

The Argument for the Use of Metasul as an Articulation Surface in Total Hip Replacement

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Metasul metal-on-metal articulations have been used for 15 years in approximately 300,000 total hip replacements. We have used Metasul articulations in three clinical studies and have shown clinical success as measured by Harris hip scores and patient self-assessment; we also have had the usual mechanical complications. The only complications have been mechanical, including two cup loosening and 24 dislocations in a total of 582 patients (619 hips; 3.8%) who had Metasul articulations and were included in these studies. In the randomized study, the group who had Metasul articulations had no clinical results or complications different from the control ceramic-on-polyethylene group. Authors of retrieval results in the literature report low annual linear wear rates and no consequences of elevated Co ion levels. Currently, the scientific evidence of the results of using the Metasul articulation would recommend its continued use in any patient who does not have compromised renal function.

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 metal-on-polyethylene (PE) articulated THRs. Initially, rapid loosening of the metal McKee-Farrar cup discouraged the continued use of this design after the early 1970s. Dandy and Theodorou⁴ reported aseptic loosening in 739 THRs with 4.4% for the acetabular component and 3.1% for the femoral component. Impingement was a prime cause of loosening. Dobbs⁶ compared 273 metal-on-metal Stanmore THRs with 248 metal-on-PE THRs. He intro-

duced survivorship to the orthopaedic literature with this study and had a survival rate of 53% at 11 years for metal-on-metal, compared with 88% at 8 years for metal-on-PE.

In spite of the concerns of some authors that biologic complications such as cancer or hypersensitivity would occur,^{12,28} currently none have been reported clinically. Metal-on-metal implants in one series have survived for 20 years with the same survivorship that occurred with the Charnley prosthesis.¹⁷ In that series, the early failures of McKee-Farrar hips were balanced by later failures of the Charnley hips. For those THRs that did not have early loosening, the McKee-Farrar metal articulated hips could survive a long time.^{17,30} Since 1988 the Metasul metal-on-metal articulation (Zimmer, previously Sulzer, Winterthur, Switzerland) has been in clinical use. Zimmer reports that approximately 300,000 of these articulations have been implanted. The differences with these implants, compared with McKee-Farrar metal-on-metal, are a smaller carbide phase in the Co-Cr metal, a standardized clearance of approximately 90 μ , and the ability to predictably reproduce the surface geometry and clearance by computerized tools.⁸ Currently, no biologic complications are known to have occurred because of an implanted Metasul articulation. The failures of these hip replacements have been mechanical.⁸ An unusual rate of loosening of the cup (or stems) in the first 4 to 7 years postoperatively has not occurred, which eliminates the early failure mechanism of the McKee-Farrar design of the 1960s and 1970s.^{8,24,26}

Wear with the original McKee-Farrar designs and the Metasul implants has been as low as anticipated. Wear cannot be measured radiographically, so assessment of wear has been done on retrievals, with autopsy retrievals providing the best information. Jantsch et al¹⁸ found an annual linear wear rate of 0.001 mm for three McKee-Farrar implants retrieved 14 years after implantation. Schmalzreid et al²⁰ reported a combined annual linear wear of the cup and the head of 4.2 μ m per year after 20 years of implantation in five McKee-Farrar hips. In a study

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by Zahiri et al³⁰ of 15 hips with McKee-Farrar THRs still in place at 21 to 26 years postoperatively, only 4 of the 15 (25%) had some osteolysis. Sieber et al²¹ reported the wear of 118 retrievals with Metasul articulation couples as 5 μ per year after the third year. They had retrievals that had been in place for as long as 8 years. These measured wear levels of metal-on-metal articulations are all well below an annual linear wear of 0.1 mm (100 μ m), which is considered to be the threshold for osteolysis.^{9,25,28}

It would seem that these highly favorable wear rates and absence of biologic complications would result in the recommendation of using the current Metasul metal-on-metal as a bearing surface that can be implanted with confidence of durability and only the usual mechanical complications or biologic complications as a result of mechanical failure.

Questions that any surgeon would ask are: (1) Are the clinical results as good as metal-on-PE articulations, (2) are the mechanical complications no greater than those seen with metal-on-PE articulations, and (3) is there radiologic evidence of osteolysis or loss of early fixation? If the answers to these questions are favorable for patients, then continued use by surgeons of Metasul as an articulation surface is justified. The purpose of this report is to answer these questions according to the results of studies in which we participated. We only have experience with Metasul articulations, and the only published data of 4 years or more are on this articulation couple, so the results with Metasul will be the focus of the data.

MATERIALS AND METHODS

We have participated in three clinical studies, and the clinical results of these three studies will be summarized for this report. These are new data that have not been published previously except for the report on the cemented Weber cups (Zimmer, previously Sulzer, Winterthur, Switzerland).⁸

One hundred twenty-four patients (127 hips) were operated on in studies before the Food and Drug Administration (FDA) approval of Metasul articulations in August 1999. Seventy patients (70 hips) had a primary THR with a cemented Weber Metasul cup and an Anatomic Porous Replacement stem (APR, Zimmer, Warsaw, IN). The postoperative results for this group of patients at 4-year to 7-year followup have been published.⁸ For this report, we combined patients who had the cemented Weber cup and the noncemented APR cup. Sixteen patients (16 hips) died, two patients (two hips) were contacted and did not have pain and had not had revision surgery but would not return for radiographs, and four patients (four hips) had revision surgery. Forty-nine patients (49 hips) with a 7-year to 11-year followup were alive, had not had revision surgery, and were examined clinically with radiographs at their last followup. These patients were combined with 43 patients (47 hips) with 5-year to 7-year followup who had a modular-APR noncemented metal

cup and modular Metasul insert with APR stems. This resulted in a total of 92 patients (96 hips) alive with complete followup for this report. The mean patient age was 60 years (range, 27–85 years). Four patients (4 hips) previously had revision surgery because of loosening in one patient and dislocation in 2 patients with the cemented Weber cup, and disassembly of the Metasul modular insert in the APR cup in 1 patient.

Clinical evaluations were done at each followup visit using the Harris hip score¹⁴ and patients were evaluated by a research assistant (LES) independent of the operating surgeon.

The patient self-assessment form (modified SF-36, Orthographics, Salt Lake City, UT) was either completed by the patient at office visits and/or mailed to the patient for completion. Activity was graded by the classifications of unlimited ambulation (does any activity that the patient wants to do), 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.⁷

An AP pelvic radiograph that included the proximal part of the femur and the entire stem, and a modified Lowenstein lateral radiograph, which was an iliac oblique view, of the involved hips were done and measurements were done by a research physician independent of the operating surgeon (ZW). All measurements were corrected for magnification using the diameter of the femoral head. The immediate postoperative radiograph and all subsequent radiographs were reviewed, and any presence of osteolysis was recorded. Measurements for wear were not able to be done using radiographs because it was not possible to distinguish between the edge of the femoral head and metal articulation surface of the acetabular components. The radiographic evaluation for the presence and extent of osteolysis was done by zones^{5,11} regardless of whether cement had been used. 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 was measured with the use of the zones described by DeLee and Charnley⁵ on the AP and lateral radiographs. Femoral radiolucent lines were recorded in each of the 14 Gruen zones on the AP and lateral radiographs.¹¹ Progression of a radiolucent line was defined as an increase in the number of zones and/or an increase in the width of a radiolucent line that appeared after 2 years. Loosening was defined by a circumferential radiolucent line of 1 mm in width, migration (more than 2 mm of horizontal or vertical change, or a change in inclination of more than 5°), appearance of a radiolucent line after 2 years, or progression of radiolucent lines after 2 years.²²

Five hundred sixty-one patients (615 hips) were enrolled in a multicenter investigational device-exemption (IDE) randomized controlled study by the FDA. Randomization was done between patients with Metasul articulation couples and patients with ceramic zirconia-on-PE couples (Zimmer, previously Sulzer, Winterthur, Switzerland). The metal shell used for the modular liners was the APR shell with or without screws, which is a Ti alloy metal with cancellous-structured Ti porous coating. The stem used for the patients in the noncemented group was the Natural

hip stem (currently Zimmer, Austin, TX) and the stem used for the patients in the cemented group was the APR stem.

The cemented group had 278 patients (301 hips) with 142 patients (153 hips) receiving the Metasul couple and 136 patients (148 hips) receiving ceramic-on-PE (control group). There were 73 hips in men and 80 hips in women in the Metasul group and 58 hips in men and 90 hips in women in the ceramic group. There were 283 patients (314 hips) who had cementless stems, with 141 patients (158 hips) receiving Metasul couples and 142 patients (156 hips) receiving ceramic couples. There were 111 hips in men and 47 hips in women in the Metasul group and 98 hips in men and 58 hips in women in the ceramic (control group). The demographics for these patients are shown in Table 1.

Clinically, the patients were evaluated by Harris hip scores preoperatively and the 5-year hip score is listed in Table 1. Complications also were recorded for loosening, infection, dislocation, pain, and a category of other for the Metasul and the ceramic groups (Table 2). The radiographic results for this IDE study will not be included in this report because they do not show any difference from those of the 92 patients (96 hips) with the cemented Weber cup and noncemented APR cups who were followed up for 5 to 11 years. There were no significant radiographic differences between the noncemented and cemented stem groups in this IDE study.

We have implanted 253 Metasul articulations in 246 patients in a selective manner since the FDA approval of Metasul in August 1999. Thirty-eight of these patients (40 hips) were eliminated because they had revision surgery from failed recalled Interop cups (Sulzer, Austin, TX). The prevalence of complications for 208 patients, (213 hips) could be tabulated from the computer data of these patients, which have been observed in a prospective manner. The data of interest from this study for this report are simply the occurrence of complications to determine if these were any different from those in the other 2 groups that have been reported in more detail.

RESULTS

The first purpose of this report was to examine clinical results. Clinical results by the Harris Hip Score are listed in Table 1. The clinical results for the group of 92 patients with 96 hips, as measured by patient self-assessment showed 67 patients (70%) scored themselves as excellent; 22 patients (23%) scored themselves as good; four patients

(4%) scored themselves as fair; and three patients (3%) scored themselves as poor. Activity levels for these same 92 patients were unlimited ambulation and activities in 61 patients (63%), community ambulation of eight blocks in 14 patients (15%), limited ambulation of two blocks in 13 patients (14%), and household ambulation in eight patients (8%).

A second purpose of this report was to determine the mechanical complications that occurred with these studies (Table 2). Revisions were done in each of the studies. In the study of 96 patients with 96 hips, four (4.2%) had revision with one for a loose cup, two for dislocation, and one for disassembly of the PE in the modular cups. In the IDE study with 615 hips, 10 of the revisions in the Metasul group were for loosening of the stem in one, revision for pain in two, two because of dislocation, and five for reasons not listed. Revisions in the ceramic (control) group were three for dislocation, pain in one, and four for reasons not listed. The total number of revisions was 18 of 615 hips (3.0%). In the group of 213 hips there were two revisions for pain, and five for dislocations. The two patients operated in this group because of a painful hip (1%) were surgically treated with a preoperative diagnosis of hypersensitivity. Tissue and blood serum samples were sent to the laboratory for examination. One patient (one hip) had one of seven samples with histologic evidence of perivascular lymphocytes and the second patient had four of five specimens with perivascular lymphocytes. Neither patient had blood serum levels of allergy to the implant.¹¹ Neither patient had elimination of the hip pain because of the exchange of the articulation surface from Metasul to ceramic-on-PE.

The third area of investigation in this report was the occurrence of early fixation loss or osteolysis. In the group of 92 patients with 96 hips there was one loose cup that occurred in 5-year to 11-year followup. Osteolysis only was observed as calcar resorption, which was present in 6 of 96 (5.5%) hips. Five of these hips had noncemented stems and one had a cemented stem. The maximum size of calcar resorption was 5 mm by 5 mm for revision. In the IDE study of 615 hips, revision for loosening occurred

TABLE 1. Demographics

Study	Number of Hips at Final Followup	Followup by Year	HHS Score (range)	Age in Years (range)	Weight in Kilograms (range)
Weber/APR/cup	96	5-11	92.5	60 ± 14.9 (27-85)	NA
IDE Metasul cemented stem	153	5	92 + 12 (36-100)	69 ± 12 (27-89)	80 ± 17 (48-130)
IDE ceramic cemented stem	148	5	93 + 11 (48-100)	67 ± 10 (38-84)	76 ± 15 (47-113)
IDE Metasul noncemented stem	158	5	95 + 12 (14-100)	51 ± 12 (18-76)	88 ± 18 (43-140)
IDE ceramic noncemented stem	156	5	94 + 11 (41-100)	52 ± 12 (19-86)	88 ± 18 (48-135)

NA = not available; HHS = Harris hip score; IDE = investigational device exemption

TABLE 2. Complications

Study	Number of Hips	Number of Patients Failed with Pain	Dislocations	Infections	Intraoperative Fractures	Radiographically Loose Implants	Revisions
Weber APR cup	96	3 (3.1%)	3 (3.1%)	0	0	0	4 (4.2%)
IDE Metasul articulation	311	2 (0.6%)	12 (4%)	1 (0.16%)	NA	0	10 (3.2%)
IDE ceramic controls	304	1 (0.3%)	12 (4%)	0	NA	7	8 (2.6%)
Post 1999	213	2 (1%)	9 (4%)	1 (0.5%)	3 (1.4%)	0	7 (3.3%)

NA = Not available; IDE = investigational device exemption

only in one of 615 hips (0.16%), which was a stem in the group that had Metasul cemented stems. In the third group of 213 THRs, there were no loose implants (acetabular or femoral), and no revisions for loose components. There was no osteolysis measured in the xrays of these patients.

DISCUSSION

The data from these three studies provide answers for the three questions asked as the purpose of this report: the current results are as good as metal-on-PE or ceramic-on-PE THRs; the mechanical complications are no greater than metal-on-PE or ceramic-on-PE hips; and there is no evidence of abnormal early loss of fixation or osteolysis. The limitations of this study are that wear cannot be measured in metal-on-metal articulations; therefore, no knowledge is present of the rate of wear and this prevents any estimate as to whether fixation loss and/or osteolysis could accelerate in the future. Also, the patients in these studies have been followed for fewer than 10 years and the occurrence of osteolysis is more prevalent in the second decade of joint replacement.

The clinical results of these three studies have results consistent with those reported using metal-on-PE articulations with these same implants.^{15,19} The complications observed all were mechanical in origin with no suggestion of biologic complications from metal particles or ions. The suggestion that patients with metal-on-metal articulations may have more pain because of hypersensitivity could not be confirmed by these studies. In the randomized IDE study, the Harris hip scores were not different and there was only one revision for pain for patients with Metasul articulations and two revisions for patients with ceramic-on-PE articulations.

Hypersensitivity is a diagnosis based on pathological findings by Willert et al²⁷ of lymphocytes adjacent to blood vessels in capsules of retrievals from failed metal-on-metal THRs. There are no reports of this being a clinical finding or reason for revision. In the third group of 213 patients in these current studies there were two patients

who were reoperated on because of pain. Neither was cured of their pain by changing the articulation surface from Metasul to ceramic-on-PE and the metal acetabular components and noncemented stems in both patients were well fixed. The blood tests in these patients were tested at another institution and the findings did not support an allergic reaction to the Co.¹³ Therefore, there is no evidence in these three studies for increased failure by either unexplained pain or occurrence of hypersensitivity.

The clinical success of Metasul articulations combined with the expected low levels of wear as observed on retrievals²¹ suggests that this modern metal-on-metal articulation can provide durability, as did successful McKee-Farrar hips. The only concern with Metasul has been the theoretical consequence of the metal ion serum levels of Co that have been measured.¹ Certainly the complications currently reported in the literature, which include results with McKee-Farrar hips over 20 years^{17,30} and 2-year to 7-year results with Metasul articulations,^{8,24,26} are only mechanical complications that also have been observed with THRs of any articulation surface. The results of the three clinical studies in this report are consistent with the historical publications, with one study currently having results up to 11 years.

Recent reports of well-fixed implants, both cemented (hybrid hip replacement)² and noncemented stem and cup¹⁰ have shown the improvement with fixation in PE articulations. Brown and Lachewicz² in 1999 reported 98 hips with hybrid fixation at 6.5 years (range, 5–9 years) postoperatively and had only one loose stem. The wear averaged 0.06 ± 0.05 mm per year with 2 of 98 (2%) having osteolysis in the femur and 4 of 98 (4%) having osteolysis in the acetabulum. Grubl et al¹⁰ had 100% of Alloclassic grit-blasted cups and stems (Zimmer, Winterthur, Switzerland) fixed at 10 years and the wear was 0.1 mm per year and no osteolysis was observed of the femur or pelvis. The articulation surface was a ceramic head mated against ultra-high molecular weight PE gamma sterilized in an inert gas atmosphere.

The most current information on ion levels with Metasul articulations has been reported by Brodner et al.¹ The implants used in the patients studied were the Ti Zweymueller stem and cup fixed without cement. In 50 patients a Metasul articulation was used, and in 50 others a ceramic-on-PE articulation was used. There was no significant difference between these patients in body mass index, serum creatine level, activity, cup position, age, gender, or Harris hip score. The only loose implant at 5 years was one cup in the patients with ceramic-on-PE articulations. The serum Co levels were not measurable in patients with ceramic-on-PE articulations (detection limit, 0.3 μ per L). In the patients with Metasul articulations the Co levels were constant up to 5 years postoperatively with a level that averaged 1 μ per L at 1 year and 0.7 μ per L at 5 years. Jacobs et al¹⁵ reported Co levels of 0.9 μ per L in eight patients at 25 years postoperatively with McKee-Farrar hip replacements. The serum Co levels at 25 years were not different from those at 1 to 5 years in the study of Brodner et al.¹ Furthermore, Campbell et al³ reported recently the findings of an autopsy retrieval of a patient 30 years after McKee-Farrar metal-on-metal THR. This patient had had a serum Co level of 0.9 μ per L when tested at 25 years postoperatively and this is the same level as found in the patients of Brodner et al¹ and Jacobs et al.¹⁶ The organs of this patient had no pathological abnormalities related to metal particles or ions. The wear of this metal-on-metal cup after 30 years was a total of 70 μ (L rate, 2.3 μ per year). Ninety percent of Charnley metal-on-PE hips, which have a linear wear rate of 100 μ per year, have been durable for up to 30 years.²⁹

If these increased ion levels were a cause of cancer, there is no evidence after 40 years of use of metal-on-metal articulations. Visuri et al²³ evaluated patients in the Finland registry who were 20 years postoperative and found no evidence of elevated risk of cancer compared with the general population, in patients with both metal-on-PE and metal-on-metal THRs. It is possible that the elevated serum Co levels measured in studies rapidly are excreted by the kidneys and that the body adapts to these serum levels much like a tachyphylactic reaction to drugs.

Mechanical complications can cause biologic consequences of osteolysis and infection, which can cause higher revision rates (and there is a death rate related to revision THR). The occurrence of revision THR has been increased by poor mechanical constructs such as poor fixation surface (patched porous coating is such an example); poor plastic quality; poor locking mechanisms of the insert in modular cups that leads to accelerated wear and disassociation of the plastic; and poor surgical constructs (such as inferior cement technique or undersized noncemented components). It would seem that the data available suggest that a patient with a Metasul articulation has a greater risk

for having revision surgery, and even death from a complication of revision surgery, than from a biologic complication such as cancer from elevated ion levels. This statement is supported by the fact that there is no report in the literature of a correlation between metal-on-metal articulations and cancer.

The clinical data of success in patients with Metasul articulations, the retrieval data of low wear as anticipated from laboratory studies, the radiographic findings of low prevalence of osteolysis, and the historical data of 40 years with an absence of clinical consequences of elevated serum Co ion levels encourage us to continue to use Metasul articulations in any patient who does not have abnormal renal function, which would not allow clearance of the serum ions.

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