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Original Article

Incidence of Adverse Reactions to Metal Debris From 28-mm Metal-on-Metal Total Hip Arthroplasties With Minimum 10 Years of Follow-Up: Clinical, Laboratory, and Ultrasound Assessment of 44 Cases

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ABSTRACT

Background: Total hip arthroplasty with metal-on-metal (MoM) bearings has been suspected to cause adverse reactions to metal debris (ARMD), with the incidence varying greatly by implant type and patient gender. The prevalence of ARMD from small-diameter MoM bearings in women is unknown, especially after 10 years of follow-up (FU).
Methods: Cementless 28-mm MoM total hip arthroplasty bearings (Metasul) were implanted consecutively in 42 active women between 1996 and 2002. They were reviewed after a minimum of 10 years' FU with clinical, laboratory, radiological, and ultrasound assessments.
Results: Mean FU was 15.9 years (range, 13-18). The mean Postel-Merle d'Aubigné and Oxford scores were 16.9 (range, 13-18) and 15.1 (range, 12-24), respectively, at FU. Mean cup inclination angle was 46.3° (range, 35°-57°). No femoral osteolysis was detected, but limited acetabular osteolysis (11%) over the screw holes occurred in 5 cases. No liquid or solid synovial reactions or ARMD were apparent on ultrasound, even in the 5 cases of pelvic osteolysis. Mean chromium levels were 1.32 μg/L (range, 0.1-7.9) and cobalt levels were 1.85 μg/L (range, 0.35-13.6). Cobalt was >3 μg/L in only 3 cases. The 15.9-year survivorship was 95% (range, 94.1%-98.9%).
Conclusion: Reliable results were obtained with 28-mm MoM bearings, notably in young, active patients. This implant configuration requires very accurate positioning. No ARMD was seen in this group at 16 years' FU.

Metal-on-metal (MoM) Metasul bearings for total hip arthroplasty (THA) were introduced in 1988 to reduce the wear [1] and osteolysis that occur with traditional metal-on-polyethylene hips [2,3]. First-generation MoM bearings [4] generated unfavorable outcomes, mainly because of implant loosening, and were gradually abandoned [5]. In 1988, Weber reintroduced MoM bearings with the Metasul configuration (Sulzer, Winterthur, Switzerland) [6]. Second-generation MoM bearings solved the wear problem and had promising medium-term results, especially in young, active patients [7,8]. This outcome was attributed to a very low wear rate, which was 20 to 200 times less than traditional metal-on-polyethylene bearings [9]. On the other hand, these bearings induced passive corrosion and triggered production of metal ions, such as chromium (Cr) and cobalt (Co), in local tissues and blood [10,11]. This gave rise to concerns about hypersensitivity reactions [12], adverse reactions to metal debris (ARMD) with aseptic lymphocytic vasculitis-associated lesions [13], and pseudotumors (PT) [14] that occurred more often with large MoM diameter heads than with small heads (due to differences in cup

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design and clearance). These appeared to be more common in women than in men younger than 40 years of age with steep cup angles [15,16]. However, it is difficult to identify risk factors of PT. Some authors have implicated cup position, cup design, and the bearing's tribological properties [17], whereas others have vindicated cup positioning and wear debris [18]. One of the main ARMD risk factors is gender. A higher incidence of ARMD was seen in women who received large-diameter or hip-resurfacing THA configurations [19].

The purpose of this study was to analyze the behavior of a small (28 mm) MoM THA in a retrospective series of female patients with a minimum follow-up (FU) of 10 years through clinical, laboratory, radiological, and ultrasound assessments.

Materials and Methods

Between February 1996 and October 2002, 49 primary 28-mm MoM THA bearings were implanted consecutively in 42 female patients. This bearing design was indicated in patients with high activity levels (University of California at Los Angeles (UCLA) score ≥4) [20], who were younger than 50 years of age without renal dysfunction or known allergy to metal. Mean age at the time of surgery was 39.2 years (range, 17-48; Fig. 1). The implants were identical in all cases: cementless (Ti6Al7Nb) Alloclassic stem (Zimmer), titanium (Ti) grit-blasted Allofit acetabular component (Zimmer), Metasul (Zimmer) high-carbon femoral head, and modular Metasul polyethylene sandwich. Of the initial 42-patient cohort, 3 patients (4 THA) died before being reviewed. None of the deaths were related to the THA or initial disease. One patient (1 THA) was lost to FU and 2 patients (2 THA) underwent revision surgery, leaving 36 patients (44 THA) for the clinical, radiological, and laboratory assessments.

Four senior orthopedic surgeons performed all the THA procedures in vertical laminar-airflow operating rooms, with patients in the lateral position. A posterolateral approach was taken to all hips. All patients were given a single intraoperative prophylactic dose of intravenous antibiotic (cefazolin), and low-molecular-weight heparin was prescribed for 35 days after surgery. No specific medication was administered to prevent heterotopic ossifications. Full weight-bearing was allowed on the first postoperative day.

The preoperative diagnosis was avascular necrosis in 19 hips (39%), hip dysplasia in 17 hips (34%), primary osteoarthritis in 12 hips (24%), and osteochondritis in 1 hip (2%).

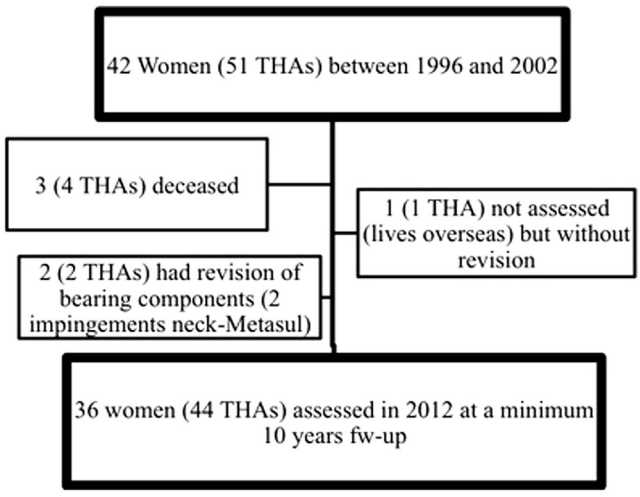

Fig. 1. Flowchart showing the inclusions and outcomes of the patient cohort. THA, total hip arthroplasty.

Clinical assessments included the Postel-Merle d'Aubigné (PMA) [21], Oxford [22], UCLA [20], and Harris hip scores (HHS) [23]. All patients also underwent a physical examination to look for groin pain and evaluate range of motion. All patients completed a questionnaire that included occupational exposure, intake of prescription or nonprescription medications that may contain Cr, Co, or Ti, and the presence of other metal implants in the body.

All hips underwent a standardized radiological examination. Radiographs were reviewed by 2 independent examiners (JG, BA) who were not involved in the surgical procedures. Acetabular cup inclination was measured using Sutherland's method [24]. All the radiographic measurements were analyzed with PACS software (Philips Healthcare, Maastrich, The Netherlands). Heterotopic ossification was assessed according to Brooker et al [25]. Acetabular radiolucent lines were analyzed in the zones described by DeLee and Charnley [26]. Femoral radiolucent lines were analyzed as described by Gruen et al [27]. A radiolucent line was recorded if it was present no matter what percentage of the zone was occupied. Migration was diagnosed if the component had shifted more than 5 mm or tilted more than 5°.

A senior radiologist familiar with the ARMD diagnosis performed the ultrasound assessment. The ultrasound findings were separated into 4 groups according to the ARMD classification of Nishii et al [28]: “normal pattern” without soft tissue abnormality, “joint-expansion pattern” with marked hypoechogenic space of 4 mm or more between the anterior capsule and the anterior surface of the femoral component, “cystic pattern” with irregularly shaped hypoechogenic lesions extending anterior to the femoral component, and “mass pattern” with a large mass extending anterior to the femoral component.

One nurse took blood samples from all patients. The first 5 mL of blood withdrawn was discarded to avoid contaminating the blood with Cr, which may be present in the needle's steel tip. Blood samples were diluted with deionized water in the Synergy 185 system (Millipore, Saint-Quentin-en-Yvelines, France) and contained 0.05% ammoniac and 0.1% triton. Metals in whole blood were quantified by inductively coupled plasma mass spectrometry: Varian 820 MS (Brucker, Wissembourg, France) equipped with an interface reaction collision device. Helium (30 mL/min) served as the collision gas.

Statistical Analysis

An independent statistician performed all statistical analyses with SAS version 9.2 and SPSS version 15.0. Bivariate comparisons were made using Student *t* test or an analysis of variance if the sample size exceeded 30. Statistical thresholds for continuous variables were established with receiver operating characteristic curves. We looked for correlation between 2 numerical variables by regression testing. If Pearson's regression coefficient (R) was above 0.5, correlation was demonstrated. The survival rate was calculated with Kaplan–Meier survivorship curves, considering revision for any reason as the end point with 95% confidence intervals (95% CI). A power study was not done.

Results

Mean age at the last FU was 51.9 years (range, 30-64). Mean length of FU was 15.9 years (range, 13-18). Two patients (2 THA, 3.9%) had early postoperative complications that did not require revision: one had early dislocation treated by closed reduction without recurrence; the second patient developed a postoperative infection that was successfully managed by surgical debridement and antibiotics for 6 weeks.