Cementless large-head metal-on-metal total hip arthroplasty in patients younger than 60 years—A multicenter early result

Po-Ting Wu a,b, Chih-Jen Wang c, Cheng-Yo Yen d, Ji-Shen Jian e, Kuo-An Lai a,*

a Department of Orthopaedics, National Cheng Kung University Hospital, Tainan, Taiwan
b Institute of Biomedical Engineering, National Cheng Kung University, Tainan, Taiwan
c Trust Orthopaedic Institute, Tainan, Taiwan
d Department of Orthopaedics, E-Da Hospital, Kaohsiung, Taiwan
e Department of Orthopaedics, Chi-Mei Hospital, Tainan, Taiwan

Received 16 December 2010; accepted 22 March 2011
Available online 15 September 2011

KEYWORDS
Large head;
Metal-on-metal;
Total hip arthroplasty;
Young adults

Abstract Large-head metal-on-metal total hip arthroplasty has the theoretical advantages of less wear and better range of motion than traditional polyethylene bearings and seems to be a better choice for young and active patients. We conducted a retrospective study and reported the early results of using such prostheses in 59 patients (70 hips) with a mean age of 43.1 years (range, 23–59 years) at the time of surgery. Osteonecrosis of the femoral head accounted for most diagnoses. Harris Hip Scores and hip range of motion both significantly improved (p < 0.001) at an average follow-up of 32.6 months (range, 24–48 months). Only one intraoperative calcar fissure was encountered, and it was fixated by cerclage wiring; there was no infection, dislocation, or osteolysis around either the cup or the stem at the latest follow-up. A postoperative gap in the acetabular component was noted in 24 hips, with a mean depth of 1.11 mm, but this was not correlated with the functional score (p = 0.291). Transient thigh pain, which resolved after 6 months, was observed in six patients but was not related to either the postoperative gap or cup inclination (p = 1.000 and p = 0.664, respectively). All patients resumed their original jobs and recreational activities with little discomfort. Thus far, large-head metal-on-metal total hip arthroplasty has shown excellent early results. The long-term results and the effects of metal debris and potentially elevated serum metal ion levels require further observation.

Copyright © 2011, Elsevier Taiwan LLC. All rights reserved.

* Corresponding author. Department of Orthopaedics, National Cheng Kung University Medical Center, No. 138, Shen Li Road, Tainan City, Taiwan.
E-mail address: laikuoan@mail.ncku.edu.tw (K.-A. Lai).

1607-551X/S36 Copyright © 2011, Elsevier Taiwan LLC. All rights reserved.
doi:10.1016/j.kjms.2011.06.021
Introduction

Wear and osteolysis have become the foremost concerns in primary total hip arthroplasty (THA) for young and active patients. Currently, high cross-linked polyethylene, ceramic-on-ceramic, and metal-on-metal (MOM) bearings are used to reduce the wear rate. The MOM bearings produce less volumetric wear debris than metal-on-polyethylene bearings and therefore may result in a decreased incidence of osteolysis-induced failure [1,2]. Furthermore, second-generation MOM technology offers other advantages, such as easy fabricability, high fracture toughness, and the ability to use large femoral heads, thereby lowering the risk of postoperative instability [3–6] and achieving better active range of motion (ROM) [7,8]. Therefore, we hypothesized that the large-head MOM design reduces the risk of dislocation, increases the ROM, and minimizes the risk of impingement, thereby enabling young, active patients to return to their jobs and recreational activities. We report the early clinical and radiological results among patients younger than 60 years, who underwent large-head MOM THA at four institutes.

Materials and methods

From October 2006 to September 2008, a consecutive series of 89 primary THAs using large-head MOM articulation were performed for 77 patients by four surgeons at four institutes. The Institutional review board at National Cheng Kung University Medical Center approved the study protocol.

The implants in our study were from one manufacturer (Zimmer Inc., Warsaw, IN, USA; Fig. 1). The acetabular component was a Durom cup, and the femoral component was a Metasul large femoral head with a VerSys Fiber Metal Taper stem (Zimmer, Inc.) and a chromium-cobalt alloy metal sleeve adapters.

Figure 1. (A and B) The Durom (Zimmer, Inc., Warsaw, IN, USA) acetabular cup, VerSys Fiber Metal Taper (Zimmer, Inc.) stem, Metasul (Zimmer, Inc.) large femoral head, and chromium-cobalt alloy metal sleeve adaptors used in the study.

Inclusion criteria were any patients aged 19–59 years, evaluated by the treating surgeon as suitable for THA, and approved by the Taiwan Bureau of National Health Insurance for use of this prosthesis. Exclusion criteria were diagnoses of (1) osteopenia or osteoporosis, which was assessed on routine pelvis radiographies according to the Singh index [9]; (2) previous femoral or pelvic osteotomy; (3) hip dysplasia requiring structural bone graft; (4) hepatic or renal failure; and (5) current pregnancy. Other durable bearing choices and the benefits and risks of large-head MOM articulation, particularly the potential elevated serum ion level, were thoroughly discussed with all patients. All enrolled patients were willing to use such prostheses. Moreover, prostheses for resurfacing MOM hip arthroplasty are not approved by our National Health Insurance system.

In total, 59 patients with 70 hips met the inclusion criteria. There were 20 women and 39 men with a mean age of 43.1 years (range, 23–59 years) at the time of surgery. There were six women of childbearing age (≤45 years), with the potential of becoming pregnant. The mean weight was 67.1 kg (range, 50–90 kg), the mean height was 163.5 cm (range, 145–176 cm), and the mean body mass index was 25.1 (range, 18.4–33). The patients’ physical job demands were self-assessed [10] as follows: 12 patients with low demand, 32 patients with moderate demand, and 15 with high demand. Staged bilateral hip replacement was performed in 11 patients (18.6%). The primary diagnosis was osteonecrosis of the femoral head in 43 hips (61.4%, 36 patients), followed by osteoarthritis secondary to dysplastic hip in 12 hips (17.1%, 10 patients), primary osteoarthritis in 6 hips (8.6%, 6 patients), proximal femoral neck fracture with the sequela of osteonecrosis in 4 hips (5.7%, 4 patients), ankylosing spondylitis with hip arthropathy in 2 hips (2.8%, 1 patient), Perthes disease in 2 hips (2.8%, 2 patients), and septic hip sequela in 1 hip (1.4%, 1 patient).
Surgical methods

A mini-incision lateral approach by the senior author (K. A. L.) was performed on 38 hips, and a standard posterior approach was used on the other 32 hips. If needed, the acetabulum was over-reamed by 1 mm, depending on the acetabular bone quality. For sclerotic bone stock, the over-reaming was performed to facilitate the impaction of the component. The acetabular and femoral components were applied using the press-fit technique. A modular neck and head with a diameter 6 mm smaller than the cup was assembled. The hip was reduced and stability was checked before wound closure.

Partial weight bearing with a walker or crutches was allowed 8 hours after surgery. No dislocation precautions were taken after the operation. Extreme ROM was achieved by each patient at his or her own pace. Full weight bearing was allowed beginning in the sixth week.

The patients were followed up at 3 months, 6 months, and 1 year after surgery, and then annually. Hip function was assessed using Harris Hip Scores (HHS) and clinical examination at every clinical visit. The clinical examination included assessment of ROM and impingement tests; a positive diagnosis was given for pain and a mechanical block on maximum flexion and internal rotation or in maximum extension and external rotation. Standard anteroposterior radiographs for THA were taken postoperatively after 3 months and then annually. Two observers (P. T. W. and K. A. L.) assessed the radiographs for evidence of osteolysis in each of the three acetabular zones as described by DeLee and Charnley [11] and the seven femoral zones as described by Gruen et al. [12]. Stem migration was measured by quantifying any change in distance between the tip of the proximal femoral stem and the tip of the greater trochanter. Inclination of the acetabular component was measured via a line drawn between the teardrops. Movement of more than 5 mm between follow-up radiographs was defined as migration [13]. In the event that the patient did not return for a regular follow-up, evaluation via the HHS questionnaire was performed by telephone. The hip ROM score in the HHS questionnaire was recorded as the score in the latest clinical visit.

All statistical analyses were performed with SPSS software (Version 16.0; SPSS Inc., Chicago, IL, USA). The results are expressed as percentages for the categorical variables and as means and ranges for the numerical variables. Percentages were compared using the Chi-square test with Yates’s correction for continuity or Cramer’s V coefficient. The HHS and the ROM scores were analyzed using the paired t test. The correlations between the categorical and numerical variables were analyzed using binary logistic regression. The significance level was set at less than 5%.

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Preoperation</th>
<th>Postoperation</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Harris Hip Score mean (range)</td>
<td>53.6 (32–77)</td>
<td>95.2 (85–100)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Flexion mean (SD)</td>
<td>103.4° (7.1°)</td>
<td>133.6° (6.8°)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Extension mean (SD)</td>
<td>5.9° (9.2°)</td>
<td>10.0° (3.3°)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Abduction-adduction mean (SD)</td>
<td>43.8° (5.5°)</td>
<td>58.8° (4.9°)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>External-internal mean (SD)</td>
<td>37° (10.2°)</td>
<td>68° (6.7°)</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

SD = standard deviation.

Figure 2. A 27-year-old woman with left hip traumatic osteonecrosis received left total hip arthroplasty with the implants used in our series. (A) The anteroposterior radiography of the pelvis with Harris Hip Score of 100 in latest follow-up. (B) She could fully squat with ease, with her heels in contact with the buttocks.
Results

The HHS and the ROM (Table 1) had significantly improved after a mean follow-up of 32.6 months (range, 24–48 months). Six patients underwent the latest follow-up evaluation via telephone. Of the 70 hips, 66 (94%) had excellent results (HHS > 90) and 4 (6%) had good results (HHS > 80). Of the 59 patients, 57 (96.6%) could achieve at least 120° of active and painless hip flexion, and 54 patients (91.5%) could squat with the heels in contact with the buttocks (Fig. 2). As shown in Table 2, in the five squat-limited patients, the impediments to a full squat included the range-limiting effects of obesity (body mass index > 30; n = 2), weakness of the contralateral revisional THA (n = 1) with fibrous union of the greater trochanter osteotomy restricting the ipsilateral hip that had an adequate ROM (maximum flexion angle = 130°), and poor preoperative hip ROM because of chronic severe hip deformity (n = 2). None of the patients had a positive result in the impingement test. No dislocations or infections were noted during our follow-up period. Of the 70 hips, 6 (8.6%) experienced transient thigh pain, which was correlated with motion but did not experience the characteristics of iliopsoas impingement or bursitis; all improved after analgesic use and resolved after 6 months. One intraoperative calcar fissure was encountered during broaching, and cerclage wiring was used for fixation; there was no stem-related complication with the bony union in later follow-up visits (Fig. 3).

No cup loosening, migration of stem or cup, or osteolysis in any zone was noted on the serial radiographs during the follow-up. On the acetabular component, there were postoperative gaps in 24 hips, with 22 in Zone II, at a mean depth of 1.07 mm (range, 0.7–1.73 mm; Table 3). As shown in Fig. 4, there was no correlation between the presence of a gap and the occurrence of transient thigh pain (p = 1.00) or the HHS (p = 0.344). All gaps filled after 1 year, except in two patients (HHS = 100 and 91, a statistically insignificant clinical relationship). The mean acetabular component inclination angle was 43.2° (range, 33–62°) and between 40° and 50° in 44 hips. There were 20 cups in a too-close position (<40°) and 6 cups in a too-open position (>50°). However, as shown in Fig. 5, cup inclination was not correlated with transient thigh pain (p = 0.075) or HHS (p = 0.48).

Discussion

Previous studies have shown favorable results in MOM hip arthroplasty with either resurfacing arthroplasty [14,15] or total joint replacement [3–6,16–19]. According to previous tribology studies, the larger the femoral head diameter, the lower the wear rate [20,21] is in hard-on-hard bearings, such as MOM or ceramic-on-ceramic, because of the advantage of fluid-film lubrication. Furthermore, a larger

Table 2 Clinical features of five patients who could not fully squat

<table>
<thead>
<tr>
<th>Clinical features</th>
<th>Case 1</th>
<th>Case 2</th>
<th>Case 3</th>
<th>Case 4</th>
<th>Case 5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diagnosis</td>
<td>Osteonecrosis</td>
<td>Osteonecrosis</td>
<td>Dysplastic hip</td>
<td>Osteonecrosis</td>
<td>Osteonecrosis</td>
</tr>
<tr>
<td>Body mass index</td>
<td>31.1</td>
<td>32.3</td>
<td>20.2</td>
<td>24.6</td>
<td>25.3</td>
</tr>
<tr>
<td>Preoperative ROM (flexion/extension)</td>
<td>100°/0°</td>
<td>98°/2°</td>
<td>95°/4°</td>
<td>85°/2°</td>
<td>80°/0°</td>
</tr>
<tr>
<td>Postoperative ROM (flexion/extension)</td>
<td>120°/5°</td>
<td>120°/5°</td>
<td>130°/5°</td>
<td>118°/7°</td>
<td>117°/2°</td>
</tr>
<tr>
<td>Postoperative hip lengthening (mm)</td>
<td>2.35</td>
<td>5.75</td>
<td>8.97</td>
<td>15.2</td>
<td>14.8</td>
</tr>
<tr>
<td>Causes of failure to full squat</td>
<td>Body figure limit</td>
<td>Body figure limit</td>
<td>Contralateral hip weakness</td>
<td>Poor preoperative ROM</td>
<td>Poor preoperative ROM</td>
</tr>
</tbody>
</table>

ROM = range of motion.

Figure 3. Anteroposterior radiography of the pelvis of a patient receiving staged bilateral total hip arthroplasties. Intraoperative calcar fissure was encountered during broaching and cerclage wiring was immediately applied. Plain radiography conducted at the patient’s latest follow-up showed bony union and no stem sinking.

Table 3 The gap area distribution, hip numbers, and mean gap depth

<table>
<thead>
<tr>
<th>Gap area</th>
<th>Hip number</th>
<th>Depth (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zone I</td>
<td>2</td>
<td>1.62 (1.44–1.8)</td>
</tr>
<tr>
<td>Zone II</td>
<td>22</td>
<td>1.07 (0.5–1.73)</td>
</tr>
<tr>
<td>No gap</td>
<td>46</td>
<td></td>
</tr>
</tbody>
</table>
femoral head diameter can offer more ROM and stability. Therefore, the large-diameter femoral head should be the preferred choice for MOM bearing design. Such a design used to be applied with resurfacing hip arthroplasty. However, compared with THA, resurfacing hip arthroplasty should still be performed with caution because of the femoral side effects related to malpositioning or inappropriate patient selection, more extensive soft tissue release, difficulty dealing with limb length and offset, and technique familiarity [6].

In our study, 57 patients (96.6%) could achieve at least 120° of active and painless hip flexion and 54 patients (91.5%) could fully squat. All patients could return to their previous jobs and recreational activities. With such extreme ROM, there was still no dislocation after at least 24 months of follow-up. This result is superior to those reported with conventional THA (2.1–9.5%) [22–24] and also superior or similar to other total hip replacement studies with large MOM femoral head procedures (0–1.8%) [3,5,6,25,26]. Compared with other studies of nonanatomic head THA in young, active adults, our study showed a better dislocation rate [27,28]. Stuchin [6] believed that the anatomic size head not only reduced the dislocation rate but also might more closely approach the kinematics of the normal hip.

Delayed-type hypersensitivity, which may induce early osteolysis or unexplained pain, is still a concern and has been reported in multiple studies [29–33]. However, this phenomenon was not observed in our study. Only six hips (8.6%) had transient thigh pain, which disappeared after 6 months. The occurrence of thigh pain was not correlated with either the radiological signs or the preoperative HHS (p = 0.101). The mechanism of transient thigh pain was not clear. We conjectured that it may have resulted from more extensive soft tissue release because of more severe hip deformities, but we were not able to prove or disprove this theory using our current data.

In MOM designs, aseptic cup loosening because of either poor bone quality [5] or poor bone ongrowth [25,34] should be kept in mind. Berton et al. [25] believed that the smaller pore size and larger inclination (>50°) of the Durom cup contributed to revision because of the poor bone ongrowth on the cup. In our study, there were no cup component complications with either optimal inclination (40°–50°) or suboptimal inclination (<40° or >50°). Cup stability resulted from primary fixation via impaction and secondary fixation via subsequent bone ongrowth. Too large a postoperative gap may not only decrease primary fixation strength but also weaken secondary fixation. Long et al. [34] found that the flare design of the Durom cup may prevent full contact of the fixation surface throughout the prepared acetabular bone and may thus limit bone ongrowth. Although we could neither prove in this study nor did other studies [25,26] prove that the postoperative gap is

![Figure 4](image-url)
a risk factor related to aseptic loosening of the cup component, we strongly suggest that, for sclerotic acetabular bone stock, over-reaming by 1 mm better facilitates the seating of the component because the Durom cup is 2 mm wider at the rim than the dome.

An elevated metal ion level with the possible risk of carcinogenicity is another issue that calls for more attention. Various cobalt and chromium elevation ratios have been shown in different studies [35–37], and metal ion level elevation is a fact. Garbuz et al. [35] suggested avoiding the use of large-head MOM THA, compared with MOM resurfacing arthroplasty, because of the relatively high metal ion levels after a 1-year follow-up. The mismatch between the titanium stem and the chromium-cobalt alloy adapter was the major cause of the relatively high ion levels. But other long-term studies showed no increase in the overall cancer risk [38,39] and no cases of renal insufficiency [40] in patients receiving MOM THA. In our study, the serum metal ion level was not checked because no patients presented with unexplained pain or other special complications. Therefore, systemic side effects related to metal debris and serum-elevated metal ion levels must not be overlooked and should be monitored in further follow-up. Furthermore, the possible deleterious effect of elevated metal ion levels on the fetus cannot be overemphasized. The indication of such prostheses for women with a gestational potential should be circumspect. In our study, there were six women of childbearing age who were willing to use such prostheses after clearly explaining and informing them of the potential risks, including the inability to conceive in the future.

The early results of large-head MOM THA in appropriately selected patients younger than 60 years are encouraging. All patients were able to resume their previous jobs and social activities with little limitation of movement or discomfort. However, there were some shortcomings to our study, such as inadequate radiographs that included only one view, the short follow-up, and the small number of patients. Thus, longer-term observation is necessary to determine the functional and radiological outcome, possible immune reactions, and possible side effects induced by metal debris and ions.

Acknowledgments

The authors would like to thank Miss Yu-Ying Chen for her excellent assistance. The authors did not receive any outside funding or grants in support of their research or for preparation of this manuscript. No commercial entity paid or directed, or agreed to pay or direct, any benefits to any research fund, foundation, division, center, clinical
practice, or other charitable or nonprofit organization with which the authors are affiliated or associated.

References


