Fixation and Osteolysis With Metasul Metal-on-Metal Articulation

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Abstract: The purpose of this study was to report the prevalence of osteolysis and loss of fixation using Metasul metal-on-metal articulation couples. Ninety-two patients with 96 hips with Metasul articulation couples were followed for 5 to 11 years. By patient self-assessment, 89 (93%) patients scored themselves as good or excellent. The occurrence of osteolysis and the grading of fixation were obtained from plain radiographs. The clinical evaluation for these patients was performed by patient self-assessment. With the use of plain radiographs, there was no osteolysis observed in these 96 hips other than calcar resorption (6 hips [6.3%]). All components were fixed, except for 1 loose cup that was revised, and this level of fixation allowed a fair evaluation for osteolysis around well-functioning implants. Key words: Metasul, metal-on-metal, fixation, osteolysis, hip arthroplasty.

A new metal-on-metal articulation for total hip arthroplasty (Metasul, Centerpulse Orthopedics, Austin, TX) was introduced in the late 1980s because of concern with the effect of polyethylene debris on bone [1,2]. In the 1990s, osteolysis was the predominant cause of reoperation of total hip arthroplasty [3,4]. The possibility of manufacturing metal-on-metal articulation that did not cause excessive loosening of the acetabular component and maintained a low volume of wear debris was suggested by Dr. Bernard Weber of Switzerland [5]. We used the Metasul metal-on-metal couple since 1991. Initially, the cemented Weber cup (Centerpulse, Austin, TX) was used, and the 4- to 7-year results in these patients have been reported [6]. Subsequently, a Food and Drug Administration (FDA) investigational device–exemption study was performed with the porous-coated modular anatomic porous replacement cup (APR, Centerpulse, Austin, TX) using a modular polyethylene-backed Metasul insert. Since 1999, Metasul has had FDA approval for community use. The purpose of this study was to determine if loosening and osteolysis occurred in the patients with both cemented and noncemented cups with Metasul couples and 5 to 11 years of follow-up.

Materials and Methods

The surgeries were not performed in a consecutive fashion, nor were they randomized. There was a limitation in the number of cemented monoblock components that were available at random times at the beginning of this study. The cementless modular components were performed as an investigational device–exemption study.
The cemented monoblock Weber cup had a stainless-steel outer mesh, a polyethylene substrate, and a 3-mm cobalt-chrome metal articulation surface molded into the polyethylene. The technical details of this component have been previously published [6]. Seventy patients with 70 hips initially had a primary total hip arthroplasty with the cemented Metasul metal-on-metal articulation. Sixteen patients with 16 hips had died; none of these deaths resulted from the surgery. All of these patients had been followed postoperatively and had well-functioning hips at the time of death. Two patients were contacted, did not have pain, and had not been revised; however, they would not return or obtain radiographs. Three hips were revised and previously reported [6]. Forty-nine patients with 49 hips with a 7- to 11-year follow-up were alive and not revised. They were examined clinically and with radiographs at last follow-up.

In 1995, a modular Metasul couple was used with the anatomic porous replacement cup. Fifty-two patients with 57 hips initially had a primary total hip arthroplasty with the cementless Metasul metal-on-metal articulation. Four patients with 4 hips died; none of these deaths resulted from the surgery. All of these patients had been followed postoperatively and had well-functioning hips at the time of death. Four patients (or their family) with 5 hips were contacted and did not have pain, and had not been revised; however, they would not return or obtain radiographs. One patient with 1 hip was revised for a disassembled insert. Forty-three patients with 47 hips with a 5- to 7-year follow-up were alive and not revised. They were examined clinically and with radiographs.

Because the focus of this study was the occurrence of osteolysis and/or fixation failure, these hips were combined into a single group. Combining cemented and cementless Metasul couples, there were 124 patients with 127 hips. Twenty patients with 20 hips died, 6 patients with 7 hips were lost to follow-up, and 4 hips were revised, leaving 92 patients with 96 hips alive with complete follow-up. The mean patient age was 72 years (range, 20–84 years). All patients were 55 years or older at the time of surgery, except for 1 patient who was 29 years at the time of surgery and died 1 year after surgery from a drug overdose. The principal diagnosis of these 96 hips was osteoarthritis in 75 patients, avascular necrosis in 12, posttraumatic arthritis in 5, congenital hip dysplasia in 3, and rheumatoid arthritis in 1 patient.

Four patients with 4 hips had been previously revised because of loosening in 1 hip, 2 with dislocation with the cemented Weber cup [6], and 1 with disassembly of the Metasul modular insert in the anatomic porous replacement cups. The diagnosis for all 4 was osteoarthritis. The mean age at the time of surgery for these 4 patients was 63.5 years (range, 47–71 years). Three of these hips had a noncemented stem, and 1 had a cemented stem.

Clinical evaluations were performed at each follow-up visit using the Harris Hip Score [7]. The patient self-assessment form (Modified SF-36, Orthographics, Salt Lake City, UT) was completed by the patient either at office visits and/or by mail. Activity was graded by the classification of unlimited ambulation (performs any activity that they want to do), active community ambulation (can walk at least 8 blocks), limited community ambulation (can walk 2 blocks), household ambulation (ambulation basically limited to the house), or wheelchair-bound [8].

An anteroposterior pelvic radiograph was made of the involved hips that included the proximal part of the femur and the entire stem as a modified Lowensteint lateral radiograph, which was an iliac oblique view. 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 from radiographs were not able to be performed, because it was not possible to distinguish between the edge of the femoral head and the metal articulation surface of the acetabular components. The radiographic criteria for the recording of the presence and extent of osteolysis were the same for all hips, regardless of whether cement had been used. Linear acetabular osteolysis by zones [9] in cemented cups, and focal osteolysis [2] in noncemented cups, was measured on the anteroposterior and lateral radiographs. Femoral osteolysis was measured in each of 14 zones on the anteroposterior and lateral radiographs as described by Gruen et al [10]. If a single osteolytic lesion spanned 2 or more zones, each zone was recorded as being involved by the lytic process. The length and width of any lesion was manually measured with digital calipers (Fowlew Sylvac, Zurich, Switzerland) on the anteroposterior and lateral radiographs; from these measurements, the size of the lesion could be determined.

Calcar resorption was a focal radiolucent area that was seen immediately underneath the collar of the stem. It was identified by its location between the calcar cortical bone and the medial stem. These small radiolucent areas were not considered in the definition of osteolysis by Goetz et al [5].
Fixation by radiolucent lines was measured with the use of the zones described by Delee and Charnley [9] on the anteroposterior and lateral radiographs. Femoral radiolucent lines were recorded in each of the 14 Gruen zones on the anteroposterior and lateral radiographs [10]. 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 1 mm in width, migration (>2 mm of horizontal or vertical change, or a change in inclination >5°) appearance of a radiolucent line after 2 years, or progression of radiolucent lines after 2 years [11].

All data were analyzed statistically using SPSS software (SPSS Inc., Chicago, IL). Categorical variables were analyzed with the use of the chi-square test or Fisher’s exact test where appropriate. The Student 2-tailed t-tests were used to compare continuous variables.

Results

Clinical results using the Harris Hip Score showed a total score for the 96 hips of 92.5, a pain score of 40, and a limp score of 10.4. Clinical results by patient self-assessment showed that 67 patients (70%) scored themselves excellent, 22 patients (23%) scored themselves good, 4 patients (4%) scored themselves fair, and 3 patients (3%) scored themselves poor. Activity levels were unlimited ambulation and activities in 61 patients (63%), community ambulation of 6 blocks in 14 patients (15%), community ambulation of 2 blocks in 13 patients (14%), and household ambulation in 8 patients (8%).

No focal or linear acetabular osteolysis was measured in any of the 96 hips with the cemented or noncemented cups. This finding was limited to plain radiographs. We measured only the radiographs that we had available (anteroposterior pelvis and lateral with iliac oblique). No computerized axial tomographic scans were performed. No focal or linear osteolysis was measured in any of the 96 femurs.

Six hips had calcar resorption. Five hips had noncemented stems, and 1 hip had a cemented stem. The maximum size of calcar resorption was 5 × 5 mm. There were no new revisions or impending failure in these hips. The only revisions were the 4 previously described, with 3 of these previously reported [6].

Twenty-two of 96 hips had radioluencies at the bone-cement or bone-component interface of the acetabular component. Fifteen of these 22 hips had a radiolucent line in 1 zone and 7 in 2 zones. No noncemented acetabular components had progressive radiolucent lines, none had migration, and none was graded as being radiographically loose. No cemented acetabular component had linear osteolysis or migration, and none were loose.

A radiolucent line was seen in 16 of 96 femoral components in at least 1 zone of either the bone-cement or the bone-component interface. Thirteen of these femoral components were noncemented, and 3 were cemented. Seven of 13 noncemented stems had a radiolucent line only in zone 4; 3 had a radiolucent line in 1 zone other than zone 4; 1 had radioluency in 5 zones; and 2 had radiolucencies in 8 zones. The single hip that had radioluencies in 5 zones and the 2 that had radiolucencies in 8 zones did not have any radiolucencies in the proximal porous-coated zones, and thus were not graded as loose stems. Three cemented stems had a radiolucent line in 1 zone only. No hip had a progressive radiolucent line at the time of the latest follow-up. No stem had migration, and none was graded as radiographically loose.

Discussion

The total hip arthroplasties in these patients were successful. There were 4 revisions in the original cohort of 127 hips (3.2%), with 1 performed because of loosening of the cup and 3 because of dislocation. It is important that all components, except 1 cup, were well-fixed. In many studies, just the stem or cup are reported in detail, with a failure rate and reoperation of 13% to 56% for the opposite component [3,4,12–15]. In this study, a fair measurement of isolated osteolysis could be performed because the components of our hips, whether fixed with cement or noncemented, were in place and not loose.

Osteolysis was absent in these patients with Metasul articulation—at least with the radiographs used to measure for this. Calcar resorption, which was indicated by small focal, radiolucent areas immediately beneath the collar of the prostheses, was seen in 6 of 96 hips. Goetz et al [4] did not consider calcar resorption in the definition of osteolysis, because it was difficult to differentiate whether this was caused by stress shielding or lysis. We elected to consider this as lysis for completeness of reporting.

One weakness of this study was that radiographic views other than the anteroposterior pelvis and
lateral femur with pelvis iliac oblique view may have revealed some lesions. Claus et al [16] reported that anteroposterior radiographs had a sensitivity of 47% (chance of seeing a lesion), and that the iliac oblique view added just 16% sensitivity. Four views (anteroposterior, lateral, iliac, and obturator oblique views) gave 73% sensitivity. Therefore, osteolysis that we did not observe may be present in our hips. A second weakness was the mixture of noncemented and cemented cups, which have different forms of osteolysis. However, there was no linear osteolysis of the cemented cups and no focal osteolysis of the noncemented cups; thus, it was not necessary to further differentiate between them.

The problem of osteolysis dominated the discussion of total hip arthroplasty in the 1990s [3–5,12–15]. Historical evidence of osteolysis in the literature shows a prevalence of 18% to 39% of hips with osteolysis. Interestingly, improvements in fixation, in polyethylene preparation, the use of oxygenless packaging, and congruence of the polyethylene into the metal shells seems to have lowered the prevalence of osteolysis and excessive wear, even without the use of alternate bearing surfaces such as Metasul. We showed that there was a correlation of wear and osteolysis to poorly fixed stems with the anatomic porous replacement I prosthesis [14,17]. Recent reports of well-fixed implants, both cemented (hybrid hip arthroplasty) [18] and noncemented stem and cup [19] have illustrated the improvement with fixation and polyethylene preparation. Brown and Lachewicz [18] reported on 98 hips with hybrid fixation at 6.5 years’ (range, 5–9 years’) postoperatively, and had only 1 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%) in the acetabulum. Grubl et al [19] had 100% of Alloclassic grit-blasted cups and stems (Centerpulse Orthopedics, Winterthur, Switzerland) fixed at 10 years, with wear being 0.1 mm per year and no osteolysis observed in the femur or pelvis. The articulation surface was a ceramic head mated against ultra-high-molecular-weight polyethylene gamma-sterilized in an inert-gas atmosphere.

New articulation couples such as Metasul were designed as a response to osteolysis. Metasul did not perform better, in the same time period postoperatively, than one series of hybrid hip arthroplasty with metal-on-polyethylene articulation [18] or the grit-blasted Alloclassic stem with ceramic-on-polyethylene articulation [19]. Metasul is associated with less osteolysis, and certainly fewer cup revisions, than the most commonly used noncemented total hip arthroplasties of the 1990s [4,5,12–15]. Focus on articulation surfaces in the next 5 years will help clarify whether changes in polyethylene preparation performed in the 1990s, such as highly crossed linking, sterilization in inert gases, and design changes for better congruence, have lessened the need for hard-on-hard couples. To best evaluate the performance of articulation surfaces, authors should report results of total hip arthroplasties—not just stems or cups—combined with the prevalence of wear and osteolysis. The performance of an articulation couple can only truly be evaluated and compared if both the stem and cup are well-fixed.

References