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Is Second Generation Metal-On-Metal Primary Total Hip Arthroplasty With a 28 mm Head a Worthy Option? ☆
A 12- to 18-Year Follow-Up Study

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ABSTRACT

To determine whether MoM THA with a small head is still worthy of use, we investigated survivorship, complications, and factors influencing failure. Of 149 consecutive patients (195 hips), 141 (180 hips) of mean age 43 (19–55) years were available for review at a mean of 14.4 years postoperatively. Survivorship for cup revision for any cause was 97.8% at 18.4 years postoperatively. Nine hips generated complaints of groin pain; six showed periacetabular osteolysis, one had pain without radiological change, and two were diagnosed as symptomatic pseudotumors. Four of six hips with periacetabular osteolysis or aseptic loosening were revised. Surgery- and patient-related factors had no effect in results. Our results are encouraging, however, further study will be necessary to determine the incidence and fates of pseudotumors after MoM THA with a small head.

Periprosthetic osteolysis due to wear debris is a major threat to long-term THA survival. Metal-on-polyethylene bearing surfaces are the mainstay of THA [1], however, wear debris from polyethylene can cause periprosthetic osteolysis and eventual loosening of components [2,3]. In order to minimize wear debris, alternative bearing surfaces with improved tribologic properties have been developed and second generation metal-on-metal (MoM) bearings have been used since the late 1980s. MoM bearings have been reported to eliminate osteolysis and loosening associated with polyethylene wear debris [4,5], however, many authors have reported early osteolysis and aseptic failure after metal-on-metal THA [6,7]. Some authors have suggested metal hypersensitivity as a major factor [8,9], whereas others have reported that osteolysis and early failure are more common in malpositioned hips [10,11]. Perhaps of greater concern, many authors have concluded that MoM bearings are more likely to generate metal ions than metal-on-polyethylene bearings, and commented that the long-term biological effects of MoM bearings have not been well established [7,12]. In addition, development of pseudotumor has recently been associated with use of MoM bearings [13,14], and in one study, it was suggested that behaviors of small and large diameter metal heads differ [15].

In order to add substance to the debate on problems associated with small head MoM bearings, we examined the following factors: (1) What is the survival rate of MoM THA? (2) What are the long-term complications and adverse effects of MoM THA? (3) What factors are responsible for MoM bearing failures? Finally, we sought to determine whether the combination of MoM bearings and a small diameter head is a viable option.

Materials and Methods

All patients provided informed consent, and the study protocol was approved by the institutional review board of our university hospital. Between December 1993 and May 1999, 149 patients (195 hips) underwent primary cementless THA with a Metasul second generation MoM bearing at our institution. All procedures were performed by the senior author (Y-H Kim). Of these patients, two (four hips) died at eight and nine years after surgery for reasons unrelated to THA. In addition, six of the 149 patients (11 hips) were lost to follow-up between two and six years postoperatively and could not be contacted. Therefore, 141 patients (180 hips) who had been followed for at least 12 years constituted the study cohort, which included 95 men (126 hips) and 46 women (54 hips) of mean age 43.3 (19–55) years at the time of index surgery. The most common reason for THA was osteonecrosis of the femoral head (Table 1), and the average duration of follow-up was 14.4 (12–18) years.

A Wagner standard cup (Sultzer, Winterthur, Switzerland) and a high carbon (>0.2%) wrought CoCr head articulating into a high carbon (>0.2%) wrought CoCr inlay were used in all patients. In 1988,

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Table 1
Diagnosis, and Patient Demographics.

Diagnoses [No. (%) of hips]	
Osteonecrosis	124 (74.4)
Osteoarthritis	19 (10.2)
Dysplastic hip	17 (7.9)
Sequelae of Tuberculosis	9 (4.4)
Rheumatoid arthritis	11 (3.1)
Mean Age [range, (year)]	49.8 (19–85)
Male	50.5 (19–85)
Female	49.1 (21–74)
Gender [No. of patients (hips)]	
Male	95 (126)
Female	46 (54)
Mean body mass index [range, (kg/m^2)]	23.3 (14.4–40)
Male	23.1 (14.4–40)
Female	23.8 (14.8–34.4)

Weber and Fiechter [16] developed a second generation MoM implant called Metasul (Sultzer, Winterthur, Switzerland). In Metasul articulations, the metal inlay is contained in an ultra high molecular polyethylene sandwich, which is inserted into the acetabular shell. The diameter of the head of the femoral component was 28 mm in all hips. A cementless CLS titanium alloy stem (Sultzer, Winterthur, Switzerland) with a grit-blasted surface was used in all patients. The Metasul bearings were implanted most often; however, other bearings were also adopted on occasion, based on surgeon's preference without selection criteria.

All operative procedures were performed through a posterolateral approach. In each hip, an acetabular cup with a tight press-fit was implanted and fixated with one or two screws. After tightly inserting the stem, impacted bone graft was applied to the space between the stem and femoral cortex in order to increase bone-stem contact and to diminish potential joint space to prevent distal migration of wear particles.

For postoperative rehabilitation, patients performed quadriceps setting exercises, and a tolerable range of hip and knee motion exercises immediately after surgery. Patients were allowed to sit on their beds one day after surgery. From seven days postoperatively, patients were allowed to walk with a walker, and from six weeks postoperatively full weight bearing was allowed.

Clinical and radiographic evaluations were performed at 6 weeks, at 3, 6, and 12 months, and annually thereafter. Two of the authors who did not participate in surgery performed independent clinical and radiographic evaluation of patients. Harris hip scores were determined and thigh and groin pain was evaluated preoperatively, at 6 weeks and 12 months postoperatively, and at final follow-up. Medical records and radiographs were reviewed retrospectively.

All hip anteroposterior and cross table lateral radiographs taken postoperatively and at latest follow-up visits were independently evaluated. Cup abduction angle was measured by drawing a horizontal line through teardrops in the plane of the cup opening. Cup anteversion angle was defined as the angle formed by the bottom of the radiographic plate and the opening plane of the cup. Anteroposterior radiographs of hips on the acetabular side were analyzed as described by DeLee and Charnley [17] and on the femoral side as described by Gruen et al [18]. Acetabular loosening was defined as a rotational alignment change of >3° in anteroposterior radiographs, or an axial cup migration of >2 mm [17]. Definite loosening of the femoral component was defined as progressive axial subsidence of >2 mm or varus or valgus tilting on serial radiographs. Osteolysis was defined according to the classification developed by Zicat et al [19], as a complete radiolucent line having a width of 1 mm in all three Gruen zones or as a radiolucent line having a width of 2 mm in two of the three zones on serial radiographs.

During revision procedures, periprosthetic tissues were retrieved from hip capsules and bone–implant interfaces, and multiple microbiological cultures, hematoxylin and eosin staining, and immunohistochemical analysis were performed.

To identify factors that influenced outcomes, we examined stem alignment, cup position, and age, gender, and body mass index (BMI).

Implant survival, with 95% confidence intervals, was determined using the Kaplan–Meier method and SPSS 16 ver. 16 (SPSS, Chicago, Illinois). Failure was defined as revision for acetabular cup loosening or for development of periacetabular osteolysis.

Results

Survivorship at final follow-up using acetabular cup revision for any reason as a cause was 97.8% (95% CI, 96.7% to 98.9%) at 18.4 years. Survivorship at final follow-up (mean at 18.4 years) using development of acetabular osteolysis as an end point was 96.7% (95% CI, 95.4% to 98%). Six hips developed periacetabular osteolysis, and four of these were revised due to aseptic loosening or osteolysis around the cup. Femoral revisions were performed in two hips due to periprosthetic fractures following trauma at 1 month and 5 years postoperatively.

Mean preoperative Harris hip score of 50.5(46–67) points had improved to 91.9 (62–100) points at the final follow-up. Clinical results were excellent for 142 hips, good for 32 hips, fair for 3 hips and poor for 3 hips. Two patients (two hips) experienced transient thigh pain, which was relieved spontaneously after less than 1 year. Eight patients (nine hips) experienced groin pain. No diagnosis of renal disease or malignancy was established in any patient during follow-up.

Femoral radiographic parameters were also evaluated. Stem alignment was neutral in 154 hips, varus in 16 hips, and valgus in 10 hips. Incidence of endosteal bone formation was highest in Gruen zone 2 (151 hips, 84%) and lowest in zone 4 (95 hips, 53%). A radiolucent line was observed most frequently in zone 4 (28 hips, 16%) and least frequently in zone 2 (2 hips, 1%). Focal osteolysis was found in zones 1 and 7 in 11 hips (6.1%). No femoral stem loosening was observed. Endosteal bone formation was found in 159 hips (88%) in zone I (according to the DeLee classification), in 156 hips (87%) in zone II, and in 136 hips (76%) in zone III around the acetabular cup. A radiolucent line was noted in 13 hips (7.2%).

Nine hips (8 patients) were associated with groin pain. No osteolysis was found in 3 hips (3 patients) by simple radiographic examination. Of these 3 hips, one had a palpable mass lesion in the inguinal area, which appeared to be a large fluid filled cyst, probably a pseudotumor, on ultrasound and CT images (Fig. 1A, B); the patient complained of mild groin pain, however, no radiographic change was observed around the cup or stem (Fig. 1C, D). This patient had a well functioning hip and refused a second operation. Mild groin pain in another hip was diagnosed by CT as having been caused by a small pseudotumor. The other hip had a well-fixed cup and no radiographic change with unexplained mild pain. All three of these patients were prescribed a non-steroidal anti-inflammatory drug and were followed closely.

Six (5 patients) of the 9 hips with groin pain were associated with periacetabular osteolysis or cup loosening (Table 2); 2 hips (2 patients) had focal periacetabular osteolysis with mild pain, and four (3 patients) were associated with severe groin pain. One patient (1 hip) underwent revision surgery because of early cup loosening (25 months postoperatively). Another patient (1 hip) showed osteolysis around the cup and proximal femur on radiographs taken at 24 months postoperatively, which proved to be progressive and resulted in cup loosening. This patient underwent revision at 63 months after primary THA. During revision surgery, the osteolytic lesion was curetted and allogenous morselized bone was grafted. The acetabular cup was press-fitted and two acetabular screws were placed. The femoral stem was well fixed. In addition, the MoM bearing was replaced with a ceramic-on-polyethylene bearing. The groin pain was resolved after revision arthroplasty. In the third patient (2 hips),