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Research Article

Findings in Non-Recalled Metal-on-Metal Total Hip Arthroplasty Patients

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Abstract

Introduction: Metal-on-metal (MoM) total hip arthroplasty (THA) has gained widespread attention in recent years due to several potential complications. Though several MoM THAs have been recalled, there remains a large subset of patients with retained MoM THAs that are believed to be doing seemingly well. No long-term report on these patients have been publicized and our aim was to report long-term follow-up on our MoM THA patients.

Methods: A retrospective review of 305 patients who had non-recalled MoM THA was performed. Of these, a total of 100 patients were evaluated. Patients were evaluated using the Harris Hip score, PASE questionnaire, Oxford Hip score and UCLA activity score. Radiographic position of the acetabular cup and femoral components were analyzed and metal ion levels of chromium and cobalt were obtained.

Results: Thirty-four patients (34.0%) had at least one current unconcerning problem with their hip (i.e. bursitis, groin pain, stiffness, or weakness). Twelve patients (12.0%) had a cobalt (Co) ion level > 7.0 µg/L. Six patients (6.0%) had a chromium (Cr) ion level > 7.0 µg/L. A greater proportion of patients with occasional hip noise had elevated levels of chromium ($p = 0.005$) and cobalt ($p = 0.010$). No differences in mean Harris Hip score, Oxford Hip score, PASE questionnaire, or UCLA activity score were observed in patients irrespective of Co and Cr levels, ($p = 0.178$, $p = 0.211$), ($p = 0.117$, $p = 0.318$), ($p = 0.170$, $p = 0.511$)and ($p = 0.135$, $p = 0.169$), respectively. A total of three patients (3%) required revision surgery.

Conclusions: Some patients may demonstrate significant elevations of metal ion levels or radiographic abnormalities which merit immediate attention or revision surgery. However, for patients who are doing seemingly well, we recommend continued clinical surveillance and evaluation of Co or Cr levels in patients with non-recalled MoM THA.

Keywords: *Metal-On-Metal; Metal Ion Levels; Total Hip Arthroplasty*

Introduction

In the 1990s, efforts to improve the outcomes and longevity of total hip arthroplasty (THA) led to the resurgence of several different models of metal-on-metal (MoM) hip implants. These implants were designated "metal-on-metal" in reference to the two main articular bearing surfaces, the femoral head and acetabular cup liner. The theoretical benefits of improved wear properties and greater stability with the implantation of larger diameter femoral heads greatly influenced their utilization [1,2]. Prior to the renewed interest of MoM, the standard articulation surface was a combination of a metal head and a polyethylene liner. At that time, conventional polyethylene liners demonstrated unacceptable wear rates [3-6], which led to undesirable results such as periprosthetic bone loss [7,8] and eventual need for revision due to osteolysis [9].

Early use of MoM total hip arthroplasty (THA) showed favorable outcomes [10-13]. However, over time this bearing combination was found to produce small but numerous amounts of wear particles, which led to increases in cobalt and chromium levels in the blood stream [14-17]. The presence of these ions in the body is thought to be due to aseptic lymphocyte-dominated vasculitis-associated lesions (ALVALs) in the periarticular tissues [18-22]. Elevated ion levels are also commonly associated with implant malalignment [23-26], actual hip design [27], head size [27]and acetabular version [27,28] which can eventually necessitate a revision of the hip implant [29]. Yet, many patients continue to experience good outcomes and do not experience any significant issues, even if their cobalt and chromium ion levels are high [30]. Unfortunately, the long-term effects of exposure to these ions remains unknown and, to our knowledge, remains unreported in the literature. It stands to reason that long-term exposure to cobalt and chromium could cause additional problems unrelated to the implant itself [31-33].

At this time, the long-term consequences of non-recalled MoM THA is not well documented. Our aim was to report on long-term follow-up on patients who received a non-recalled MoM THA between 10 and 14 years prior. We evaluated for unexpected metal ion levels elevations, x-ray changes and subtle clinical symptoms. We then sought to establish correlations of elevated metal ions and osteolysis with implant positioning, clinical symptoms, hip score and patient activity level.

Methods

A retrospective review of our institution's joint replacement repository of patients who had non-recalled MoM THA performed by a single adult reconstruction fellowship trained surgeon was performed. There were 305 patients who underwent a non-recalled MoM THA between 1998 and 2011. Implant types included Depuy Ultamet, Biomet Magnum, Depuy Metal-on-Metal 1-piece, Zimmer MMC and Wright Medical Profemur.

Attempts were made to contact all 305 patients. Only one hundred patients (126 MoM THA) chose to return for follow-up. Patients were evaluated using the Harris Hip score (HHS), Physical Activity Scale for the Elderly (PASE) questionnaire, Oxford Hip score and University of California Los Angeles (UCLA) activity score. Radiographic position of the acetabular cup and femoral components were analyzed and serum metal ion levels of chromium (Cr) and cobalt (Co) were obtained. Metal ion levels were considered elevated if greater than 7 μg/L.

Radiographic analysis

The acetabular component was reviewed based on zones of radiolucency described by DeLee and Charnley [34]. Acetabular inclination was measured by the angle formed between inter-teardrop line and the line parallel with the acetabular cup. An acetabular inclination within normal limits included 45 ± 10 degrees. The femoral component was analyzed for radiolucencies utilizing the Gruen classification [35]. Utilizing an AP radiograph of the pelvis, leg length discrepancy was measured radiographically by determining the distance between the line made from the inferior margins of the ischial tubersosities and a connecting line from the proximal aspect of the lesser trochanter. Femoral offset was described as the distance from hip center (center of femoral head) to the center of the femoral canal. Heterotopic bone was analyzed and classified using the Booker classification on both AP and lateral radiographs [36]. All measurements were made by one of two authors (SS or MI). Radiographs were accessed on the Kodak Picture Archiving Communication System (PACS) (Eastman Kodak Company, 10.1_SP1, 2006, Rochester, NY).

Statistical analysis

Demographic and clinical characteristics were analyzed using frequencies and percentages for categorical data and means and standard deviations or medians and ranges for continuous data. Categorical variables were compared using chi-square tests or in the case of small cell counts, Fisher's exact chi-square tests. Normally distributed continuous variables were compared using two-sample t-tests and non-normally distributed continuous variables were compared using Wilcoxon rank sum tests. Statistical significance was set at $p < 0.05$ for all tests.

Results

A total of 305 patients were found to have non-recalled MoM THA. Of these, 100 patients presented for long-term follow-up evaluation, thus meeting our inclusion criteria. Of the 100 patients who received a primary MoM THA since 1998, 26 patients (26.0%) had bilateral THA. Mean follow-up evaluation occurred on average 8.2 years (range, 1.7-13.5 years) after the date of surgery. Types of implants included Depuy Ultamet (n = 87; 69.0%), Biomet Magnum (n = 19; 15.1%), Depuy MoM 1-Piece (n = 8; 6.3%), Zimmer MMC (n = 7; 5.6%) and Wright Medical Profemur (n = 2; 1.6%).

In 50.4% of the hips replaced, patients reported a history of at least one postoperative problem relating to the hip. Postoperative problems included bursitis (36.4%), stiffness (3.3%), groin pain (1.7%), dislocation (0.8%) and numbness in the lower extremity (0.8%). However, at most recent long-term follow-up, patients reported no current bursitis (74.2%), groin pain (93.4%), stiffness (94.2%), or weakness (95.6%). A positive correlation of patients with a postoperative complaint and elevated Co levels was observed ($p = 0.042$). Eighteen patients (18%) with a history of any postoperative problem with their hip had Co levels >7 μg/L, while 4.6% of patients without a history of any postoperative problems had Co levels < 7 μg/L. No significant correlation was found with Cr levels ($p = 0.325$). Of those patients with current symptoms, 9.2% had elevated Co ion levels, but this was not found to be statistically significant ($p = 0.398$). Lastly, 11.8% of the patients with at least one current hip problem had elevated Cr levels compared to 3.1% without current complaints ($p = 0.207$).

In total, we found 12 (12.0%) patients had elevated cobalt ion levels (range: 7.0 μg/L to 149.8 μg/L), while six (6.0%) patients had elevated chromium ion levels (range: 7.0 μg/L to 96.2 μg/L). There was no difference in length of follow-up between patients with elevated and non-elevated metal ion levels (Co: $p = 0.587$, Cr: $p = 0.942$). No correlation was present in the proportion of patients with elevated ion levels among those patients who had bilateral hip replacements and those with unilateral THA (Co: $p = 0.760$, Cr: $p = 0.942$).

Acetabular cup inclination was within accepted limits, defined as 45 ± 10 degrees, for 82 patients. We found no difference in patients with elevated Co levels who had acetabular cup inclination within normal limits (12.2%) compared with outlier inclination angles (12.5%) ($p > 0.999$). Co and Cr levels showed no correlation with offset ($p = 0.663$, $p = 0.728$) or LLD ($p = 0.517$, $p = 0.560$), respectively. Periacetabular osteolysis was present in 14 patients (14.0%), evenly spread amongst all three zones. There was no difference in the proportion of patients with elevated Co ($p = 0.463$) and Cr levels ($p = 0.413$) amongst those with and without periacetabular osteolysis. Only two patients had any significant femoral osteolysis.

A total of 12 patients reported subjective hip noise. A greater proportion of patients with hip noise had a Co level >7 μg/L (41.7%) compared to those without hip noise (7.3%) ($p = 0.009$). Additionally, more patients with hip noise had Cr level >7 μg/L (33.3%) compared to those that denied hip noise (2.5%) ($p = 0.004$).

Mean values for scoring systems among patients with and without elevated ion levels are found in figure 1. There was no significant difference in mean Harris hip score ($p = 0.211$), PASE score ($p = 0.511$), UCLA activity score ($p = 0.169$)and Oxford hip score ($p = 0.318$) among patients with Co levels >7 μg/L and those with Co levels < 7 μg/L. Co levels showed no correlation with the Harris hip score ($p = 0.730$), PASE score ($p = 0.972$), UCLA activity score ($p = 0.337$)and Oxford hip score ($p = 0.387$). There was no difference in patients with Cr levels > 7 μg/L and those with Cr levels < 7 μg/L in terms of Harris hip score ($p = 0.178$), PASE score ($p = 0.170$), UCLA activity score ($p = 0.135$) and Oxford hip score (0.117). We found Cr levels had no significant correlation with the Harris hip score ($p = 0.972$), PASE score ($p = 0.103$), UCLA activity score ($p = 0.747$) and Oxford hip score (0.091).

A total of three patients required revision surgery. The first hip had extensive periacetabular and greater trochanteric osteolysis with elevated metal ion levels that subsequently required THA revision. After revision, the patient's ion levels continued to decrease over the course of a year. The second patient had significantly elevated ion levels, high abduction angle and an extensive fluid collection noted on MARS-MRI. This patient's cup was revised and the bearing was changed to metal-on-polyethylene bearing. At 10-month follow-up, the patient's ion levels decreased significantly but continued to be elevated likely secondary to the patient's other hip, which was a MoM

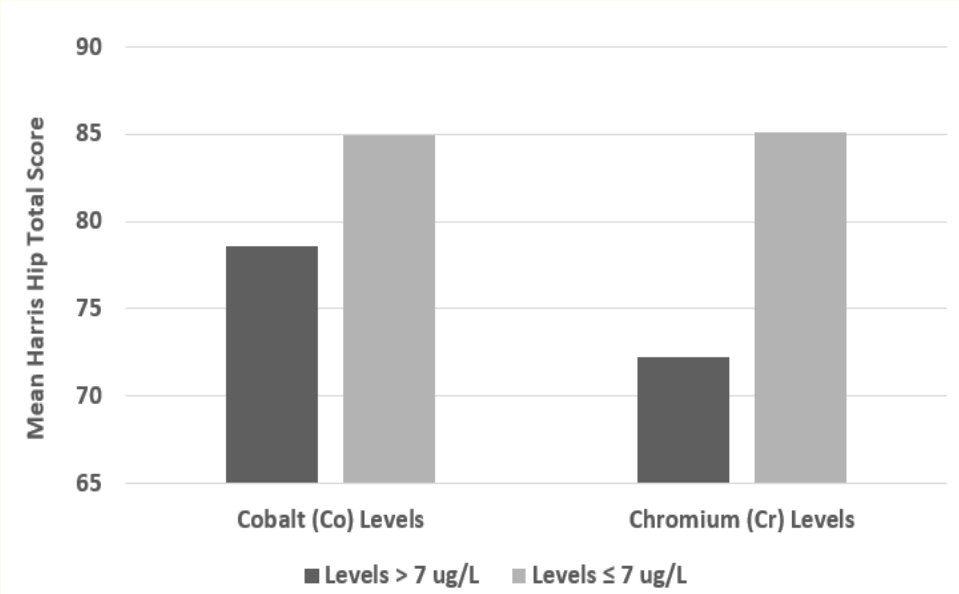

Figure 1A: *Mean Harris Hip Total Score by Cobalt and Chromium Levels among Patients who Received a Primary Metal-on-Metal Total Hip Replacement since 1998 by Metal Ion Level.*

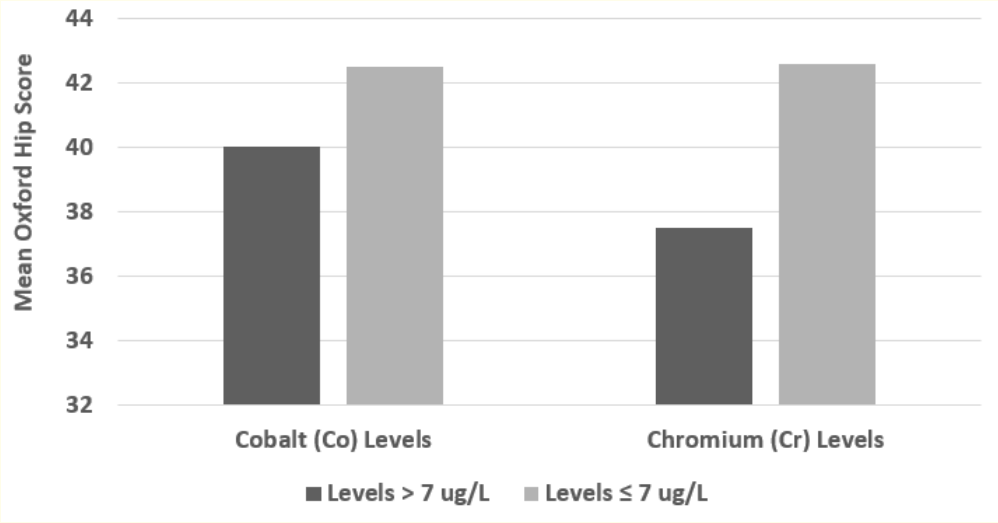

Figure 1B: *Mean Oxford Hip Score by Cobalt and Chromium Levels among Patients who received a Primary Metal-on-Metal Total Hip Replacement since 1998 by Metal Ion Level.*

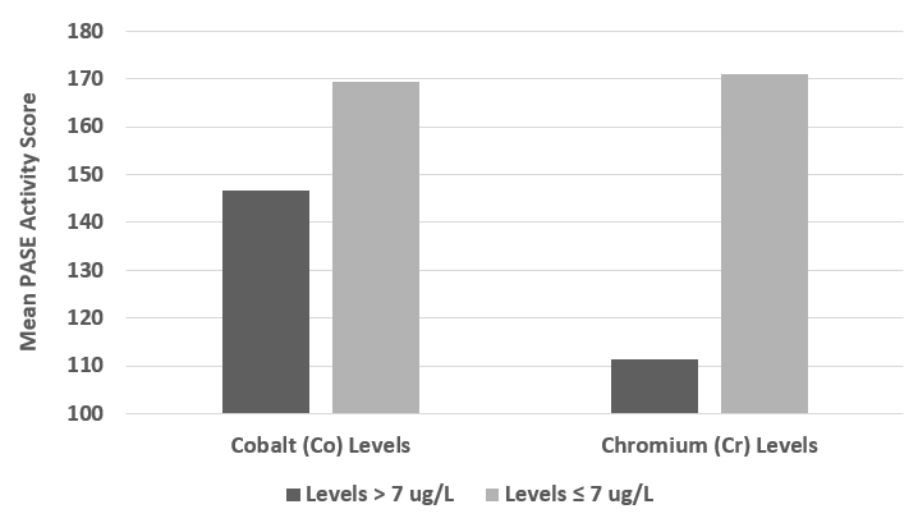

Figure 1C: *Mean PASE Activity Score by Cobalt and Chromium Levels among Patients who Received a Primary Metal-on-Metal Total Hip Replacement since 1998 by Metal Ion Level.*

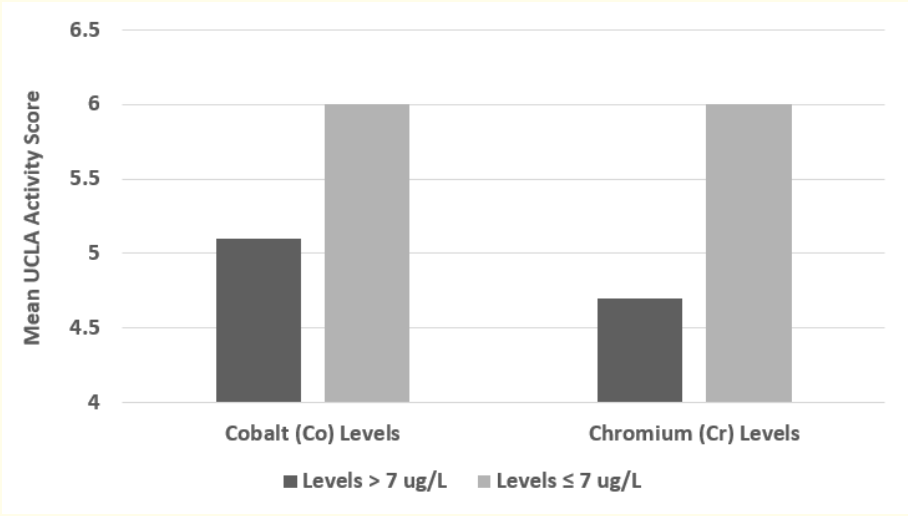

Figure 1D: *Mean UCLA Activity Score by Cobalt and Chromium Levels among Patients who Received a Primary Metal-on-Metal Total Hip Replacement since 1998 by Metal Ion Level.*

THA. Lastly, our third revision patient had groin pain, significantly elevated ion levels and a pseudotumor. She was revised to a ceramic-on-polyethylene bearing.

Discussion

Total hip arthroplasty continues to be one of the most successful procedures in terms of pain relief, improvement in function and overall patient satisfaction [37], even though traditional articulating designs develop wear and osteolysis. Contemporary MoM articulations in THA had a resurgence during the early 2000s but are now mostly unavailable. The goal of this study was to assess our patients who received a MoM THA greater than 10 years ago, particularly those doing seemingly well without recent follow-up. We felt this group was at risk for problems that were undiagnosed. We found 18% of our cohort required revision surgery or had elevated ion levels that required close follow-up.

Previous studies have shown higher revision rates for MoM hip replacements due to cup inclination angle [38], implant design [39], high cobalt and chromium levels [40] and edge-loading [38]. Previous studies have reported a higher systemic concentration of metal ions with inclination angles greater than 55 degrees [23]. We found no significant difference in the proportion of patients with elevated cobalt ($p > 0.999$) or chromium levels ($p > 0.999$) amongst patients with high abduction angles. We did however, identify 12 patients in our cohort that had elevated ion levels and are now being followed more closely. Of our cohort of patients, only three patients required revision surgery. One patient required revision due to elevated ion levels while the other two symptomatic patients had significantly high ions levels with pseudotumor formation.

The authors do note that there are several limitations to our study. The retrospective nature, as well as inability of randomization, could both influence results by introducing bias. Our data was collected from a single, high-volume, fellowship-trained joint arthroplasty surgeon and therefore surgeon preference may have influenced the results in the perioperative and post-operative period. Nevertheless, a single surgeon methodology allows for the same post op and rehab protocols throughout the patient cohort. This limits the confounding factors associated with a large multi-surgeon study considering perioperative and postoperative management. We also found that there was considerable variation among long-term patient follow-up as well having a low follow-up rate. An additional limitation is that acetabular inclination angles were evaluated using plain radiographs and not computed tomography, but this was consistent across the whole study.

Conclusion

In conclusion, we recommend continued clinical surveillance of even unconcerned patients with non-recalled MoM THA. Some patients will have significant elevations of metal ion levels or radiographic abnormalities needing immediate attention, revision surgery, or closer follow-up.

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