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High Complication Rate After Revision of Large-head Metal-on-metal Total Hip Arthroplasty

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Abstract

Background Previous studies have indicated poor outcomes in patients having revision of hip resurfacing resulting from adverse local tissue reaction and pseudotumor.

Questions/purposes We reviewed all patients at our institution who had revision of failed large-head metal-on-metal total hip arthroplasty to determine (1) complications including reoperations; (2) radiologic outcomes; and (3) changes in serum ions after removal of the metal bearing.

Methods From our research database, we identified 32 hips in 30 patients. Revisions were performed through a posterior approach; 17 were performed with a titanium fiber-metal shell and 15 with a porous tantalum shell, and 29 of the 32 revisions were performed with large (36- or 40-mm) femoral heads. Clinical records were reviewed and interviews conducted in the clinic or by telephone. Nineteen hips had a pre- or intraoperative diagnosis of adverse local tissue reaction, three had deep infection, and 10 had loosening of the acetabular component.

Results Major complications occurred in 12 (38%) of the 32 revisions. Nine of 32 hips (28%) sustained dislocations. Four of 17 fiber-metal acetabular components failed to ingrow; none of the porous tantalum cups failed to ingrow. Seven repeat revisions were performed in six patients: three for acetabular loosening, three for recurrent dislocation, and one for recurrent adverse local tissue reaction. The mean WOMAC pain score was 78 of 100 and the function score was 83 of 100. Metal ion levels decreased after revision in most patients.

Conclusions As a result of the high rate of failure of the fiber metal cups, we have elected to use an enhanced fixation surface with a high-porosity cup for revision of these cases. We observed a high rate of dislocation despite the use of 36-mm and 40-mm heads.

Level of Evidence Level IV, therapeutic study. See the Guidelines for Authors for a complete description of levels of evidence.

Each author (JTM, BAM, CPD, DSG) certifies that he or she has or may receive payments or benefits in any one year, an amount of USD 10,000–USD 100,000 (eg, serve as a consultant [JTM, BAM, CPD, DSG] or speakers bureaus [CPD]) from a commercial entity (Zimmer, Inc, Warsaw, IN, USA); and an amount of USD 10,000–USD 100,000 (speakers bureaus [CPD]) from a commercial entity (DePuy Synthes Canada Ltd, Markham, Ontario, Canada) related to this work. The institution of the authors (JTM, BAM, CPD, DSG) has received funding from Zimmer Inc (Warsaw, IN, USA), DePuy Synthes Canada Ltd, Johnson & Johnson (Canada) Inc (Markham, Ontario, Canada), Stryker Canada (Hamilton, Ontario, Canada), and Bayer Inc (Toronto, Ontario, Canada).
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Each author certifies that his or her institution approved the human protocol for this investigation, that all investigations were conducted in conformity with ethical principles of research, and that informed consent for participation in the study was obtained.

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Introduction

Large-head, metal-on-metal (MoM) THA was proposed as a procedure that combined a large-diameter head with high head-neck ratio without the technical difficulty of hip resurfacing. Unfortunately, the failure rate of these implants has been higher than expected [29] with joint registry data showing inferior medium-term survival [2, 26]. The medical device industry has reacted to some of these concerns with implant recalls [13].

It is known that MoM hip implants release significantly higher amounts of metal ions than metal-on-polyethylene (PE) articulations [1, 5]. The local and systemic significance of higher metal ion concentrations still are not fully understood, but adverse local tissue reactions (ALTRs) or adverse reaction to metal debris [14] have been associated with MoM implants [8, 11, 20, 22, 24]. These lesions are characterized by areas of necrosis bounded by perivascular lymphocyte-dominated inflammation [6]. In cases in which large infiltrative soft tissue masses have formed, they have been referred to as pseudotumors [4, 28]. ALTRs can cause pain, damage to local bone and soft tissue, and instability of the prosthetic joint. Although high rates of complication and rerevision have been reported after revision of large-head MoM resurfacing devices [2, 9, 17], to our knowledge, there are no published reports of outcomes after revision of large-head, MoM THA. We therefore sought to determine (1) complications occurring after revision, including reoperations; (2) radiologic outcome; and (3) changes in metal ion levels after revision of the bearing to metal-on-polyethylene.

Patients and Methods

From 2005 to 2008, 360 primary large-head, MoM THAs were performed at our institution using the Durom® MoM articulation (Zimmer, Warsaw, IN, USA). A further 15 Durom® resurfacings with failed femoral components were revised to large-head, MoM THA with retention of the acetabular component in the same period. Twenty-eight (8%) of the 360 primary THAs subsequently required revision along with one large-head THA performed as revision for a failed femoral component of hip resurfacing. Additionally, three patients (three hips) were referred from other centers with failure of their primary large-head THA. A total of 32 large-head MoM THAs in 30 patients were revised between January 2008 and June 2011. Minimum followup was 10 months (mean, 25 months; range, 10–48 months).

Demographic data were collected for all patients. The mean age at primary surgery was 54.6 years (range, 43–75 years) and the mean time to revision was 34 months (range, 7–59 months). The mean age at revision was 57.5 years (range, 46–76 years). Eleven were women and 19 were men. Thirty-one hips had been implanted with the Durom® acetabular component (Zimmer) and one with an ASR™ (DePuy, Warsaw, IN, USA). The median head size was 48 mm (range, 38–56 mm). The femoral stems were the M/L Taper® (Zimmer) in 29 cases and one each of the CLS® (Zimmer), Tri-Lock® (DePuy), and Wagner Cone Prothesis™ (Zimmer). The primary diagnosis was osteoarthritis in 28 cases. One patient with a failed resurfacing had a femoral component revised with retention of the Durom® cup. Two patients had nonunions from subcapital neck of femur fracture treated initially with internal fixation and in one case a valgus intertrochanteric osteotomy. One patient had degeneration secondary to developmental dysplasia of the hip. All index THAs were performed through a posterior approach except one primary replacement in which a Hardinge approach was used.

The indication for revision surgery was pain associated with ALTR in 19 patients, deep infection in three, and loosening of the acetabular component in 10. ALTR was diagnosed based on preoperative imaging correlated to intraoperative findings and histopathology. Of the deep infections, one patient was managed with débridement and then direct exchange of the acetabular component and femoral head with stem retention. The others had two-stage procedures, one with a PROSTALAC® spacer (DePuy) and one in which a spacer was used in the acetabulum but the stem was retained. In two cases, the infecting organism was *Staphylococcus aureus* and in one *S epidermidis*. All were sensitive to methicillin.

All revisions were conducted by a posterior approach. If reactive tissue or pseudotumour was present, this was resected during exposure when it was easily accessible. The femoral component was well fixed in every case and retained in 31 hips. In one patient with a leg length discrepancy, the well-fixed CLS® stem was removed and revised to a Wagner Cone Prothesis™. In all but two cases the cup was loose and required a small amount of force at the rim to dislodge. All the acetabuli had Type I bone loss according to the classification of Sporer and Paprosky [30].

The acetabular components inserted at revision were a titanium fiber metal cup (Trilogy® Acetabular Hip System; Zimmer) in 17 cases and a porous tantalum cup (Trabecular Metal™ Modular Acetabular System; Zimmer) in 15 cases. The Trilogy cup was selected for earlier revisions based on cost advantage and the minimal bone loss encountered. Revisions were performed by one of three reconstruction surgeons at our hospital (CPD, BAM, DSG). All revision liners were highly crosslinked PE (Longevity® Highly Crosslinked Polyethylene; Zimmer). Twenty-four cases were revised to metal on PE and eight cases to ceramic with a titanium sleeve on PE. Head size was 32 mm in three cases (one ceramic), 36 mm in 20 cases (five ceramic), and 40 mm in nine cases (two ceramic).

To ensure all complications were captured, available medical records were reviewed inclusive of outpatient clinic records, operative reports, and hospital records for readmissions and interviews with patients were conducted either in the clinic or by telephone. The following were considered to be major complications for purposes of this specific review: instability, neurovascular injury, deep infection, reoperation, component loosening, and recurrence of ALTR. Of the 30 patients in this series, complete followup was available for 23 (25 hips) and telephone followup along with radiographs on seven patients. None were lost to followup.

AP pelvis, Judet, and lateral hip radiographs were performed before revision, postoperatively, and at followup. Loosening of the acetabulum was defined as continuous lucency around the cup [34], superior migration > 2 mm measured from Kohlers line [10], protrusion, or progressive tilt of the socket or fracture of the screws. Loosening of the stem was defined as subsidence > 2 mm, circumferential progressive lysis at the bone-stem interface, multiple small foci of osteolysis, or any large osteolytic defect around the stem [12].

Trace metal cobalt and chromium ion testing was conducted in 16 patients using the protocol as published by Williams et al. [33]. Eleven patients (13 hips) who underwent revision early in the series and three patients with infection did not undergo baseline testing. The protocol for routine testing was adopted during the period in question. Serum samples were collected at baseline and postoperatively at 2 months, 6 months, 12 months, and 24 months. Serum was frozen at −20° C and then sent for processing at the Trace Elements Laboratory, Department of Laboratory Medicine, London Health Sciences Centre, London, Ontario, Canada, using accurate high-resolution inductively coupled plasma mass spectrometry [23].

C-reactive protein (CRP) was used as a routine screening tool for infection in all patients. If CRP was elevated (> 5), a radiologic-guided aspirate was obtained and sent for culture and cell count.

Fisher's exact test was used to test for an association between cup type (Trilogy® cup versus Trabecular Metal™ cup) and failure to ingrow. Fisher's exact test was also used to test for an association between ALTR (yes/no) and dislocation. Statistical significance was set at $\alpha = 0.05$.

Results

At mean followup of 25 months, at least one major complication had occurred in 12 (38%) of the 32 revisions (Table 1). Failure as defined by rerevision or a loose implant was 19% (six of 32 hips). Dislocation requiring reduction under anesthesia occurred in eight patients with one additional patient reporting a dislocation reduced in the community with traction alone (28% dislocation rate, nine of 32 hips). Three of these patients had 32-mm heads, four had 36-mm, and two had 40-mm heads. There was no significant difference in dislocation between those diagnosed with ALTR and loosening. Two patients had large pseudotumors associated with ALTR and both sustained nerve injuries. In one case, the sciatic nerve was directly injured during exposure because the pseudotumor was wrapped completely around the sciatic nerve. Microscopic repair was conducted at the time of revision and there was partial recovery after 2 years. The other case involved a femoral nerve paresis that has completely recovered although this patient sustained multiple dislocations. Six patients had further revision surgery. In three cases in which rerevision was performed for recurrent dislocation, two head sizes were increased from 36 mm to 40 mm, and in one, a +0 40-mm head was changed to a +7 36-mm head with a 10° elevated lip liner. All have remained stable to date.

Table 1. Complications grouped by diagnosis

Complication	ALTR (N = 19)	Loosening (N = 10)	Infection (N = 3)
Dislocation	5 (26%)	4 (40%)	0
Nerve injury	2 (11%)	0	0
Infection	0	1 superficial (10%)	0
Cup loosening	3 (16%)	1 (10%)	0
Rerevision	4* (21%)	2 (20%)	0
ALTR recurred	3 (16%)	–	–

* Four patients with ALTR had rerevision; one was revised again to exchange the femoral head to ceramic; ALTR = adverse local tissue reaction.

Four of 17 (24%) fiber metal acetabular components showed evidence of loosening. All four were multihole cups inserted with a press fit technique, underreaming the acetabulum by 2 mm, and augmented with two screws (two cases) or three screws (two cases). Three have been revised after failure to ingrow: two to porous tantalum cups (Trabecular Metal™) and one to a porous titanium cup (Tritanium®; Stryker, Mahwah, NJ, USA). The fourth patient had a cup migrate with a broken screw but has fibrous ingrowth and does not wish to have further surgery. Two of the cases revised for failed cup ingrowth were also dislocating and in both, the head size was increased from 32 mm to 36 mm. One of these patients had recurrence of pseudotumor after revision to a metal on PE bearing so was revised again, exchanging the 36-mm chrome-cobalt head to a 40-mm ceramic head with a titanium taper sleeve. Lytic lines less than 2 mm confined to one zone were observed in three fiber metal cups and one porous tantalum cup. None of the 15 porous tantalum components demonstrated evidence of radiologic or clinical loosening. The difference in failure to ingrow was not statistically significant with the small numbers available ($p = 0.104$). No stems were loose.

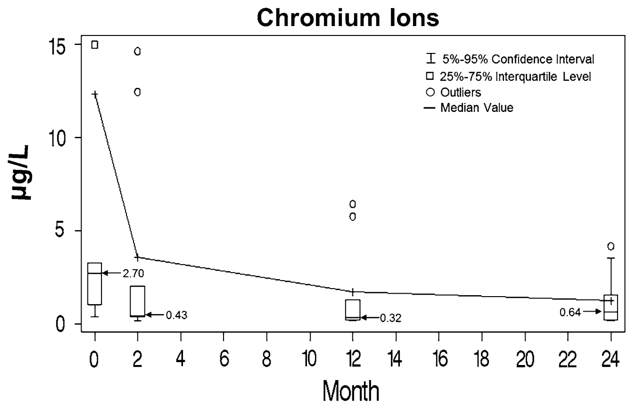

Fig. 1 Trimmed box plot graph showing serum chromium ion levels (µg/L) over 24 months. Boxes are joined through the means. Note: Two extreme outliers (at baseline) are outside the area shown in the box plot.

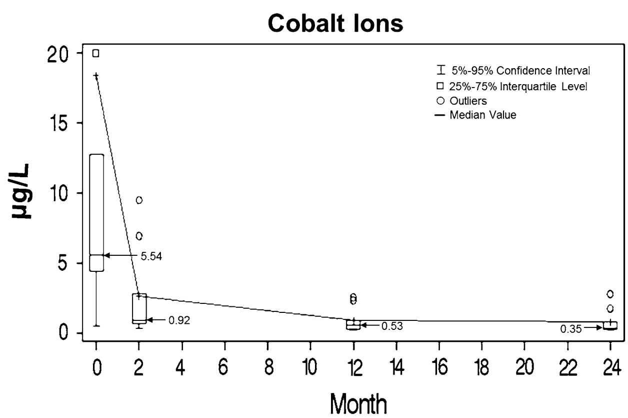

Fig. 2 Trimmed box plot graph showing serum cobalt ion levels (µg/L) over 24 months. Boxes are joined through the means. Note: Two extreme outliers (at baseline) are outside the area shown in the box plot.

Recurrence of ALTR occurred in three patients during the followup period. This did not occur in the two patients with large pseudotumors. One had a ceramic head with a titanium sleeve and two had cobalt-chrome heads. One of the cobalt-chrome heads has since been rerevised to a ceramic head with a sleeve.

Both chromium ion levels (Fig. 1) and cobalt ion levels (Fig. 2) decreased in 14 of 16 patients after revision. Nine of the patients had complete data for each of four followup tests. The median baseline level for chromium was 2.70 µg/L and for cobalt 5.54 µg/L. Two years after revision, the median chromium levels had reduced to 0.64 µg/L and cobalt to 0.35 µg/L. Both patients with increasing levels were males revised to 40-mm cobalt-chrome heads. Neither has any other known source for metal ions. In the first case, chromium and cobalt levels at baseline were 2.70 µg/L and 4.41 µg/L, respectively. After an initial decline, the levels had increased again at 2 years to 1.52 µg/L and 2.78 µg/L, respectively. In the second case, baseline levels of chromium and cobalt were 0.53 µg/L and 1.18 µg/L, respectively. Although the chromium level dropped initially, by 1 year, it had increased to 0.60 µg/L, and cobalt levels continued to rise after revision to 4.45 µg/L by 1 year. Two patients had extremely high ion levels on presentation (> 50 µg/L). Both were female and both were revised for pseudotumor. Their ion levels had decreased to < 5 µg/L by 2 years.

Discussion

Failure rates of stemmed MoM hip replacements have been unacceptably high compared with other bearing surfaces. Bolland et al. [3] reported a failure rate of 8.5% at 5 years using large-head, MoM implants on a cemented cobalt-chromium stem. Langton et al. [22] reported a 6-year failure rate of 25% for the Articular Surface Replacement (ASR®) resurfacing (DePuy, Leeds, UK) and 48.8% for the ASR THA. Review of the National Joint Registry of England and Wales [25] found an overall 5-year revision rate of 6.2% for large-head MoM THA articulations of all types. In this study we assessed the complication rate, radiologic outcome, and changes in metal ions after revision of large-head MoM THA.

Our study had a number of limitations. First, the small numbers meant that we did not see a statistically significant result when comparing cup failure rates. Nonetheless, failures by this mechanism with little bone loss are concerning. Second, the use of revision implants was not standardized. At the time a considerable cost difference meant that high-porosity designs were generally reserved for those cases with severe bone loss. This should have been detrimental to the high-porosity cup that would theoretically have been used in cases with more severe bone loss. As it was, acetabular bone loss in this series is mild, which was a further concerning factor when observing failure to ingrow. Third, the source of metal ions may arise not only from the articular surface, but also corrosion at the head-neck junction. We did not perform retrieval analysis to quantify the contribution of wear from specific surfaces. This is an important direction for future investigation, especially the contribution of taper wear associated with 40-mm heads. Fourth, our followup period was short; however, complications are only able to increase with time.

We observed a high complication rate (38%, 12 of 32 hips) after revision of failed large-head, MoM THA. We are unaware of other published reports of complications after revision of these devices, although others have observed similar problems after revision of hip resurfacing [9, 17]. The rate of dislocation in this study was 28% overall (nine of 32 hips). All three patients with 32-mm heads dislocated. Four of 20 36-mm heads (20%) and two of nine 40-mm heads (22%) also dislocated. This is much higher than the recently reported rate of 1.1% for 36- and 40-mm heads used in revision THA [15] at our institution. The reason for this is not entirely clear. Soft tissue destruction associated with pseudotumor has been associated with higher revision rates after resurfacing. Grammatopoulos et al. [17] identified 53 hip resurfacings that required revision at an average of 1.59 years after primary surgery. Sixteen were revised for pseudotumor, 21 for fracture, and 16 for other reasons. The incidence of major complication after revision for pseudotumor was 50%, significantly higher ($p = 0.018$) than that after revision for other causes (14%). We did not see a difference between those revised for loosening and ALTR as the primary diagnosis. Importantly, in all but two cases revised for ALTR in our series, there was limited muscle and bone destruction, in contrast to other reports [21]. This may be attributed to the relatively short period between primary and revision surgery. Alternatively, all but one of the cups in this series was a Durom and it is possible that failure of this particular design generates less metal debris. We did not routinely order three-dimensional imaging to define bone and soft tissue loss as others have suggested [19], but this may be appropriate depending on the clinical findings and the surgeons' experience. We have débrided reactive tissue on the basis that the biologic activity remains unknown and our concerns about leaving a necrotic tissue dead space. This was associated with nerve injury in two cases so careful consideration should be given to taking an aggressive approach until better information is available.

The most suitable revision articulation to reduce the dislocation rate is a matter of ongoing debate. Use of constrained liners raises concerns about impingement and later failure [27], especially in young active patients. Dual-mobility devices have been proposed as a solution [18] but these lack long-term followup and suitable registry data. We predominantly used 36- and 40-mm heads on PE with the option of elevated lipped liners. However, there is increasing concern about taper wear with head sizes > 36 mm [21]. With little evidence of advantage to stability for 40-mm heads [7], 36 mm may present the best option. Ceramic bearings with titanium taper sleeves remove the potential for chromium and cobalt ions generated by the head, although use of ceramic liners is constrained by the cup used for reconstruction.

We observed several failures of the fiber metal-backed cups used for revision despite an absence of bone defects. Additional screws were used in all cases. This design is used in the majority of primary THAs at our hospital. In contrast, none of the porous tantalum cups failed. The reason for this is not clear. Metal ions including cobalt and chromium are known to alter osteoblast gene expression [31] and decrease osteoblast proliferation [32] at subcytotoxic levels. These residual effects may impair bone ingrowth. As a result of the small numbers in this study, the difference was not statistically significant; however, we have altered our practice to only use high-porosity cups with screws in all cases of failed MoM bearings, regardless of bone quality. This association requires further investigation with a larger cohort to prove a true effect.

Recurrence of pseudotumor occurred in three patients, two of whom were revised to metal-on-PE bearings. One was subsequently revised to ceramic-on-PE. The contribution of cobalt and chromium ions from wear at the stem taper is of increasing interest. Garbuz et al. [16] found significantly increased ion levels in MoM THA compared with hip resurfacing in devices with the same articular surface. Langton et al. [21] conducted an extensive retrieval analysis of hip implants. Volumetric wear at the taper junction increased as head diameter and offset increased. The amount of wear was not correlated to local tissue damage. Although not studied specifically as an end point in this study, further research is needed to determine the efficacy of revising patients with pseudotumor to ceramic heads with titanium sleeves, thus reducing potential sources of metal ions. In our study, serum ion levels generally decreased after change of the bearing surface. Two of 16 patients defied this trend. We continue to follow one patient, who remains asymptomatic at 2 years, with annual blood tests and radiologic and clinical review. The only known source is the 40-mm metal head. In the other case, also revised to a 40-mm head, ion levels dropped initially but had risen again at 12 months. The patient subsequently underwent revision for recurrent dislocation to a 36-mm head with a lip liner and has to date remained stable. He is otherwise asymptomatic and has refused further ions level testing.

In summary, we observed a high complication rate after revision of large-head, MoM THA. If possible, femoral heads should be revised to a 36-mm head with careful counsel regarding activity during recovery to reduce dislocation risk. Further investigation of the lowest risk solution to dislocation is warranted. Based on our experience with failure of fiber metal-backed cups, we now use high-porosity cups with screws regardless of bone loss. The question of taper wear contributing to failure needs further investigation but consideration should be given to using ceramic heads with titanium sleeves to reduce the potential for ion generation.

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