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Small-head metal on metal total hip arthroplasty is associated with a high rate of complication and reoperation at mid-term follow-up

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Abstract

Background: Adverse reactions to metal debris are significant complications after metal-on-metal total hip arthroplasty. Recently, late appearances of adverse reactions to metal debris and subsequent need for reoperations have been reported with small-diameter head metal-on-metal devices. We retrospectively investigated mid-term clinical outcomes of small-head metal-on-metal total hip arthroplasty.

Methods: We reviewed 159 hips in 139 patients who had a small-head metal-on-metal total hip arthroplasty (M2a Taper; Biomet, Warsaw, IN) with a minimum 5-year follow-up and documented postoperative complications.

Results: Focal osteolysis in either the femur or acetabulum was observed in 12 hips (7.5%, 44 months after surgery on average), with pseudotumor observed in 8 hips (5%, 120 months after surgery on average). Four hips (2.5%) had dislocations (84 months after surgery on average) and six hips (3.8%, 122 months after surgery on average) underwent reoperation.

Conclusion: Small-head metal-on-metal total hip arthroplasty is associated with a high degree of complications at mid-term follow-up period. Considering this, we discourage the use of metal-on-metal total hip arthroplasty regardless of head size.

Keywords

Metal on metal, total hip arthroplasty, adverse reactions to metal debris, focal osteolysis, complication, reoperation

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Introduction

Two decades have passed since the second generation of metal-on-metal (MoM) total hip arthroplasty (THA) gained popularity as an alternative surgical option for relatively younger patients. This alternative aimed to induce fewer wear-related complications than THA with polyethylene bearings.[1,2] However, since their introduction, large-head MoM bearings have provoked concern among surgeons due to patients' adverse reactions to metal debris (ARMD).[3–7] Subsequently, some of the available large-head MoM devices have been recalled, and the regulatory authorities in the United Kingdom, the United States, and Australia have released medical device alerts.[8–10] At that time, the small-head diameter MoM bearings continued to be reported as safer for THA than the large-diameter bearings given the development of fewer ARMD.[11–16] However, recent studies have reported that small-head MoM devices also have substantial rates of ARMD.[17–22]

To date, few studies have quantified the adverse reactions of small-head MoM THA devices. In addition, as far as we are aware, none of the reported studies have evaluated the timing of the development of post-surgical complications. This study aimed to investigate the mid-term clinical results of small-head MoM THA focusing on the rates of various complications and their time of occurrence.

Methods

This retrospective study was approved by an independent institutional review board, and all patients provided informed consent. Between January 2010 and January 2016, 163

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patients (187 hips) at our institution underwent primary MoM THA using M2a Taper (Biomet, Warsaw, IN) for osteoarthritis, femoral head avascular necrosis, rapidly destructive coxopathy (RDC), or nonunion of the femoral neck fracture. The M2a Taper utilizes a small head (28 or 32 mm diameter) with articulating surfaces made from high carbon CoCrMo alloy. We typically chose this MoM THA device for relatively young and active patients. All MoM THAs using this device in the above period were considered for inclusion. Patients who were not followed for at least 5 years were excluded. This left 159 hips in 139 patients for inclusion in the study. 59% of the patients were females. The mean age of patients was 59.2 years (range, 32–80 years) with a mean follow-up period of 8.2 years (range, 5–14 years). A 28-mm head was used in 44 hips and 32 mm in 115 hips. All devices were inserted with a cementless fixation, using a direct anterior approach (DAA) with the patients in the supine position on a standard surgical table. All the surgeries were performed by a single experienced surgeon.

We explored the complication rates of MoM THA using the M2a Taper recording the incidence of focal osteolysis in either the femur or acetabulum, pseudotumors, dislocations, infections, and reoperations, as well as their time of occurrence since the surgery. We used radiography for a primary evaluation and computed tomography (CT) scans when ARMD were suspected clinically or radiographically. CT was performed using a Canon Alexion TSX-034A (Canon Medical Systems, Tokyo Japan), with a setting of 16 slices of 0.5 mm width.

Statistical analysis

Osteolysis-free survival and revision-free survival were estimated using the Kaplan–Meier survival method. The log-rank test was used to determine significant differences in the incidence of osteolysis according to gender, age, body mass index (BMI), diagnosis, head size, and cup size. Excel add-in Software "multi tahenryo" was used for the statistical analysis. A p value of <0.05 was considered statistically significant.

Results

Focal osteolysis in either the femur or acetabulum was observed in 12 patients (7.5%), with pseudotumor observed in 8 patients (5%). Four patients (2.5%) had dislocations and six patients (3.8%) underwent revision surgery. The mean time between surgery and post-surgical complications was 44 months for osteolysis (range, 12–96 months), 120 months for pseudotumor (range, 84–144 months), 122 months for reoperation (range, 84–144 months), and 84 months for dislocations (range, 36–144 months). Three of the four patients with dislocation also had osteolysis in either the femur or acetabulum. There was one case of periprosthetic infection that occurred at 144 months postoperatively, which was treated with open drainage and antibiotics. The pseudotumor that occurred in this same patient was thought to be the culprit of this late occurrence of periprosthetic infection. Reoperation was required due to symptomatic pseudotumor in three cases, dislocation as a result of focal osteolysis in the femur in two cases, and periprosthetic infection secondary to the pseudotumor in one case. In all the cases that underwent revision surgery, the inner metal cup was removed, a highly cross-linked polyethylene liner was fixed with cement to the original cup, and the metal head was replaced with a new metal head of same size. It should be noted that all cases were seen to have successfully achieved bone ingrowth to the implants at the initial follow-up period, without apparent radiolucency around the cup or stem.

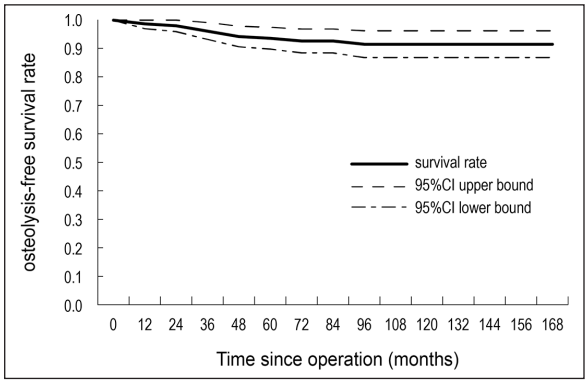

Figure 1. Osteolysis-free survival rate. Osteolysis-free survival rate was 91.6% (95% CI, 86.9–96.3) at 168 months after THA.

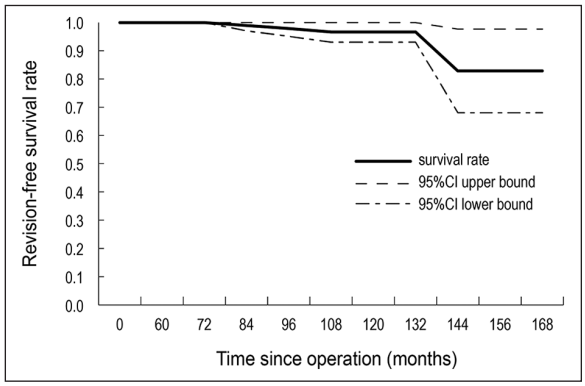

Figure 2. Revision-free survival rate. Revision-free survival rate was 82.9% (95% CI, 68.1–97.7) at 168 months after THA.

The osteolysis-free survival rate and revision-free survival rate at 168 months after THA were 91.6% (95% confidence interval (CI), 86.9–96.3) and 82.9% (95% CI, 68.1–97.7), respectively (Figures 1 and 2). Regarding the incidence of osteolysis, there was significant difference between diagnosis (6.8% vs 25.5% for osteoarthritis vs avascular necrosis, respectively, $p=0.006$**), but no significant difference between male and female (8.2% vs 8.8%, $p=0.849$), age (5.0% vs 11.0% for patients aged <60 vs

Table 1. Patient demographics.

Variable	Osteolysis group	Non-osteolysis group	p value
Number, *n* (%)	12 (7.5)	147 (92.4)	
Age, years, mean (SD)	62.8 (± 3.7)	58.9 (± 9.4)	0.198
Sex, male/ female, *n* (%)	5 (41.7)/7 (58.3)	56 (38.1)/91 (61.9)	0.849
BMI, kg/m^2, mean (SD)	24.0 (± 5.6)	23.8 (± 3.6)	0.832
Disease, OA/AN/RDC/NU, *n* (%)	8 (66.7)/4 (33.3)/ 0 (0)/0 (0)	131 (89.1)/12 (8.2)/2 (1.4)/2 (1.4)	0.006**

BMI: body mass index; SD: standard deviation; OA: osteoarthritis; AN: avascular necrosis; RDC: rapidly destructive coxopathy; NU: nonunion of the femoral neck fracture.

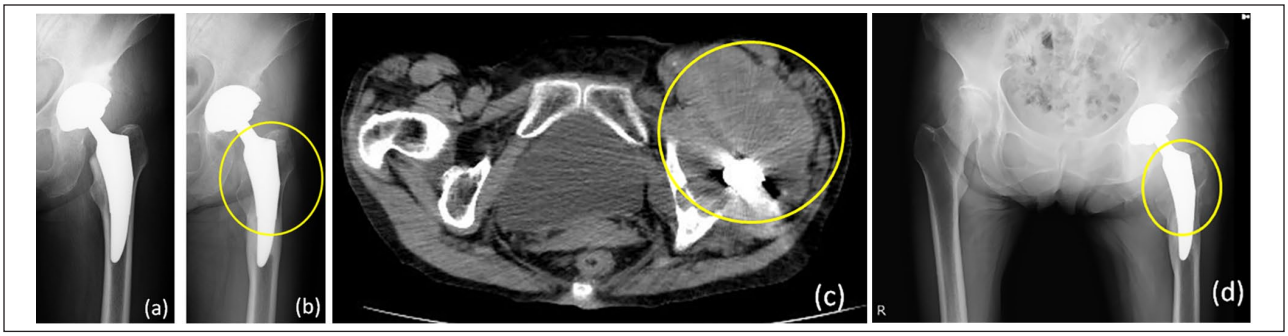

Figure 3. Postoperative radiography of a 68-year-old female patient who underwent MoM THA of the left hip using M2a Taper with head-size of 32 mm. The patient experienced no complications until 8 years postoperatively, when she developed left hip pain. At that time, focal osteolysis at the femur and the acetabulum were recognized by radiography (Figure 3(a) and (b)). A CT scan and radiography at 9 years postoperatively showed a pseudotumor around the stem and further advanced osteolysis at the femur (Figure 3(c) and (d)). The patient subsequently underwent reoperation changing the bearing surface to highly cross-linked polyethylene, and intraoperative findings were consistent with ARMD. (a) Postoperative X-ray. (b) X-ray performed 8 years postoperatively shows osteolysis (yellow circle) of the femur and acetabulum. (c) A CT scan performed 9 years postoperatively shows a pseudotumor (yellow circle) around the proximal stem. (d) X-ray performed 9 years postoperatively shows further advanced osteolysis at the femur.

⩾60, respectively, $p=0.198$), head size (7.5% vs 8.7% for 28 mm vs 32 mm, respectively, $p=0.759$), cup size (10.5% vs 6.0% for <54 mm vs ⩾54 mm, respectively, $p=0.505$), and BMI (8.0% vs 12.5% for BMI <30 vs ⩾30, respectively, $p=0.832$).

Patient demographics of the osteolysis group and non-osteolysis group are described in Table 1. Two example cases of late-onset, ARMD-related complications of small-head MoM THA are presented in Figures 3(a)–(d) and 4(a)–(h).

Discussion

This is the first study to investigate complications post-THA with small-head MoM bearings. We found significant rates of ARMD and ARMD-related complications among patients treated at our center. There are a few important findings from this study. First, in THA with small-head MoM bearings, complications such as pseudotumor and dislocation were common leading to a relatively high rate of reoperation (3.8%). Second, observed complications tended to occur late after THA and were mostly devastating. On average, reoperations were performed 10 years after surgery, reflecting this late occurrence. This study therefore emphasizes the importance of long-term follow-up. In addition to the high frequency of dislocations (2.5%), first-time dislocations in small-head MoM THAs occurred on average of 7 years after THA, which is later than for THAs in general. In contrast, a study of all patients receiving THAs at the same institution, Tamaki et al. reported that the cumulative risk of first-time postoperative dislocation after DAA-THA was 0.80% at 1 year postoperatively, and 0.93% at 5 years postoperatively, and the risk of dislocation after the first month was considerably low.[23] The high dislocation rate and its later onset seen in this study of small-head MoM THAs is concerning. Most of the dislocations occurred in cases where osteolysis was observed in the femur. Based on the intraoperative findings during the revision surgeries (see Figure 4(e)–(h)), the observed redundant capsules that occurred due to the debris were thought to be the primary cause of dislocations.

In this study, the occurrence of osteolysis was significantly higher in patients with diagnosis of avascular necrosis than osteoarthritis. Some publications still encourage the use of MoM THA for young and active patients especially with osteonecrosis, because of concern of higher failure rates with THA.[24–26] However, this study shows that MoM THA does not benefit patients with osteonecrosis in the long-term period even if a small-head is used.

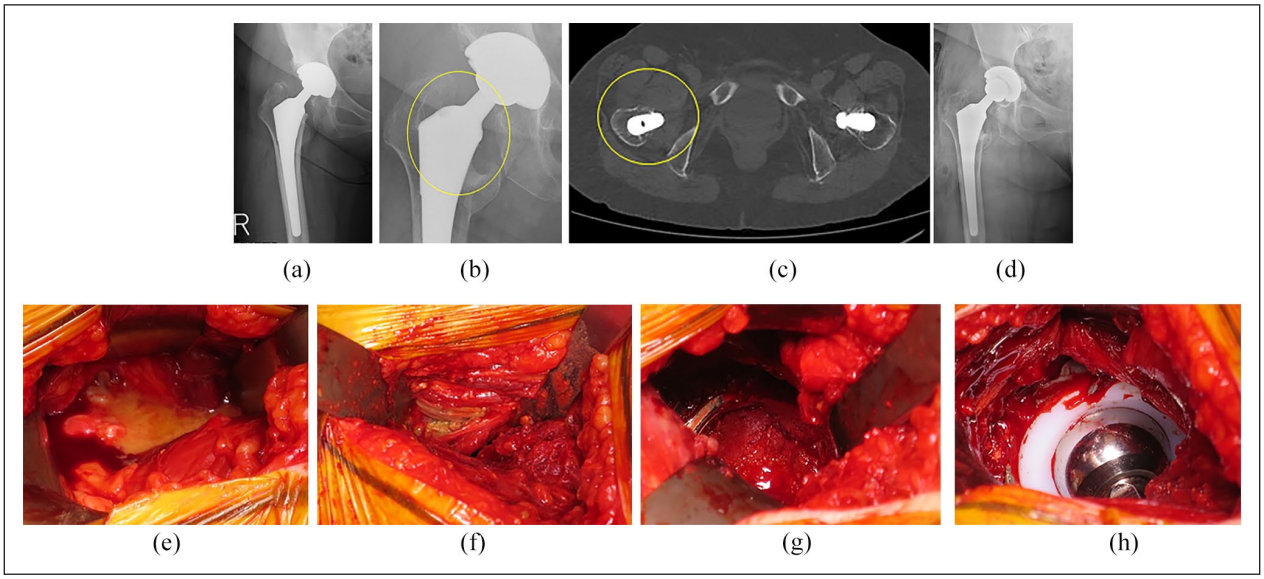

Figure 4. Postoperative radiography of a 59-year-old female patient who underwent MoM THA of the right hip using M2a Taper with head-size of 28 mm (a). The patient experienced no complications until 6 years postoperatively, when she developed right hip pain. At that time, focal osteolysis of the femur and the acetabulum were observed on radiography. A CT scan and radiography at 12 years postoperatively showed a pseudotumor around the stem and further advanced osteolysis at the femur (b) and (c). The patient subsequently underwent reoperation by changing the bearing surface to highly cross-linked polyethylene, and intraoperative findings were consistent with ARMD (d)–(h). (a) Postoperative X-ray. (b) X-ray performed 12 years postoperatively shows osteolysis (yellow circle) at the femur and acetabulum. (c) A CT scan performed 12 years postoperatively shows a pseudotumor (yellow circle) that developed around the proximal stem. (d) X-ray after revision surgery at 12 years from the THA. Intraoperative findings: (e) the capsule was filled with yellow-colored liquid; (f) a pseudotumor was filled with viscous debris inside; (g) the cup was filled with debris; and (h) after removing the debris, a highly cross-linked polyethylene liner was fixed with cement to the original metal cup, and the metal head was replaced to new one of the same-size.

In 2008, Dastane et al.[27] retrospectively studied MoM THA in patients 60 years of age or younger with minimum follow-up of 2.2 years and compared the performance between patients with osteonecrosis and osteoarthritis. They reported no osteolysis was observed in osteonecrosis group and showed similar clinical and radiographic results between both groups, which is contrary to the outcome of this study. In their study, they used Metasul (Zimmer, Inc., Warsaw, IN) MoM articulation, which is composed of a metal-polyethylene sandwich-type acetabular insert. It is possible that the unique feature of the specific MoM device they used might have resulted in better outcomes in patients with osteonecrosis compared with our study. However, in their study, the mean follow-up period was limited to 5.5 years and only plain radiography was used for imaging analysis; longer follow-up and appropriate use of CT scans could have detected higher occurrence of osteolysis.

Our observations indicate that focal osteolysis is an important early sign of ARMD, for which radiography is a useful screening tool. When focal osteolysis is observed on radiography, and ARMD is suspected, careful monitoring or more detailed imaging with CT is recommended. The early fixation of the cup and stem in small-head MoM THA results in adequate short-term clinical outcomes in the majority of cases; however, a significant subset of cases go on to develop ARMD. The first presentation of ARMD symptoms is typically hip or thigh pain. Focal osteolysis in the femur may be seen on radiography prior to symptoms and hence plays a key role as a warning sign that the impending ARMD-related complications may occur. ARMD subsequently caused the late appearance of dislocations, pseudotumors, and infections. The pseudotumors were typically identified on CT scans as progression of ARMD following the development of swelling, a palpable mass, or vague pain in the hip. The late occurrence of reoperations and dislocations is a significant issue in small-size MoM bearings, which necessitates long-term close monitoring of these devices.

In 2013, Mokka et al.[7] studied 80 hips that underwent MoM THA with large-head M2a Magnum (Biomet, Warsaw, IN) with a mean follow-up time of 6.0 years. A revision surgery due to ARMD was needed in 3 out of 80 hips. The authors discouraged the use of this device because of the high incidence of ARMD-related failure. MoM bearings with small head sizes were initially thought to reduce the risk.[11–16] However, in 2015, Lombardi et al.[17] studied 300 THA with small-head MoM bearings (M2a Taper) with a minimum of 2 years follow-up and reported that ARMD incidence was 5% and represented 70% (14 of 20) of revisions performed. The authors concluded that the development of ARMD was not exclusive to large-head

THA and recommended the discontinuation of all MoM devices due to the late-onset and devastating nature of these metal-related failures. The results of our study further highlight these risks.

Our study has several limitations. First, there was no control group because we deliberately chose this MoM device for younger patients. Second, all patients who received the device were included in the study, and since 2016, we stopped using the device due to safety concerns. Hence, power calculation for estimation of the sample size was not performed. Third, due to the restrictive cost, we did not measure ion levels or perform magnetic resonance imaging (MRI) for the diagnosis of ARMD, which has been recommended in several studies.[28,29] However, as reported by Fokter et al., ion levels cannot reliably predict the development of the metal debris.[30] This study suggests that these tests are not necessary if adequate radiographic and clinical monitoring is implemented. From our observations, focal osteolysis in the proximal femur occurred during the early phase of ARMD, before occurrence of a pseudotumor became obvious on CT scans.

Conclusion

Our observations suggest that complications related to ARMD in small-head MoM-THA are significant, and these can occur late, even more than 10 years after surgery. Therefore, long-term close monitoring is necessary. In light of these high complication rates, we discourage the use of MoM-THA regardless of head size.

Declaration of conflicting interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Ethical approval

Ethical approval for this study was obtained from Funabashi Orthopaedic Hospital, Institutional Review Board. The IRB number is 2020047.

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Informed consent

Written informed consent was obtained from all subjects before the study.

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