyethylene articulation.[21] It was also higher than that reported by Hofmann and associates[20] in a series of implants with metal-on-polyethylene articulation.

The most current information on ion levels for implants with metal-on-metal articulations has been reported by Brodner and associates.[22] The implants used in the patients studied were the titanium Zweymueller stem and cup (Sulzer Medica) fixed without cement. A metal-on-metal articulation was used in 50 patients and a ceramic-on-polyethylene articulation was used in 50 others. There was no significant difference between these groups regarding body mass index, serum creatine levels, activity levels, cup position, age, sex, or Harris hip scores. The only loose implant at 5-year follow-up was one cup in the ceramic-on-polyethylene group. The serum cobalt levels were not measurable in patients with ceramic-on-polyethylene articulations (detection limit, 0.3 mm/L). In the patients with metal-on-metal articulations, the serum cobalt levels were constant to 5 years postoperatively, with a level that averaged 1 mm/L at 1 year and 0.7 mm/L at 5 years. Jacobs and associates[23] reported serum cobalt levels of 0.9 mm/L in eight patients with McKee-Farrar implants at 25 years postoperatively. In another study, the serum cobalt levels at 25 years were not significantly different than those at 1- to 5-year follow-up.[22] Furthermore, Campbell and associates[24] recently reported the findings of an autopsy retrieval of an implant in a patient 30 years after undergoing McKee-Farrar metal-on-metal THR. This patient had a serum cobalt level of 0.9 mm/L when tested at 25 years postoperatively, which is the same level reported by Brodner and associates[22] and Jacobs and associates,[23] and no pathologic evidence of abnormalities related to metal particles or ions was detected. The total wear of this metal-on-metal cup after 30 years was measured as 70 mm (linear rate, 2.3 mm/yr), whereas 90% of Charnley metal-on-polyethylene implants have been reported to have a linear wear rate of 100 mm/yr and have survived as long as 30 years.[25]

If these increased ion levels are a potential cause of cancer, no evidence supporting this theory has been reported after 40 years of use of metal-on-metal articulations. Visuri and associates[26] evaluated patients in the Finland Registry who underwent THR (with either metal-on-polyethylene and metal-on-metal implants) and at 20-year follow-up found no evidence of elevated risk of cancer compared with the general population. It is possible that the reported elevated serum cobalt levels are the result of a mechanism in which the metal ions are rapidly excreted by the kidneys and the body adapts to these serum cobalt levels much like a tachyphylactic reaction to drugs.

The clinical success of implants with metal-on-metal articulations combined with the expected low levels of wear on retrieved implants[12] suggests that this articulation can provide a level of durability comparable to that achieved with McKee-Farrar implants. The only concern with the metal-on-metal articulating implants has been the theoretic consequences of the metal ion serum levels of cobalt.[22] Complications reported thus far in the literature, which include results with McKee-Farrar implants beyond 20 years[5,6] and 2- to 7-year results with the Metasul implant,[7-9] are typically the same type of mechanical complications that have been reported for THR implants with any articulation surface. The overall clinical findings (some of which are drawn from an ongoing study now in its 11th year) are consistent with those in the medical literature.

Mechanical complications can cause osteolysis and infection, which, in turn, can result in higher revision and mortality rates (there is a significant risk of death associated with revision THR). Mechanical complications include poor fixation surfaces (patched porous coating, for example), poor plastic quality, poor locking mechanisms of the insert in modular cups that can lead to accelerated wear and disassociation of the plastic, and poor surgical constructs (such as inferior cementing technique or the use of undersized noncemented components). Available data suggest that patients with metal-on-metal articulating implants have a greater risk for requiring revision surgery than for biologic complications such as cancer resulting from elevated ion levels. This is further supported by the fact that there is not a single report in the literature that correlates metal-on-metal articulating implants with cancer.

Clinical data have demonstrated successful outcomes in patients with metal-on-metal articulating implants, retrieval data demonstrating low wear as was anticipated from laboratory studies, radiographic findings demonstrating low prevalence of osteolysis in patients with metal-on-metal articulating implants, and a 40-year track record demonstrating no clinical consequences to the elevated serum cobalt ion levels found in patients with these implants. As a result, the authors recommend the continued use of metal-on-metal articulating implants for THR in any patient with normal renal function.

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