Metal-on-Metal Total Hip Arthroplasty
Five- to 11-Year Follow-Up

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Abstract

Metal-on-metal (MoM) total hip arthroplasty (THA) has been introduced in an attempt to reduce the wear rate and the consequent osteolysis around implants. The aim of this study was to present the intermediate to long-term clinical and radiological outcomes and to investigate the metal ion levels in the blood of patients who had undergone primary uncemented MoM THA in our institution. Between July 1997 and November 2003, 166 patients (193 hips), with a mean age of 50 years (range, 18-65 years), underwent primary MoM THA. Clinical data, radiographs, and blood samples were obtained at regular follow-up visits. Cobalt (Co), chromium (Cr), and molybdenum (Mo) ions were measured by inductively coupled plasma-mass spectrometry (ICP-MS) from the patient’s whole blood. All patients were prospectively followed for a minimum of 5 years (mean, 7 years; range, 5-11 years). The mean Harris hip score (HHS) and the University of California at Los Angeles (UCLA) activity score at the latest follow-up was 88 ± 11 and 7 ± 1.8 points, respectively. Ten acetabular components had early failure, due to factory manufacturing problems. All other implants have been found stable, with no signs of aseptic loosening. The probability of survival at 11 years, if the hips that were revised due to manufacturing problems were excluded, was 98.4%. The Co and Cr metal ion levels, after increasing significantly during the first 4 to 5 years post-surgery, remained stable, with a tendency to decrease thereafter, but not significantly. During the same follow-up period, Mo ion levels remained stable. In this 5-to-11 year follow-up study of MoM THA patients, excellent survivorship, with low complications rates, was found. Results of longer follow-up studies are necessary to clarify the possible long-term effects of metal ion release.

Metal-on-metal (MoM) total hip arthroplasty (THA) was introduced in an attempt to reduce the wear rate1 and the consequent osteolysis around implants which has been a well-recognized complication of conventional metal-on-polyethylene THAs.2,3 The first generation of resurfacing implants was introduced in 1938 with the Wiles prosthesis but became more common with the Ring and McKee-Farar prostheses, both made from cobalt-chromium (Co-Cr) alloy later during the early 1960s.4 These early designs of MoM THAs failed, mainly due to imprecise tolerances between the femoral head and acetabular component, resulting in high frictional forces and early loosening.4

In 1988, Weber re-introduced MoM articulations in THA with the Metasul® (Sulzer, Basel, Switzerland) prosthesis.5 This second generation prosthesis had improved manufacturing technology and better clearances, as well as improved metal hardness. Since then, short- and mid-term clinical results of modern MoM THAs have been promising, especially in young, active patients.6,9 Studies have shown that MoM bearings produce 20- to 200-times less wear than conventional metal-on-polyethylene bearings.10 However, due to the increased metal ion levels in serum, plasma, or erythrocytes of patients with MoM THA,11-19 concerns have been raised regarding the long-term use of these prostheses. Hypersensitivity reactions20-22 and formation of
pseudotumors,\textsuperscript{23} as well as the risk of carcinogenicity,\textsuperscript{24,25} or fetal exposure to metal ion levels in pregnant females,\textsuperscript{26} are all concerns with these devices. The aim of the current study was to present the intermediate and long-term clinical and radiological outcomes and to investigate the metal ion levels in the blood of patients who had undergone primary uncemented MoM THA at our institution.

**Materials and Methods**

**Demographics**

Between July 1997 and November 2003, 166 patients (193 hips), with a mean age of 50 years (range, 18-65 years), underwent a primary MoM THA at our institution by one of three experienced hip surgeons. Patients who had a previous infection, the presence of any other metal hardware, a known metal allergy, a renal insufficiency, or a severe medical disability that limited their ability to walk were excluded from the study. Table 1 summarizes the baseline demographics of the study group as well as the diagnosis for the surgeries. Approval by our institutional review board (IRB) was obtained, and all patients signed the approved consent forms for the use of their blood and clinical data. The characteristics of implants are summarized in Table 2.

**Outcome Measures**

Two validated outcome measures, the Harris hip (HHS) score\textsuperscript{27} and the University of California at Los Angeles (UCLA) activity score,\textsuperscript{28} were obtained at each postoperative visit. The HHS score was also obtained in all patients pre-operatively.

**Radiographic Evaluation**

Anteroposterior and lateral radiographs of the pelvis were taken at each postoperative visit and at the latest follow-up; the films were analyzed at that time for implant position and signs of loosening. Vertical inclination of the acetabular component was quantified by the angle formed between a line passing through the teardrop signs and a second line representing the acetabular component’s greatest diameter. Radiolucent lines and osteolysis around the femoral stem were measured according to the zones described by Gruen and colleagues.\textsuperscript{29} Acetabular radiolucent lines were measured with use of the zones described by DeLee and Charnley.\textsuperscript{30}

**Metal ions**

Cobalt (Co), chromium (Cr), and molybdenum (Mo) ions were measured by inductively coupled plasma-mass spectrometry (ICP-MS) in the whole blood of patients, as previously described.\textsuperscript{21} We compared median metal ion levels in the blood of patients with the acetabular component positioned outside the “safe zone” (anteversion of 15° ± 10° and a lateral opening of 40° ± 10°)\textsuperscript{11} to the levels in patients within this “safe zone.” Overall, we identified 19 hips in 19 patients with components outside this “safe zone.” There were no significant differences in age, follow-up time, and outcome scores for patients within or outside the “safe zone” (Table 3).

**Statistics**

Normally distributed data (age, follow-up, HHS, UCLA, acetabular orientation) were analyzed with t-tests, while nonparametric data (metal ions) were analyzed with the Mann-Whitney U test and then expressed as medians. Implant survival probabilities were computed using Kaplan-Meier analysis, counting revision of one or both components, for any reason, as the terminating event and censoring patients at the time of their death or at the end of the follow-up period. The GraphPad Prism 4 software (La Jolla, California) was used for all calculations.

**Results**

At the time of database closure (January 2009), 13 hips had been revised. All other patients were prospectively...
followed for a minimum of 5 years (mean, 7 years; range, 5-11 years).

**Outcome Measures**

The mean pre-operative HSS score was 39 ± 10 points, which reached 88 ± 11 points at the latest follow-up. Figure 1 shows the evolution of the HSS scores throughout the study period: no significant differences were observed at the different follow-up visits. The mean UCLA activity score was 7 ± 2 points at the first postoperative visit (2 years) and also 7 ± 2 at the latest visit (p > 0.05). Figure 2 shows the evolution of the UCLA activity scores throughout the study period. As observed for HHS, no significant differences were observed at the different follow-up times (p > 0.05).

**Radiographic Results**

Apart from the 13 hips that were revised, all other implants have been found stable, with no signs of aseptic loosening. The mean postoperative acetabular inclination was 40.1° ± 7.5°, while the mean inclination at the latest follow-up reached 40.7° ± 6.4° (p = 0.55). The mean postoperative acetabular version was 16.8° ± 8.7°, while it reached 18.3° ± 9.5° at the latest follow-up (p = 0.39). Overall, 19 hips were found to be outside the “safe zone” of 40° ± 10° of inclination and 15° ± 10° of version, as defined by Lewinnick and coworkers. Non-progressive radiolucent lines greater than or equal to 2 millimeters around the femoral stem were found in four hips. In six hips, radiolucent lines greater than or equal to 2 millimeters were found. None of the femoral or acetabular implants were observed to be loose.

**Metal Ions**

In order to rule out bias, we excluded patients with bilateral THAs, which left 132 hips to analyze. Figure 3 shows the levels of metal ions in the whole blood of patients during the study period. After increasing significantly during the first 4 to 5 years post-surgery (p < 0.0001), Co (Fig. 3A) and Cr (Fig. 3B) levels tended to decrease, but not significantly thereafter, in comparison with the levels observed at 4 to 5 years (p = 0.06 and p = 0.11 for Co and Cr, respectively). Cobalt levels passed from 2.16, 2.94, 2.33, and 2.30 µg/L in 1 to 3 years, 4 to 5 years, 6 to 7 years, and more than 7 years groups, respectively (Fig. 3A). Cr levels passed from 0.35, 0.74, 0.70, and 0.40 µg/L in the 1 to 3 years, 4 to 5 years, 6 to 7 years, and more than 7 years groups, respectively (Fig. 3B). During the same follow-up period Mo ion levels...
remained stable between 1.46 µg/L (6 to 7 years) and 1.70 µg/L (1 to 3 years).

**Effect of Acetabular Orientation on Metal Ion Levels**
Results showed that in patients with acetabular components positioned outside the “safe zone,” the levels of Co (2.93 µg/L) and Cr (1.34 µg/L) ions at the last visit were significantly higher (p = 0.018 and p = 0.020, respectively) than levels of Co (2.00 µg/L) and Cr (0.683 µg/L) in the blood of patients whose components were inside the “safe zone” (Fig. 4). There were no differences in the levels of Mo (p = 0.79) (Table 3).

**Revisions**
From the 13 hips that have been revised (Table 4), 10 had an early failure, due to early loosening of the acetabular component. All of these patients had an uncemented Sulzer Interop™ acetabular component implanted. This implant was recalled by the company in December 2001, after several surgeons reported cases of early failure. The cause of this complication is believed to be a failure of bony in-growth, due to a residue of machining oil left on the backside of the component at the time of manufacturing. One other hip developed an early infection and was treated with washout and liner exchange. One additional acetabular component had been revised the same day, due to intra-operative poor technique. One hip has been revised because of aseptic loosening of an under-sized femoral component (natural hip).

Overall, the revision rate was 6.7%. If we exclude the hips that have been revised due to the manufacturing problems of the acetabular component, the revision rate was as low as 1.55%. With “revision for any reason” as the end point, survival at 11 years was 93.8%. If we exclude the hips that were revised due to manufacturing problems of the acetabular component, then survival was 98.4% (Fig. 5).

**Discussion**
The results of the present study show that, at the intermediate follow-up time of 5 to 11 years, uncemented MoM THAs performed well, with a survivorship at 11 years of 98.4%. Additionally, the radiographic analysis of the THAs did not reveal any progressive signs of loosening in any of the implanted prostheses. The outcome for patients with this

<table>
<thead>
<tr>
<th>Patient</th>
<th>Gender</th>
<th>Age (Years)</th>
<th>Side</th>
<th>Time to Revision (Months)</th>
<th>Cause</th>
</tr>
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<tbody>
<tr>
<td>1</td>
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<td>57</td>
<td>R</td>
<td>7.4</td>
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</tr>
<tr>
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<td>F</td>
<td>60</td>
<td>R</td>
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</tr>
<tr>
<td>3</td>
<td>F</td>
<td>60</td>
<td>L</td>
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<tr>
<td>4</td>
<td>M</td>
<td>48</td>
<td>R</td>
<td>33.3</td>
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<tr>
<td>5</td>
<td>M</td>
<td>42</td>
<td>R</td>
<td>19.2</td>
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</tr>
<tr>
<td>6</td>
<td>F</td>
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<td>L</td>
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<tr>
<td>7</td>
<td>F</td>
<td>52</td>
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<td>0</td>
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<tr>
<td>8</td>
<td>F</td>
<td>53</td>
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<tr>
<td>9</td>
<td>F</td>
<td>34</td>
<td>L</td>
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<tr>
<td>10</td>
<td>F</td>
<td>43</td>
<td>L</td>
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<tr>
<td>11</td>
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<tr>
<td>12</td>
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<tr>
<td>13</td>
<td>M</td>
<td>64</td>
<td>L</td>
<td>1.3</td>
<td>Early infection: underwent exchange of liner</td>
</tr>
</tbody>
</table>

![Figure 4](image-url) Cobalt (Co) and chromium (Cr) levels in the blood of patients, within or outside the “safe zone” at their last follow-up visit.
second generation of MoM THA appears better than what was reported for the first generation of MoM prostheses.

The long-term results of the second generation of MoM THAs reported in the literature have shown excellent outcomes. Grubl and associates analyzed results from 105 cementless primary MoM THAs and reported an overall survival of 98.6% at 10 years. In another study, Neumann and colleagues reported at a mean follow-up of 10.5 years 98% survivorship of the stem and 96% for the cup. At mid-term (4 to 7 years), Dorr and coworkers reported a survival rate of 98.2% on 70 MoM THAs. Kim and associates reviewed the results of a series of active patients who were less than 50 years old when they underwent cementless THA with the use of the Metasul® MoM articulation. They found that, at a mean 7-year follow-up, only one out of the 70 THAs had been revised for liner exchange due to focal pelvic osteolysis.

In our series, a total of 13 hips (out of 193) have been revised at the time of database closure. Ten hips had early revision due to aseptic loosening. These prostheses were parts of the Sulzer Interop® acetabular component, recalled by the company in December 2001, after several surgeons reported cases of early failure. A residue of machining oil that was left at the backside of the component at the time of manufacturing is believed to be the cause of early loosening. As a result, inflammation at the bone-implant interface led to failure of bone in-growth. Patients experienced groin pain and early acetabulum loosening. If we exclude revisions due to this cause, only three hips have been revised during 5- to 11-year follow-up, resulting in a survivorship of 98.4% at 11 years. These results confirm the results obtained by other groups with second generation MoM THAs.

One of the main concerns that has been raised about the use of MoM THA involves the elevation of the metal ion levels in the blood and urine of patients with these bearings. The increase of Co and Cr levels is a well-proven fact in patients with the first generation of MoM THAs, as a result of wear of the implants. For example, Sauvé and colleagues analyzed metal ion levels in patients who had primary, well-fixed, Ring MoM THAs for more than 30 years. They found that Co and Cr ion levels were elevated by five- and three-times, respectively, compared with those in their reference groups. In another study, Jacobs and coworkers found a nine-fold elevation in serum Cr and three-fold elevation in serum Co concentrations in patients with long-term use (more than 20 years) of McKee-Farrar hip arthroplasties, as compared to controls.

There is relative paucity of evidence regarding the long-term metal ion release in patients with second generation MoM THAs. In a recent study, Grubl and associates reported metal ion concentration in the serum of 22 patients with unilateral MoM THA after a minimum 10-year follow-up. They found that the median serum Co concentration was 0.75 µg/L (range, 0.3-50.1 µg/L), and the median serum Cr level was 0.95 µg/L (range, 0.3-58.6 µg/L). However, the investigators only measured metal ion levels at a single point in time. In another study, Lazennec and colleagues investigated metal ion levels in patients with unilateral MoM-backed polyethylene cemented hip arthroplasties with 28-mm femoral heads. They reported stable serum Co over time (1.3 to 1.7 µg/L up to 9 years post-surgery) and a tendency for decreased levels of Cr from 2.18 µg/L at 1 year to 1.49 µg/L at 9 years. These studies are in agreement with the present study, showing a rapid increase of both Co and Cr ions, followed by a tendency to decrease thereafter.

Extensive acetabular inclination or version has been linked with high rates of polyethylene wear in cases of metal-on-polyethylene THAs and also with high metal ion release in cases of metal-on-metal hip resurfacing. Also, the extreme anteversion or inadequate anteversion angles have been associated with a rise in metal ion levels in hip resurfacing. In their study, Brodner and coworkers investigated the correlation between cup inclination and serum Co or Cr concentrations in patients with MoM THAs. They found no statistically significant differences in ion levels in the three groups of patients with different acetabular component inclination. However, there were three patients with cup inclination angles of more than 55° who exhibited 9.8- to 53.6-fold elevated Co and 9.5- to 30.5-fold elevated Cr levels when compared to the median concentrations of their trial. Our study showed that patients with acetabular orientations outside the “safe zone” of 40° ± 10° of inclination and 15° ± 10° of version, as defined by Lewinnick and associates, had significantly higher levels of Co and Cr ions at the last visit than levels of Co and Cr in the blood of patients within the “safe zone.” Also, outlier values were mainly found in this group of patients, suggesting that positioning the acetabular component in the “safe zone” is important towards the attempt of reducing metal ion levels in patients with MoM THA.

A limitation in our study is the absence of pre-operative Co and Cr level values for our group of patients: we cannot
References

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Disclosure Statement
None of the authors have a financial or proprietary interest in the subject matter or materials discussed, including, but not limited to, employment, consultancies, stock ownership, honoraria, and paid expert testimony.

Conclusion
The present 5- to 11-year follow-up study of patients with MoM THA demonstrated excellent survivorship, with low complication rates. After an early increase during the first 4 to 5 years, metal ion levels in patients’ blood remained stable, with a tendency to decrease. Results of longer follow-up studies are necessary to further confirm our findings and clarify the possible long-term effects of metal ion release in patients’ circulation.

References


