

An American Experience With Metal-on-Metal Total Hip Arthroplasties

A 7-Year Follow-Up Study

William T. Long, MD, Lawrence D. Dorr, MD, and Vlad Gendelman, MD

Abstract: This study reviews the clinical performance of 161 hip arthroplasties (154 patients) with the Metasul metal-on-metal articulation and an uncemented modular acetabular component. Between 1995 and 2002 clinical evaluation and radiographic follow-up of patients included Harris hip scores, patient self-assessment, and radiographs. Twelve operative site complications (7.5%) included 6 revision operations, (3.7%) and 3 other complications (1.9%) not needing reoperation. Six revision operations (3.7%) included 1 femoral revision for aseptic loosening (0.06%) and 5 acetabular revisions (3.1%). One cup revision was for recurrent dislocation, 1 for disassociation of the acetabular insert from the cup, 1 for infection, and 2 for unexplained pain. Histologic evidence did not support the diagnosis of metal hypersensitivity in either case of unexplained pain, and 1 had relief following spine surgery. A focal radiolucency, identified as calcar resorption, was observed in 9 patients. **Key words:** total hip arthroplasty, metal-on-metal, aseptic loosening.

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Total hip arthroplasty with the use of cobalt chromium alloy (CoCrMo) metal-on-metal articulations was popularized by McKee and coworkers and Watson-Farrar [1,2]. Early acetabular loosening due primarily to impingement [3,4] discouraged the continued use of these metal-on-metal hip arthroplasties. Longer follow-up of patients with McKee-Farrar hip arthroplasties showed that bearing surface wear and osteolysis were not major causes of failure [5]. The combined annual linear wear of the cup and the head of .0042 mm was established by Schmalzried on McKee-Farrar retrievals [5,6]. The

annual linear wear of 0.01 mm (100 microns) is considered to be the threshold for osteolysis with metal-on-polyethylene bearing surfaces [7–10]. The measured annual linear wear threshold for osteolysis with metal-on-metal bearing surfaces has not been established.

Osteolysis has rarely been associated with well-fixed metal-on-metal articulations [6,11–14]. The incidence of particle-induced osteolysis in first-generation metal-on-metal total hip arthroplasties has not been well established, ranging from 4.5–35.5% [5,15]. Zehri and others found osteolysis in 4 of 15 hips (26.6%) with McKee-Farrar hip arthroplasties still in place 21–26 years after hip arthroplasties [5]. This report did not describe the size or location of the osteolytic lesions. The authors also reviewed clinical radiographic and histologic findings for 15 McKee-Farrar hip arthroplasties that had failed because of aseptic loosening. Six of the revised hips had radiographic evidence of osteolysis. Histologic sections of tissue from the revised group

From The Arthritis Institute at Centinela Hospital, Inglewood, California USA.

No benefits or funds were received in support of the study.

Reprint requests: William T. Long, MD, The Arthritis Institute at Centinela Hospital, 501 East Hardy Street Suite 300, Inglewood, CA 90301

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0883-5403/04/1908-3007\$30.00/0

doi:10.1016/j.arth.2004.09.018

showed no gross evidence of metallosis. Multinucleated histiocytes (foreign body-type giant cells) were mostly found along the edges of polymethylmethacrylate globules, and metal and polymethylmethacrylate particles of various size and shape suggested that the particles were the result of debris caused by aseptic loosening and they were not generated by bearing surface wear.

Based on the past performance of metal-on-metal bearing surfaces for hips, one could conclude that by decreasing or eliminating early metal-on-metal failures due to acetabular loosening, patients could benefit from a long-lasting bearing surface and decreased incidence of osteolysis. The purpose of this study was to determine the clinical performance of a metal-on-metal bearing surface, to identify implant related failures, to define systemic or local complications, and review the radiographic changes following 161 total hip arthroplasties with this bearing surface.

Materials and Methods

From 1995–2002, the senior author performed 1186 primary total hip arthroplasties, 345 of which were done with noncemented modular cups with a Metasul metal-on-metal articulation (Zimmer GmbH, Winterthur, Switzerland). These operations were selected and nonconsecutive. One-hundred and fifty-five patients (45.8%) were eliminated from the study because they were included in the 2000 Sulzer Orthopaedics Manufacturing Implant Device Recall [16]. Of the 345 hips (338 patients) that initially had a primary total hip arthroplasty with the metal-on-metal articulation, 6 patients died (1.8%) 1–6 years after the operation, but none of the deaths was a result of the operation. All of these patients had been followed-up postoperatively, and all had well-functioning hips at the time of death. Twenty-three patients (6.8%) were contacted, did not return for follow-up, and no radiographs were available. None of these hips had been revised. One-hundred and sixty-one hips (154 patients; 45.6%) were available for both clinical and radiographic evaluation 2–9 years (average, 6.5 years) after the operation, and these patients made up the study group. The average age of the 154 patients was 55.5 ± 11.6 years (range, 27–83) at the time of the index arthroplasty. Ninety-three hip arthroplasty operations (57.8%) were performed on men and 61 on women (37.9%). One hundred and twelve hips had primary osteoarthritis, 4 had developmental dysplasia, 39 had osteonecrosis, 3

had posttraumatic arthritis, and 3 had rheumatoid arthritis.

Forty-seven hips (43 patients; 27.9%) were treated with an anatomic porous arthroplasty cup (APR, Zimmer, Inc., Warsaw, IN) and 114 hips (111 patients; 72.1%) had InterOp cups (Zimmer GmbH). Both of these are porous-coated titanium cups. The acetabular insert was a polyethylene-backed cobalt-chromium metal articulation surface. The femoral head was made of Protasul-21 WF (Zimmer, Inc.) cobalt-chromium alloy. The diameter of the femoral head was 28 mm for all hips. This study is based on 161 total hip arthroplasties with this bearing surface with an average follow-up of 6.5 years (range, 2–9).

One hundred and thirty-two stems (82%) were uncemented. These femoral components included 129 APR stems and 3 Natural Hip stems (Zimmer, Inc.). The uncemented femoral stems were titanium alloy with porous coating. Twenty-nine stems (18%) were cemented with 14 nonporous APR stems and 15 Apollo stems (Zimmer GmbH).

Clinical evaluations were performed prospectively preoperatively, immediately postoperatively, at 6 months, and annually thereafter using the Harris hip score [17] and the patient-self-assessment form HKB-21 (Orthographics, Salt Lake City, UT), which is a modification of the Short Form-36 questionnaire for pain and functional outcome [18]. The form was either completed by the patient during the office visit or mailed to the patient for completion. All of the 154 patients completed the questionnaire. Activity was graded by the classification of unlimited ambulation, community ambulation (can walk at least 8 blocks), limited community ambulation (can walk 2 blocks), household ambulation, or wheelchair bound [19].

At the time of clinical evaluation, an anteroposterior pelvic radiograph was taken that included the proximal part of the femur and the entire stem, as well as a 17-inch modified Lowenstein lateral radiograph, which was an iliac oblique view of the involved hips. The radiographs were analyzed by 2 examiners who were not involved in the care of the patients. All measurements on the radiographs were corrected for magnification using the diameter of the head of the femoral component.

The radiographic criteria for the recording of the presence and extent of loosening and osteolysis of the acetabulum were done by zones described by Delee and Charnley [20,21] on the anteroposterior and lateral radiographs. Femoral radiolucent lines were recorded in each of the 14 zones on the anteroposterior and lateral radiographs [21,22]. A radiolucent line adjacent to either the femoral or

acetabular component was recorded only if it occupied at least 50% of the zone. 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. Osteolysis of the femur or pelvis was measured with the zonal technique used for radiolucent lines. Radiographic 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 the inclination of more than 5°) appearance of a radiolucent line after 2 years or progression of radiolucent lines after 2 years [23]. Measurements for wear were not done because it was not possible to distinguish between the edge of the femoral head and the metal articulation surface of the acetabular components.

Results

Six of 161 hips (3.7%) had revision surgery, including 5 hips (3.1%) that had revision of the acetabular component and 1 hip that had revision of the femoral component (0.06%). One acetabular revision (0.06%) was performed because of recurrent dislocation, 2 were revised (1.2%) because of unexplained pain and suspected hypersensitivity, 1 (0.06%) for infection, and 1 (0.06%) for disassociation of the acetabular liner from the cup. The insert disassociation occurred 3 years after the index operation and was associated with the cup that had a 34° degree angle of inclination. The locking mechanism of the retrieved insert was found not to be defective and the disassociation was attributed to chronic impingement. One revision (0.06%) of a femoral component was because of aseptic loosening of the cemented stem. One-hundred and fifty-five hips (148 patients; 96.1%) did not have a revision. The average total Harris hip score was 97.8, standard deviation 3.21. The average pain score was 43, standard deviation 2.15, and the average limp score was 10.51, standard deviation 1.1 at final follow-up of 6.5 years. At the time of follow-up, 130 patients (87.2%) were unlimited community ambulators, 14 (9.3%) patients were community ambulators, and 5 (3.3%) were limited community ambulators. None was a household ambulator, and none was confined to a wheelchair. Of 156 hips in 148 patients without revision who completed the self-assessment questionnaire, 143 (96.6%) rated the results as excellent; 3 (2%) as very good; 2 (1.4%) as good, and none as fair and none as poor.

In addition to the 6 hips that had revision of the index operation, there were 6 operative site complications that did not require revision surgery (3.7%). Three hips (1.9%) had a single dislocation treated by closed reduction, 2 hips (1.2%) had trochanteric bursitis that resolved after cortical steroid injections, and 1 hip had a nondisplaced femur fracture that was discovered on the immediate postoperative radiograph, treated with protected weight for 6 weeks, and healed without surgical intervention.

No patient had revision for aseptic loosening of the acetabular component and radiographs at latest follow-up revealed that there were no loose cups. Of the 156 cups that were not revised, 32 (21.1%) had a radiolucent line in at least 1 zone; and all of these were present on the immediate postoperative radiographs. Eighteen of these 32 hips (56.3%) had a radiolucent line in 1 zone; 12 (37.5%) had a radiolucent line in 2 zones; and 2 (6.3%) had a radiolucent line in 3 zones. No hip had progressive radiolucent lines and no hip had radiographic evidence of focal pelvic osteolysis.

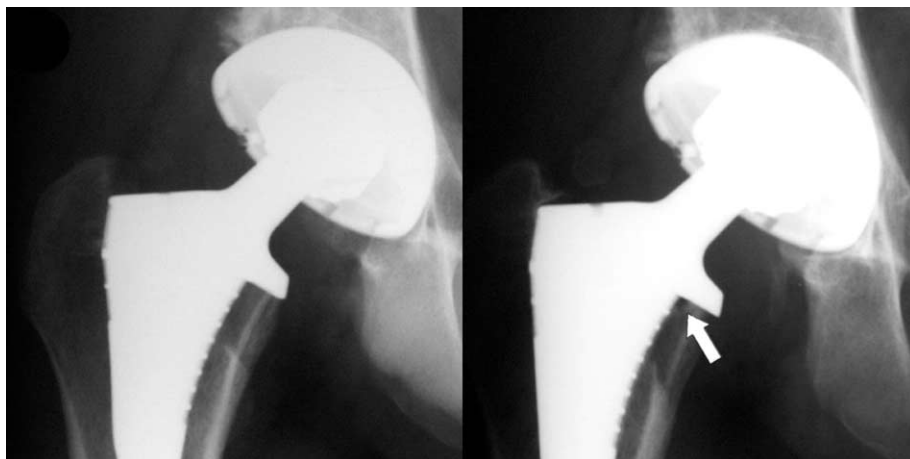
Femoral radiolucencies were associated with 1 cemented and 14 cementless stems. Fifteen (9.9%) of 151 stems had a radiolucent line in at least 1 zone with 13 (8.3%) of 156 hips in 1 zone, and 2 (1.2%) of 156 in 2 zones. One cemented femoral stem (0.06%) of 156 stems had a circumferential radiolucent line around the stem at the bone cement interface and this patient had revision of the femoral component.

The hip radiographs of 9 patients had findings described as calcar resorption. Calcar resorption was a focal radiolucent area seen immediately beneath the collar of the stem, identified by its location between the calcar cortical bone and the medial stem. In 8 of 9 hips the size of the calcar resorption was from 1 × 1 mm to 2 × 2 mm (Fig. 1). One hip had a lesion that increased in size from 1 × 1 mm at 1 year, to 19 × 20 mm at 5-year follow-up (Fig. 2). These radiolucent areas were not classified as osteolysis according to the description by Goetz et al. [18].

Discussion

There were 3 important findings in this study. First, this series of hips has shown that there is not an early failure of cup fixation as occurred with the McKee-Farrar articulations [1–4]. The McKee-Farrar hips fell out of favor because they had a high rate of acetabular loosening during the first 5 years and this was in contrast to Charnley hips that did not have this ace-

Fig. 1. Radiographs demonstrate 8 out of 161 (5%) hips developed a $1 \times 1\text{--}2 \times 2$ mm radiolucency directly beneath the collar during the first year of follow-up. Radiographs taken (A) immediately postoperatively and after (B) 6 years follow-up. The location of the lesion corresponds to a surface directly beneath the collar devoid of porous coating.



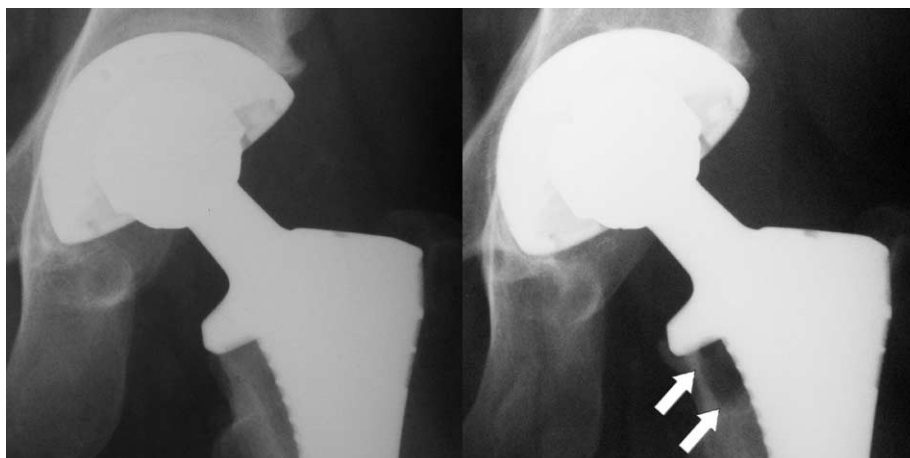
tabular failure rate caused by mechanical loosening in the same time frame [4,20,24,25]. In 1974, Peter Walker described femoral neck impingement against the acetabular rim as a cause of failure of the McKee-Farrar prosthesis [26]. To clearly illustrate the mechanism of failure, he cut out a portion of the acetabular cup and photographed the mark on the femoral neck that corresponded to impingement against the rim of the acetabular component. The under-favorable head/neck ratio was a design flaw that contributed to the early failures of this prosthesis. The only revisions of the acetabular components in these hips were for reasons other than loosening.

The clinical results of the patients in this study were as good as any series of hip arthroplasties for this follow-up time period. No patients graded their results as fair or poor and 93% graded their results as excellent. Perhaps the most significant result is that 155 of 161 hip arthroplasties (96%) have re-

mained intact since the index operation. The revisions that have been required have been for reasons other than aseptic loosening.

The second important finding is that there was no radiographic evidence that a high volume of particulate debris is being produced at the metal-on-metal interface. It is not possible to measure wear from the metal-on-metal articulation so the only way to judge the particulate debris is by the occurrence of progressive fixation loss from debris accumulation at the interface or by the occurrence of osteolysis. The only bone erosion that was measured in this study was calcar resorption. It was not possible to determine whether this calcar resorption was from stress shielding or particulate debris. Furthermore, other authors have not classified calcar resorption as osteolysis [18]. Goetz's description of osteolysis included only those lesions that caused scalloping of the endosteal cortex. Small focal radi-

Fig. 2. Radiographs demonstrate 1 hip out of 161 (0.06%) had a 1×1 mm radiolucency beneath the collar at 1 year follow-up and it increased to 10×20 mm after 5 years. Radiographs taken (A) immediately postoperatively and after (B) 5 years follow-up.



olucent areas that were seen immediately under the collar of many of the prostheses were not considered in the definition of osteolysis. In contrast, Maloney and Woolson [27] defined relatively small punched-out areas of osteolysis under the collar as typical zone 7 osteolytic lesions. Other authors have not classified calcar resorption as osteolysis [18]. The low volume of wear that has been observed on implant retrievals seems to be occurring clinically in this series of hips because of the absence of radiographic signs that a pathologic volume of debris is being generated. Our results are in agreement with a recent study of 118 Metasul retrievals that reported no failures because of osteolysis [24].

The third finding in this study was that there were no unique complications with these total hip arthroplasties with Metasul articulation. Hypersensitivity has been suggested as a possible unique complication and cause of failure for metal-on-metal hip arthroplasties [10,28]. Hypersensitivity is a diagnosis described by Willert, based on the occurrence of lymphocytes adjacent to blood vessels in capsules of retrievals from failed metal-on-metal total hip arthroplasties [29]. Two of 161 hips (154 patients; 1.2%) in this study underwent reoperation because of unexplained persistent pain. Lymphocytes adjacent to blood vessels in capsules could not be identified as the cause of pain in either of these patients. Neither patient was cured of their pain 1 year after changing the articulation from metal-on-metal to ceramic-on-polyethylene. One of the 2 patients had complete resolution of symptoms 3 years after the articular surface exchange following surgery of the lumbosacral spine for degenerative disease. The second patient had a contralateral total knee arthroplasty 1 year after articular surface exchange and the symptoms resolved. Lymphocyte-mediated hypersensitivity was ruled out by the histologic specimens obtained during revision surgery; however, the cause of pain in this patient remains unexplained.

Metal ion levels were not tested in patients as part of these studies. After 40 years of use, there is no evidence that metal-on-metal articulations have been a cause of cancer. Paavolainen et al. [30] evaluated all patients who had total hip arthroplasty in the Finland Registry from 1980–1995 and concluded that there was no evidence of elevated cancer risk compared with the general population. Visuri also could not confirm a causal relationship between total cancer incidence and hip arthroplasty with metal-on-metal bearing surfaces [30–32]. In our patients there is no evidence of any disease from metal ions, including cancer. Our series is only 154 patients and is a nonconsecutive series of se-

lected patients. One-hundred and fifty-one hips in 151 patients were eliminated due to the implant recall and this weakened the data. The time frame is only to 9 years so a larger body of data would be necessary to confirm the true incidence of unique complications. The strength of this study is that it confirms that the high incidence of early aseptic loosening has been improved with this modern metal-on-metal articular system. The continued use of the Metasul bearing surfaces is supported by these data, and the continued study of results associated with this articulation surface is recommended.

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