Long-Term Screening is Necessary in Patients with Metal on Metal Total Hip Arthroplasty

Martin J1, Odum S1, Griffin W1

Abstract

Background: Adverse reactions to metal debris with catastrophic failures have been seen with a number of metal on metal (MoM) total hip designs. Understanding survivorship and factors associated with failure will allow for more targeted surveillance of those patients at highest risk for failure. The purpose of this study was to assess the mid to long term survivorship and specific factors associated with failure for a large cohort of a single modular MoM design.

Methods: Consecutive patients treated with a modular metal on metal bearing with a five to fourteen year follow-up were included. Clinical outcome scores and radiographic data were prospectively collected. Failure was defined as revision of either component for any reason during the study period. Multiple implant, surgical, and patient factors were analyzed for associations with elevated ion levels or revision due to adverse reactions to metal debris.

Results: The average age at the time of surgery for the 253 patients included in the study was 55. There were 28 revisions (7.5%), eight due to metallosis (2%). Survivorship was 89% at 12.6 years with revision for any reason as the end point. Survivorship was 93% when limited to revision for ALTR as the end point. Time in situ was the only variable that was statistically associated with an increased risk of failure due to ALTR (p<0.0001)

Conclusion: In this large series of a single design modular metal-metal total hip we found relatively low rates of revision due to adverse reactions to metal debris. The only variable associated with a statistically significant risk of ALTR was time in situ. Therefore, long-term surveillance is necessary in patients with a MoM THA.

Background

Metal on Metal (MoM) total hip arthroplasty (THA) was widely used throughout the 2000’s as an alternative bearing to metal on polyethylene. Potential benefits included decreased wear rates and the ability to utilize a larger femoral head size for improved stability [1,2]. However, following the initial enthusiasm with MoM THA, numerous studies began showing increased failure rates with MoM bearing implants. Specifically, increased implant failure due to adverse local tissue reactions (ALTR) likely related to the release of metal ions from the bearing surface [3–5]. For this reason, several MoM THA designs were pulled from the market and or recalled [3,6].

Currently, screening protocols to help with the early identification of ALTR rely on metal ion levels (Cobalt and Chromium), imaging studies, or some combination of the two. The definition of an “elevated ion level” remains controversial. In the UK, 7ppb is used as a trigger for further

Keywords: metal on metal; total hip replacement; screening protocols
Level of Evidence: IV
evaluation, whereas Hart et al noted that ion levels above 4ppb were associated with abnormal bearing wear. Several studies have determined that ion levels alone should not be used as a trigger for surgery, but should be used in conjunction with patient symptoms, physical exam, radiographic evaluation, and the track record of the implant involved [7–11]. Patients that are deemed to be at higher risk for ALTR should then proceed with cross sectional imaging using a MARS-MRI technique or Ultrasound evaluation to look for adverse reactions.

Multiple studies and registries have demonstrated a wide range of outcomes for the different MoM designs. The Australian registry has identified a 40% failure rate with the ASR THA at 10 years compared to 9.5% failure for the Pinnacle modular MoM. Multiple other studies have identified improved results with this same particular modular MoM THA design [11–13].

The FDA has recommended continued surveillance every two years for all patients with MoM THAs, regardless of design. It is likely that the majority of patients with a MoM bearing and low risk factors are being screened unnecessarily. Therefore, the following study was designed with two main goals: 1. To report the long-term outcomes, including revision and reoperation rates, as well as metal ion levels of the Pinnacle modular two-piece MoM THA design, and 2. To determine if we can improve surveillance by targeting high risk patient populations of MoM THAs utilizing this data.

Materials and Methods

A query of our institutional total joint patient registry was performed to identify patients who have had a primary total hip replacement with a cementless, modular Pinnacle MoM implant, by a single surgeon, at a minimum of two years, postoperatively. 318 primary THA patients (457 hips) met the inclusion criteria. After obtaining IRB approval, data collection began by reviewing electronic health records. Patients who had not been seen in the clinic within the year prior to the start of the study were contacted to return for clinical exams. In addition to the routine clinical exam, metal ion levels were tested and standard radiographs were evaluated. Patients who were unable to return to the clinic were asked to complete a telephone interview that included a Hip Disability and Osteoarthritis Outcome Score (HOOS JR.) as well as questions regarding any component revision surgery. Patient retention methods included email, a letter, and three phone calls. If we were unable to reach the patient, they were defined as lost to follow up. The following data were collected: patient demographic data (age, sex), cobalt and chromium ion levels, femoral and acetabular component size, cup abduction angle, reason for revision surgery, and time in situ. The primary outcome variable was the need for revision total hip surgery. We also defined metallosis related failure as revision for ALTR or ion levels of 4.0 ppb or greater.

Statistical Analysis: Standard descriptive statistics and analysis were carried out in SAS 9.4 (Cary, North Carolina). The distribution of the continuous variables was tested and found to be skewed. Therefore, a Wilcoxon two sample test was used to assess the bivariate association of continuous variables with failure. A Chi-square test was used with categorical variables with more than two response levels and a Fishers exact test was used to assess the bivariate association of binary variables with failure. Separate univariate logistic regression models were first fit to assess their association with failure related to metallosis (ALTR or elevated ion levels) with the intention of including significantly associated variables in a multivariate model for further assessment. A significance level of .05 was used to determine statistical significance for all statistical tests.

Study Sample Characteristics: Of the 318 patients with 457 hips identified, 253 patients (80%) with 374 hips (82%) were included. Twenty-six patients with 34 hips were deceased and 39 patients with 49 hips were lost to follow up. Of the 253 patients included, 149 were male (59%) and the average age at the time of surgery was 55 years (20-78 years). The average time in situ for the 374 hips was 8.3 yrs.

The use of metal ion levels as a screening tool for MoM THAs was not routinely available until 2010.

With this in mind, many of our patients did not have ion levels measured during the first several years following their MoM THA.

Results

Revision Rate and Survival

Twenty eight of the 374 hips were revised for an overall revision rate of 7.5% and the revision rate for adverse local
tissue reactions (ALTR) was 2% (8 of 374 hips). The most common reason for revision was infection (n=11, 3%). Table 1 lists all of revision diagnoses.

Survivorship Curves
Survivorship was 89% at 12.6 years with revision for any reason as the end point. However, survivorship was 93% when limited to revision for ALTR as the end point. Survivorship decreased to 75% when failure included revision for ALTR and/or the patient had elevated metal ion levels Figure 1.

Factors Associated with Metallosis Related Failure
We evaluated patient and implant-related factors to determine if any were significantly associated with metallosis related failure defined as revision for ALTR or ion levels > 4.0 (Table 2). There were no significant associations between patient age or sex and the rate of metallosis related failure. Additionally, there were no significant differences in head size or cup abduction between those that had a metallosis related failure and those that did not. Time in situ was the only risk factor significantly associated (p<0.0001). Because only one variable, time in situ, was found to be significantly associated with failure at the bivariate level a multivariable regression model was not pursued.

Scatterplots were then constructed to evaluate how metal ions correlate with time in situ. The scatterplots in Figures 2 and 3 illustrate minimal positive correlations between cup abduction and time in situ and metal ion levels for unilateral patients only. As the time in situ increased the

<table>
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<th>OR (95% C.I.)</th>
<th>P-value</th>
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<tbody>
<tr>
<td>Abduction Angle</td>
<td>1.012 (0.960, 1.067)</td>
<td>0.6539</td>
</tr>
<tr>
<td>Head Size</td>
<td>0.939 (0.833, 1.059)</td>
<td>0.3063</td>
</tr>
<tr>
<td>Cup Size</td>
<td>1.056 (0.969, 1.151)</td>
<td>0.2127</td>
</tr>
<tr>
<td>Age</td>
<td>1.016 (0.984, 1.048)</td>
<td>0.3347</td>
</tr>
<tr>
<td>Sex (ref. group Male)</td>
<td>0.964 (0.493, 1.883)</td>
<td>0.9143</td>
</tr>
<tr>
<td>Time in situ</td>
<td>1.322 (1.184, 1.477)</td>
<td>&lt;0.0001***</td>
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OR: odds ratio, C.I.: confidence interval, ref.: reference
***Significant at the 0.001 probability level

Figures 2 and 3: Scatterplot of time in-situ.
Screening protocols for patients with MoM THA are Surgeon dependent, but commonly involve a combination of cobalt and chromium ion levels and cross-sectional imaging with MRI or US. However, there are numerous issues with these screening techniques. First, metal ion levels do not necessarily correlate with adverse local tissue reactions [7,16]. Second, the definition of “elevated” metal ion levels is not standardized. Cutoffs of 4.0 ppb are commonly utilized, but ALTR can occur with levels under this. Finally, if a patient is identified with an “elevated” metal ion level, an MRI scan is commonly obtained. Fluid collections and or pseudotumors appear to be a common finding even in MoP and CoP THA [17,18]. Furthermore, many of these lesions identified in MoM THAs have been demonstrated to decrease with time [19].

Currently, some advocate screening patients with a MoM THA every year with cobalt and chromium metal ion levels. Screening labs at our institution cost approximately 300 dollars per patient. 8 patients were identified and revised for ALTR during a 12.6 year time interval. For this study alone, the screening costs would be approximately 175,313 dollars to identify one patient with an ALTR, not including the costs of “elevated” levels where an MRI was obtained to confirm the diagnosis.

The results from this study indicate that the time in-situ was the only variable associated with an increased rate of failure. It is unclear what caused the late release of metal ions demonstrated in this study. The modular liner, bearing surface, or taper all represent potential sites of metal ion release, but without a formal analysis of the implants, we are unable to comment on the predominant source. Cup abduction angle, head size, sex, and patient age did not correlate with ion levels. Therefore, long-term follow-up is likely necessary for continuing surveillance in this patient population.

There were several limitations to this study. First, not all patients underwent a uniform screening protocol. Patients were implanted prior to our current understanding of the risks associated with MoM THAs. Therefore, screening protocols have changed with time and are not standardized amongst all surgeons. Secondly, serial ion levels were not included in this study. It is possible that metal ion levels that are initially low will remain low, whereas elevated levels may portend a worse prognosis and continue to trend upward. Finally, we have included only one implant, the Pinnacle two-piece MoM implant. This particular implant appears to have substantially improved results compared to other MoM implant designs and therefore this data is not necessarily applicable to all MoM THAs.

Conclusion

ALTR remains a challenging problem after MoM THA. However, we identified only 8 patients (2%) who underwent revision secondary to ALTR at 12.6 years with the
Pinnacle two-piece MoM design. Therefore, the vast majority of patients with this implant are being serially screened with a low probability of identifying an ALTR. Time in-situ was the only risk factor we identified that was associated with revision for ALTR. Therefore, improved screening protocols for MoM THA surveillance are necessary to improve detection and decrease cost.

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20. Smolders JMH, Hol A, van Susante JLC. Metal ion trend may be more predictive


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