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Patient-reported outcomes after revision of metal-on-metal total bearings in total hip arthroplasty

Ana Mata-Fink, MD, MS^{1,*}, Daniel J. Philipson, MD^{2,#}, Benjamin J. Keeney, PhD^{1,2,*,&}, Dipak B. Ramkumar, MD¹, Wayne E. Moschetti, MD, MS^{1,2}, and Ivan M. Tomek, MD, FRCSC^{1,2,%}

¹Dartmouth-Hitchcock Medical Center, Lebanon, New Hampshire, 1 Medical Center Drive, Lebanon, New Hampshire, 03756-0001, USA

²Geisel School of Medicine, Dartmouth College, Hanover, New Hampshire, 1 Medical Center Drive, Lebanon, New Hampshire, 03756-0001, USA

Abstract

Background—Failure of metal-on-metal (MOM) total hip arthroplasty (THA) bearings is often accompanied by an aggressive local reaction associated with destruction of bone, muscle and other soft tissues around the hip. Little is known about whether patient-reported physical and mental function following revision THA in MOM patients are compromised by this soft tissue damage, and whether revision of MOM THA is comparable to revision of hard-on-soft bearings such as metal-on-polyethylene (MOP).

Methods—We identified 75 first-time MOM THA revisions and compared them to 104 first-time MOP revisions. Using prospective patient-reported measures via the Veterans RAND-12, we compared physical (PCS) and mental function (MCS) at pre-operative baseline and post-operative follow-up between revision MOM THA and revision MOP THA.

Results—PCS did not vary between the groups pre-operatively and at 1 month, 3 months, and 1 year post-operatively. MCS pre-operatively and 1 and 3 months post-operatively were lower in patients in the MOM cohort compared to patients with MOP revisions (Baseline 43.7 vs. 51.3, $P<0.001$; 1 month: 44.9 vs. 53.3, $P<0.001$; 3 months 46.0 vs. 52.3, $P=0.016$). However, by 1 year, MCS scores were not significantly different between the revision cohorts.

*Corresponding author: Benjamin J. Keeney, PhD, Department of Orthopaedics, Geisel School of Medicine, Dartmouth College, Dartmouth-Hitchcock Medical Center, Hinman Box 7541, One Medical Center Drive, Lebanon, NH 03756, Benjamin.J.Keeney@Dartmouth.edu, Phone: 603-653-6037, Fax: 603-653-3554.

Dr. Mata-Fink was an orthopaedic resident at Dartmouth-Hitchcock Medical Center during this research project. She is now a Fellow in Shoulder and Elbow Surgery in the Department of Orthopaedics and Rehabilitation at the Yale University School of Medicine at Yale New Haven Hospital in New Haven, Connecticut.

#Dr. Philipson was a medical student at the Geisel School of Medicine during this research project. He is now an internal medicine resident at UCLA Medical Center.

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%Dr. Tomek was an Assistant Professor and attending orthopaedic joint surgeon at the Geisel School of Medicine at Dartmouth College and Dartmouth-Hitchcock Medical Center during this research project. He is now an attending orthopaedic joint surgeon at Alice Peck Day Memorial Hospital in Lebanon, New Hampshire.

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Conclusion—Post-revision physical function in revised MOM THA patients does not differ significantly from the outcomes of revised MOP THA. Mental function is markedly lower in MOM patients at baseline and early in the post-operative period, but does not differ from MOP patients at 1 year after revision. This information should be useful to surgeons and physicians facing MOM THA revision.

Keywords

total hip arthroplasty; patient-reported measures; patient-reported outcomes; revision; metal-on-metal total bearings; physical function

INTRODUCTION

Modern large-head metal-on-metal (MOM) bearing surfaces, which were purported to have better wear properties than traditional metal-on-polyethylene (MOP) bearing surfaces, were introduced in Europe in 2003 and in the United States in 2005. However, registry studies from the United Kingdom and Australia soon demonstrated high early failure rates of metal-on-metal total hip arthroplasty (THA) implants, with revision rates of 5-10% at 5 years.^{1,2}

Traditional MOP THA often fails due to aseptic loosening with polyethylene particle-mediated osteolysis.³ Failure of MOM THA has been associated with local macrophage and lymphocyte reaction to cobalt and chromium ions released due to wear.⁴⁻⁶ The combination of increased early failure rates and local adverse reactions to metal ions, such as aseptic lymphocyte-dominated vasculitis associated lesions (ALVAL), has led to many early revisions.⁷⁻⁹ ALVAL has been linked to MOM hip implants and is thought to contribute to soft tissue destruction.¹⁰⁻¹⁵ Well-fixed implants with poor surrounding tissue can make revision surgery more complex and result in potentially worse outcomes.^{12,14,16}

To date, patient-reported outcomes (PROs) of revised MOM THA have not been thoroughly studied, making it difficult to counsel patients on expected functional recovery and most studies of clinical outcomes of revised MOM THA do not examine PROs after revision.¹⁷ Generally, patients report good health status after successful primary THA and return to a relatively good health status after successful revision THA.¹⁸ Given that approximately 40% of all hip arthroplasty performed in the United States over the last decade involved MOM hip implants,¹⁹ it is important to understand whether patients undergoing revision of MOM THA will enjoy a similar function improvement after their revision.

We assessed PROs after revision of MOM THA compared to outcomes after revision of MOP THA, using prospectively collected Veterans RAND-12 (VR-12) surveys, a validated measure of general health-related quality of life²⁰. We hypothesized that there would be no difference between PROs after revision of MOM and revision of MOP THA.

METHODS

Institutional Review Board approval was obtained for the study. Using our internal data warehouse, which is linked to the electronic medical record (EMR) system and includes both hospital and clinic institutional records, revision THAs were selected by Current Procedural

Terminology (CPT) code for revision THA (27132, 27134, 27137, 27138). Additional inclusion criteria specified first-time THA revisions and that the bearing surface was either MOM or MOP. All surgeries were performed between September 2006 and December 2012 by three fellowship-trained arthroplasty orthopaedic surgeons at a single rural tertiary academic medical center. A manual search of the operative reports in the EMR was conducted to identify primary revisions of MOM or MOP THA and to include any variable values missing in the initial data warehouse. Exclusion criteria consisted of miscoded THA primary revision, ceramic bearing surface, hemiarthroplasty, history of previous THA revision, and revisions related to infection, dislocation, or fracture. See Figure 1 for more information on the study population attrition.

Age at time of revision, gender, laterality of revision, body mass index (BMI) at the revision preoperative visit, smoking status at revision, grouped comorbidity status at revision, a histologic diagnosis of ALVAL, and known complications were abstracted from the medical record. Due to low variation among older persons in rural New England, data on race and ethnicity were available but not pursued. BMI was grouped into categories based on accepted World Health Organization (WHO) classification: normal ($< 25 \text{ kg/m}^2$), overweight ($25\text{-}29.9 \text{ kg/m}^2$), and obese ($\geq 30 \text{ kg/m}^2$). Comorbidities were grouped by organ system; patients received a point for a diagnosis in each category and this was combined for a comorbidity score (0, 1, >1). Complications were defined based on the Technical Expert Panel Evaluation of Measures.²¹ All of our revisions included either removal of the monoblock acetabular component or exchange of the metal liner for a polyethylene liner when modularity existed; however, not all femoral stems were revised. Hence, complexity of revision was defined by whether femoral stem revision was required or not, in addition to the acetabular revision.

Our primary outcomes were the VR-12 Physical Component Summary Scores (PCS) and Mental Component Summary Scores (MCS). VR-12 is a validated patient-completed questionnaire that quantifies PCS and MCS based on patient responses using a non-proprietary scoring algorithm developed from Short Form 12/36 (SF-12/SF-36®).²⁰ Prospectively collected PCS and MCS scores were recorded at each office visit, including the preoperative and post-operative visits. Lower PCS and MCS scores indicate poorer self-reported physical function and mental health respectively. PCS and MCS scores were grouped into pre-operative, 1-month post-operative, 3-month post-operative, and 1-year post-operative. Secondary outcomes included post-operative medical and mechanical complications.

Statistical analysis was performed using Stata Version 12 (StataCorp. College Station, TX: StataCorp LP, 2012). Variable range definitions, such as age, were grouped together using standard conventions as data variance allowed. Chi-squared test was used for categorical variables and a two-sample t-test was used for continuous variables. Bivariate linear regression was used to look for associations between bearing surface and primary and secondary outcome measures. We also developed multivariable linear regression models that adjusted for age at revision, BMI group, gender, and complexity of revision at each postoperative time period. Smoking status and presence of comorbidities were analyzed, but did not contribute to any model and were not investigated further. Statistical significance

was defined as $P < 0.05$. Analyses were performed using robust standard errors and patient clustering to account for observational data that included patients that underwent bilateral THA revisions.

RESULTS

The initial data search identified 382 THA revision episodes. Of these, 179 met inclusion criteria, including 75 MOM and 104 MOP THA (Figure 1). Of the 75 revised MOM surfaces, 73 were MOM THA and 2 were resurfacings revised to THA. There were nine patients with bilateral revisions of MOM THA and three patients with bilateral revisions of MOP THA. There were no differences in revision laterality, BMI, smoking status, and comorbidities between the revision types (Table 1). The MOM revision group was younger at revision than the MOP group (58 (SD 9) vs. 67 (SD 12) years, $P < 0.001$) and contained fewer women (40.0% vs. 54.8% female, $P = 0.050$).

There was no difference in rate of femoral stem revision. 53% of patients in the revision MOM THA were diagnosed with ALVAL while no patients in the MOP group carried this diagnosis among patients for whom pathology was sent (Table 1). There was no difference in medical or mechanical complications post-operatively (Table 2).

Physical Component Summary (PCS) Scores

Pre-operative mean PCS scores were not significantly different between patients with a revision of metal-on-metal versus a revision of metal-on-polyethylene THA. There was also no difference by bearing surface in mean 1-month, 3-month, and 1-year post-operative PCS scores (Table 2). There were no univariate or multivariate model associations identified between bearing surface and PCS scores at any measured post-operative time period (Table 3).

Mental Component Summary (MCS) Scores

Pre-operative MCS scores were significantly lower in patients with a revision of MOM THA compared to patients with a revision of MOP THA (43.7 vs. 51.3, $P < 0.001$) (Table 2). At one and three months post-operatively, MCS scores were also significantly lower in MOM THA revision patients compared to MOP THA revision patients (1-month: 44.9 vs. 53.3, $P < 0.001$; 3-month: 46.0 vs. 52.3, $P = 0.016$). However, there was no difference by 1-year post-operative MCS scores (53.6 vs. 50.7, $P = 0.33$).

Univariate analyses indicate an association between lower MCS scores and MOM bearing surface at the preoperative, 1-month postoperative and 3-month postoperative time frames (Table 3). When adjusted for age, BMI, gender, and revision complexity (based on whether revision of the femoral component was required) only the preoperative and 1-month postoperative time frames were different in MCS by bearing surface type.

DISCUSSION

Revisions of MOM bearing surfaces in THA have increased in recent years since the first reports of early failure rates in 2011.⁵ There are little published data to reflect patient-

reported outcomes after THA revision. In this study, pre- and postoperative VR-12 PCS and MCS scores were compared between THA revisions of MOM versus MOP bearing surfaces.

In our study, patients who underwent THA revision had similar self-reported physical function at 1 year after surgery regardless of the initial bearing surface (MOM vs. MOP). Importantly, we found no difference in physical function preoperatively, at any of 3 postoperative intervals, and no long-term difference in mental function, between patients with revision of a metal-on-metal bearing surface compared to those with revision of a metal-on-polyethylene bearing surface. There was a significant short-term (pre-operative and 1-month post-operative) difference in self-reported mental function in patients with a revision of a metal-on-metal THA compared to patients with a revision of a metal-on-polyethylene THA. However, by 3-months post-operatively, no difference in MCS scores could be detected in the univariate or multivariate analyses.

Most studies of MOM THA revisions focus on clinical and surgical outcomes rather than patient-reported outcomes. Some studies suggest high complication rate after MOM THA revision.^{22,23} Others show improvement in Oxford Hip Score and UCLA Activity Score after revision of failed hip resurfacing.^{14,24,25} However, these studies are all case series and do not compare the functional outcome scores to those of other patients with revised THA. Our study is unique because we investigated preoperative and postoperative PROs by bearing surface status in a prospectively collected cohort of THA revision patients.

There are several limitations in our study. First, while our data are strengthened by our prospective cohort design, the data remain observational in nature and may have omitted variable bias, such as the time between index surgery and revision, that may further explain any difference between the MOM and MOP THA revision groups. Not surprisingly for an observational study in a real-world setting, each successive time period has lower counts due to patients lost to follow-up, and we did not include follow-up data beyond one year postoperatively. Although we did use prospectively collected PRO for over a year post-operatively in our analysis, these PROs were in reference to global mental and physical health attributes that were not hip specific.

Additionally, there was a statistically significance difference in age at time of revision between the MOM and MOP cohorts; the mean age at revision among the MOM group was almost 10 years younger than the MOP group. However, there was no statistical difference in PCS when controlling for age at revision between the MOM and MOP groups (Table 3), nor was there a statistically significant difference between age groups for adjusted PCS at any time period (results not shown). Pathologic and histologic limitations included no formal evaluation of trunnionosis. We also did not classify tissue damage in those with a histologic diagnosis of ALVAL nor did we routinely send pathologic specimens in patients with MOP revisions, making this comparison difficult. The presence and severity of an ALVAL lesion may play a major role in the complexity of revision surgery and pre- and post-operative function but this association warrants further study.

In summary, this study suggests that post-revision physical and mental function as defined by a validated patient administered questionnaire, is similar whether the revision is for a

metal-on-metal THA or a metal-on-polyethylene THA. To further explore the outcomes after revision of metal-on-metal THA, joint specific outcome measures in an age-matched control group should be explored.

CONCLUSION

Patients with a metal-on-metal bearing surface after total hip arthroplasty revision may be counseled that patient-reported physical and mental function after revision are not significantly different than those of patients undergoing a revision of a metal-on-polyethylene bearing surface. Although this study represents a novel endeavor in assessing patient-reported outcomes in this hip revision population, more research is needed to fully understand the effects and outcomes of total hip arthroplasty revision of metal-on-metal bearing surfaces.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Figure 1.
Counts, and exclusion criteria of the patient study population comparing MOM and MOP bearing surface among primary THA revision

TABLE 1

Characteristics of patients with revised metal-on-polyethylene and revised metal-on-metal THA.

Characteristic	Counts (n=179)	Metal-on-polyethylene (n=104)	Metal-on-metal (n=75)	p-value
Demographics				
Age at revision , mean years	179	67.5	58.2	<0.001 [†]
Gender , % female	179	54.8	40.0	0.050 [‡]
Body mass index , mean kg/m ²	177	28.2	29.7	0.089 [†]
Smoking status (self reported), %	179			0.064 [‡]
Non-smoker		50.0	36.0	
Former smoker		41.3	45.3	
Current smoker		8.6	18.7	
Comorbidities , %	179			0.126 [‡]
None		39.4	52.0	
1		36.5	34.7	
>1		24.0	13.3	
Surgical characteristics				
Revision laterality , % right	179	62.5	54.7	0.293 [‡]
Complexity of revision , % stem revised	179	32.7	32.0	0.922 [‡]
Histologic diagnosis , %	179			<0.001 [‡]
ALVAL		0.0	53.3	
Not ALVAL		23.1	38.7	
No tissue sent for histology		76.9	8.0	

Due to rounding, category totals may not equal 100%

[†]p-value calculated by t-test[‡]p-value calculated by chi-squared test

TABLE 2

Outcomes of revised metal-on-polyethylene and revised metal-on-metal THA.

Outcomes	Counts (n=179)	Metal-on-polyethylene	Metal-on-metal	p-value
PCS				
Pre-operative , mean score	159	34.7	35.8	0.722
1 month post-operative , mean score	149	33.3	31.4	0.336
3 months post-operative , mean score	115	41.7	38.4	0.143
1 year post-operative , mean score	84	43.8	40.0	0.190
MCS				
Pre-operative , mean score	159	51.3	43.7	<0.001
1 month post-operative , mean score	149	53.3	44.9	<0.001
3 months post-operative , mean score	115	52.3	46.1	0.016
1 year post-operative , mean score	84	50.7	53.6	0.334
Medical complications[§], %	179	1.9	0.0	0.227
Mechanical complications[§], %	179	2.9	2.7	0.930

[§]Defined from the Technical Expert Panel Evaluation of Measures

TABLE 3

Univariate and multivariate analysis of metal bearing surface replaced on patient reported outcomes of revised THA.

Outcomes	Unadjusted score	95% CI	p-value	Adjusted score	95% CI	p-value
PCS						
Pre-operative	1.14 [‡]	-2.70 – -4.97	0.559	2.89	-1.16 – 6.93	0.161
1 month post-operative	-1.84	-5.73 – -2.05	0.351	0.47	-3.78 – 4.73	0.826
3 months post-operative	-3.30	-7.89 – -1.28	0.156	-2.29	-8.28 – 3.71	0.451
1 year post-operative	-3.38	-9.80 – -2.18	0.209	-2.32	-8.96 – 4.32	0.489
MCS						
Pre-operative	-7.58	-11.63 – -3.53	<0.001	-6.85	-11.50 – -2.20	0.004
1 month post-operative	-8.46	-13.28 – -3.63	0.001	-6.60	-11.88 – -1.32	0.015
3 months post-operative	-6.27	-11.50 – -1.03	0.019	-6.16	-12.78 – -0.45	0.068
1 year post-operative	2.90	-2.88 – 8.67	0.321	1.98	-4.39 – 8.35	0.538

[‡]Multivariable analysis adjusted for age at revision, BMI, gender, and complexity of revision. Smoking status and presence of comorbidities were analyzed and did not contribute to the model.

[‡]Difference in PRO score between revised metal-on-metal THA and revised metal-on- polyethylene THA.