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Revisions of Monoblock Metal-on-metal THAs Have High Early Complication Rates

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Abstract

Background A relatively high percentage of monoblock metal-on-metal total hip arthroplasties (THAs) undergo early revision. Revision of these THAs poses challenges unique to this implant type. The early complications after these revisions remain unreported as do the clinical and demographic factors associated with these complications.

Questions/purposes We describe (1) the frequency of early complications after revision of monoblock metal-on-metal THA; and (2) the clinical and demographic factors associated with complications.

Methods A review of our institution's total joint registry identified 107 patients who underwent 114 revisions of monoblock metal-on-metal THAs. Mean patient age at revision was 60 years (range, 17–84 years), and 65% of the patients were women. Mean followup after revision was 14 months (range, 0–122 months). Revision diagnoses included metallosis (51%), aseptic loosening (27%), infection (7%), pain (6%), malposition (4%), instability (3%), iliopsoas impingement (2%), and periprosthetic fracture (1%). Major complications (instability, infection, aseptic loosening, and wound complications) were documented and included in the analysis. Minor postoperative complications such as urinary tract infection were excluded.

Results Twenty-three of 114 procedures (20%) involved at least one early complication after revision of monoblock metal-on-metal THA with 18 (16%) undergoing at least one additional subsequent surgery. The most common complications included aseptic loosening (6%), deep infection (6%), dislocation (4%), and acetabular fracture (3%). Patients who sustained a complication after revision

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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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surgery were older on average than those who did not (66 years versus 58 years, $p = 0.003$). There were no differences in complication rate with respect to sex, time to revision, or revision diagnosis.

Conclusions Complications and reoperations occur frequently after revision for failed monoblock metal-on-metal THA (20% and 16%, respectively), and older patients appear to be at greater risk for complications after these revisions. Aseptic loosening, deep infection, and instability are all of great concern after revision and surgeons should be aware of these potential complications when undertaking revision of these THAs.

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

Introduction

Early metal-on-metal THA designs were abandoned largely as a result of the success of polyethylene bearing surfaces, but also because of design issues related to the metal-to-metal (MoM) articulation and concerns about metal sensitivity and carcinogenesis [38]. However, limitations associated with polyethylene bearings such as wear, osteolysis, and late instability, in conjunction with advances in metallurgy, improved understanding of articulation mechanics, and implant manufacturer marketing bolstered the resurgence of MoM THA. In addition to the potential for obviating polyethylene-associated complications, MoM bearing surfaces allowed for larger head sizes, thereby affording increased ROM, reduced impingement, and lower dislocation rates [11, 20, 26, 34]. Because of these apparent advantages, use of MoM implants increased, and by 2006, they accounted for more than one-third of the US market [9, 36]. Although initial reports were satisfactory [5, 14, 22, 28, 29], subsequent research demonstrated unacceptable early failure rates of monoblock MoM THAs, resulting in a substantial revision burden [2–4, 6, 7, 10, 12, 13, 15, 18, 19, 21, 24, 25, 27, 30, 32, 33, 36]. These revisions can be complicated by extensive soft tissue and bony defects, persistence of adverse local tissue reaction as well as problems associated with the general need to reduce the head size at the time of revision, perhaps increasing the likelihood of dislocation [1, 3, 7, 10, 13, 18, 19, 23, 25, 31, 33]. Previous studies reporting on the early complications after these revisions are limited and generally of small number [3, 10, 31, 35]. Furthermore, the clinical and demographic factors associated with these complications have yet to be clearly elucidated.

We therefore describe (1) the frequency of early complications; and (2) the clinical and demographic factors associated with complications after revision of monoblock MoM THA.

Patients and Methods

After institutional review board approval, we reviewed our institution's total joint registry to identify all patients undergoing revision of a THA. The study period was from December 2001 to March 2013 with all surgeries performed at a single tertiary care center. Only patients undergoing revision of a MoM THA with a monoblock acetabular component were included in the analysis with exclusion of all other revisions. This group included both patients who had their index THAs performed at our institution as well as patients who were referred to us specifically for the revision procedure. We identified 114 surgical procedures in 107 patients for revision of a MoM monoblock acetabular component among the practices of nine different fellowship-trained arthroplasty surgeons. Of the 114 index THAs, 41 (36%) were performed at our institution and 73 (64%) were performed by outside surgeons. The mean patient age at revision was 60 years (range, 17–84 years) with a female majority (70 of 107 [65%]). The mean time from index arthroplasty to revision was 47 months (range, 1–114 months).

Monoblock MoM THAs from four different manufacturers were included in the analysis (Biomet, Inc, Warsaw, IN, USA; DePuy Orthopaedics, Inc, Warsaw, IN, USA; Wright Medical Technology, Inc, Arlington, TN, USA; Zimmer, Inc, Warsaw, IN, USA). Patients were scheduled for routine clinical and radiographic evaluations after revision at the following intervals: 2 weeks, 6 weeks, 3 months, 1 year, 2 years, and 5 years. The mean clinical followup after revision was 14 months (range, 0–122 months). We did not set a minimum followup in this study to be able to identify as many early complications as possible. One patient was lost to followup after his 2-week postrevision visit. Clinical and surgical records were reviewed for demographic data, implant records, complications, and reoperations. Major complications (instability, infection, aseptic loosening, and wound complications) were documented and included in the analysis. Wound complications were defined as concerns related to the surgical site that were treated either with surgery or antibiotic therapy. Minor postoperative complications such as urinary tract infection and atelectasis were excluded.

Failed monoblock MoM THA revision diagnoses included metallosis (51%), aseptic loosening (27%), infection (7%), pain (6%), malposition (4%), instability (3%), iliopsoas impingement (2%), and fracture (1%) (Table 1). All patients revised for deep infection (eight patients) underwent two-stage surgery. In general, a diagnosis of metallosis was given based on a constellation of findings, including ion levels, patient symptoms, component position, high-risk implant type, and advanced imaging in the absence of another clear diagnosis. No

Table 1. Revision diagnoses

Revision diagnosis	Number of procedures
Metallosis	58 (51%)
Aseptic loosening	31 (27%)
Infection	8 (7%)
Pain	7 (6%)
Malposition	4 (4%)
Instability	3 (3%)
Iliopsoas impingement	2 (2%)
Fracture	1 (1%)

Table 2. Postrevision complications

Postrevision complication	Number of complications
Aseptic loosening	7 (6%)
Deep infection	7 (6%)
Dislocation	5 (4%)
Acetabular fracture	3 (3%)
Superficial infection	2 (2%)
Infected hematoma	2 (2%)
Hematoma	1 (1%)
Delayed wound healing	1 (1%)

single finding in isolation was considered sufficient for a diagnosis of metallosis.

One hundred one patients underwent isolated revision of the acetabular component. Thirteen patients underwent revision of both the femoral and acetabular components at index revision, eight for infection, two with modular neck femoral components, two for an aseptically loose femoral component in addition to a loose acetabular component, and one from a cemented stem to an uncemented stem.

The mean index acetabular component was 52 mm (range, 44–62 mm) with a mean index head size of 46 mm (range, 28–55 mm). After revision, the mean acetabular component was 56 mm (range, 44–70 mm) with a median head size of 46 mm (range, 28–56 mm). One patient was revised directly to a custom triflange acetabular component, whereas eight were initially revised to articulating antibiotic spacers for infection. Two patients were treated at the index revision surgery with a constrained liner as a result of substantial abductor deficiency.

Statistical analysis was performed using SAS® software (Version 9.2; SAS Institute Inc, Cary, NC, USA). Standard descriptive statistics are reported including frequency, proportion, mean, and variation. The dependent variable for all differential analyses was complication as a binary variable. The independent variables that were evaluated included revision diagnoses, patient age at the time of surgery, and time to revision. As a result of the number of categories of revision diagnoses, it was not possible to determine a statistical association with postoperative complication. Therefore, those data are described at the univariate level only using frequencies and proportions. The remaining two independent variables were included in bivariate analyses to determine the statistical association with postoperative complication. Fisher's exact test was used to determine differences in sex proportions. An independent t-test was used to determine statistical differences in the mean patient age at the time of surgery and the mean time to revision between those who had a postoperative complication and those who did not have a postoperative complication. An alpha level of significance of 0.05 was used to determine statistical significance for all tests.

Table 3. Additional surgeries after index revision

Additional surgery	Number of surgeries (patients)
Acetabular revision	9 (7)
Irrigation and débridement with head/liner exchange	7 (7)
Superficial irrigation and débridement	2 (2)
Constrained liner	5 (2)
Two-stage for infection	2 (2)
Abductor reconstruction with constrained liner	1 (1)
Resection for persistent deep infection	1 (1)

Results

Twenty-three of 114 procedures (20%) involved at least one early complication after revision of monoblock MoM THA. The mean time from revision surgery to complication was 5.4 months (range, 0–54 months). A total of 28 complications occurred, including aseptic loosening (6%), deep infection (6%), dislocation (4%), acetabular fracture (3%), superficial infection (2%), infected hematoma (2%), hematoma (1%), and delayed wound healing (1%) (Table 2). Four patients experienced multiple complications. Of these, two patients had aseptic loosening of the acetabular component with an associated acetabular fracture, one patient experienced instability in conjunction with a deep infection, and the final patient had three complications: aseptic loosening, acetabular fracture, and deep infection. Reoperation followed 18 of 114 procedures (16%) after revision of monoblock MoM THA (Table 3). These procedures included seven acetabular revisions, seven deep irrigation and débridements with head/liner

exchanges, two superficial irrigation and débridements, and two revisions to a constrained liner for instability. All irrigation and débridement surgeries were performed within 6 weeks of the index revision. Six patients underwent at least two additional unplanned surgeries after the index revision, whereas two underwent four total surgeries after index revision. Of the seven patients (6%) who failed revision secondary to aseptic loosening, three were directly reconstructed using a custom triflange acetabular as a result of poor acetabular bone stock. An additional two patients underwent custom triflange reconstruction after failing a second attempted reconstruction with a hemispherical revision component. Of the 13 patients who underwent combined acetabular and femoral revisions, none underwent rerevision of the femoral component for aseptic loosening.

Patients who sustained a complication were older on average those who did not (66 years [range, 45–81 years] versus 58 years [range, 18–84 years]; $p = 0.0028$). There were no differences in complication rate with respect to patient sex ($p = 0.81$) or time to revision ($p = 0.93$).

Discussion

Frequencies and types of complications after revision of THA with conventional bearing surfaces have been previously described at our institution and include instability (35% [49 of 141]), aseptic loosening (30% [42 of 141]), osteolysis/wear (12% [17 of 141]), infection (12% [17 of 141]), and periprosthetic fracture (2% [three of 141]) [37]. It has been shown, however, that MoM THAs fail at higher rates and in novel modes as compared with conventional THA, most notably by metallosis or so-called adverse local tissue reaction [16, 17]. In light of the differences in failure rates and mechanisms between MoM THAs and those with polyethylene bearings, it seems important to look at complications and reoperations after revision of MoM THAs as well as to try to identify any factors that might be associated with complications after revision of MoM THA. Currently, there is a paucity of literature, with limited patient numbers, examining the outcomes of MoM THA revisions [10, 31, 35], and no papers to our knowledge have examined the clinical and demographic factors associated with postrevision complications. We therefore described, with the largest series of which we are aware to date, (1) the frequency of early complications; and (2) the clinical and demographic factors associated with complications after revision of monoblock MoM THA.

We recognize the limitations of our study. First, as a retrospective study, it is susceptible to all the flaws inherent to this study design. The potential for selection bias exists because there was not a uniform criterion for a revision diagnosis of metallosis. Rather, the diagnosis was made when other potential diagnoses were excluded and a constellation of findings including ion levels, patient symptoms, component position, high-risk implant type, and advanced imaging supported the diagnosis. Additionally, surgeons reporting into our registry may undercode complications, although the humbling findings do not support this concern. Furthermore, no histologic examination was performed of the tissues and as such we are not able to correlate any increased risk for failure or failure mode with histology at the time of surgery. This study also is limited because it represents the results of a single center, albeit with the participation of nine different fellowship-trained arthroplasty surgeons. Also, as a tertiary care center, referral bias cannot be excluded with more difficult cases and problems being referred to our center. The limited followup in our study presents a weakness as well. Certainly, longer followup will identify additional failures, but it must be noted all identified complications occurred within 5 years of the index revision. Therefore, failures outside of this range may be related to more generalizable issues as opposed to those specific to revisions of monoblock MoM articulations. Finally, although it represents the largest series of revision monoblock MoM THA to our knowledge to date, the current study may be underpowered to correlate clinical and demographic factors with complications and revisions that might be available in a larger cohort such as a national registry might provide.

Extensive soft tissue damage is more commonly encountered in MoM hips revised for aseptic loosening than hips with other bearing surfaces with severe bone loss reported as well [1, 8]. The extent of adverse local tissue response confronted at the time of revision poses genuine concern for outcome as it pertains to fixation, stability, and, potentially, infection [7, 10, 13, 39]. Previous reports have been limited in patient numbers compared with this study; however, many of the same kinds of complications have been reported, which suggests that patients undergoing these revisions indeed are at risk for serious complications. Browne et al. [10] briefly commented on the outcomes of their series of 37 patients revised from MoM hip arthroplasties, both total and resurfacing. They noted one deep infection, one femoral component loosening, one acetabular component with radiolucencies in an asymptomatic patient, and one case of persistent disabling pain; however, this was not analyzed to differentiate between revisions of resurfacings and THAs [10]. Another series reported on revisions of 13 failed MoM THAs [35]. The authors reported using primary components in all but one patient with immediate symptomatic relief in all patients. In the largest series of large-head MoM revisions published to date, Munro et al. [31] reported a major complication rate of 48% with a 28% dislocation rate in 32 revisions.

The authors similarly noted a high rate of aseptic failure after revision, reporting that four of 17 fiber-metal acetabular components failed to ingrow.

Our study revealed a major complication rate of 20% and a reoperation rate of 16% after revision of a monoblock MoM THA with all identified complications occurring within 5 years of the index revision surgery. The three most common complications were aseptic loosening (6%), deep infection (6%), and instability (4%), which we feel are likely related to soft tissue damage and bone necrosis often seen in this population.

Additionally, analysis of the current cohort indicates that older patients were more prone to complications after revision of monoblock MoM THA. No association between complication rates with respect to sex or time to revision was identified.

Our institution currently uses a systematic approach to the evaluation and treatment of patients with monoblock MoM THAs. In addition to clinical examination and plain radiographs, we also routinely obtain serum ion levels as well as metal artifact reduction sequence MRI. Porous metal acetabular implants are consistently used at the time of revision and augmented with judicious screw fixation. At surgery, necrotic tissue is débrided with careful preservation of healthy tissue so as not to unnecessarily create large tissue voids or destabilize the joint. Large femoral heads are used as able for enhanced stability and constrained liners should be considered in instances of abductor loss if stability cannot be achieved intraoperatively. Furthermore, we counsel patients on the potential complications encountered after revision surgery of this type.

In conclusion, revision of monoblock MoM THA poses challenges unique to this implant type. Aseptic loosening, deep infection, and instability are all of great concern after revision and surgeons should be aware of these potential complications when undertaking revision of failed monoblock MoM THAs, particularly in older patients.

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