Retrieval analysis and principle variable analysis of 127 M2a-38mm™ metal on metal hip replacements

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INTRODUCTION: The need to revise metal on metal (MoM) implants early due to adverse reaction to debris and corrosion products is a major concern within the orthopaedic community. However the in-vivo performance of these joints depends on a range of variables related to the patient, the joint design and the surgical positioning. These variables can impact on the performance of the bearing but also the taper interface in modular components, with both capable of metal debris and corrosion products capable of causing the adverse reactions and pain which results in the need for joint retrieval. The objective of this study was to investigate the design, alignment and patient specific factors which affected the level of material loss for the bearing surfaces and taper of a cohort of M2a-38mm™ MoM hip replacements.

METHODS: The cohort consisted of 127 M2a-38mm™ retrieved femoral head and acetabular components which had been paired with Bi-metric™ un cemented titanium stems. Each joint had patient specific data for the weight, height, BMI, age at Primary surgery, functional time. They also had positional data including neck angle, horizontal and vertical offset, neck length, cup inclination and version angles, the bearing clearance, the taper angle and taper clearance angle based on the perfect trunnion angle of the Bi-metric™ stem. Material loss analysis was undertaken on the femoral and acetabular bearing surfaces and the taper interface of the head using an OrthoLux (RedLux, Southampton, UK). In addition wear scar location on the bearings was analysed to differentiate the joints into one of three groups, either edge worn (EW), normally wearing (NW) or edge interaction (EI). The patient, implant and positional variables were compared to the material loss values using both Spearman and Pearson’s correlations so as to determine the variables having significant effects but also to account for linear and non-linear relationships.

RESULTS SECTION: Based on the wear scar location classification the 28 joints were wearing normally, 12 had edge interaction and 87 showed signs of having been edge wearing. Table 1 shows the mean volumetric loss rates and ranges of the loss for the joints in the different classifications. The comparisons between the loss values and the independent variables showed a number of significant correlations but varied between the wear scar location groups. For the NW joints, only the bearing clearance was significantly linked to the femoral head volumetric loss rate (r = 0.419). The EW joints had a larger number of significant correlations. The femoral head volumetric loss was linked to both the bearing clearance (r = 0.379) and the version angle (r = 0.23) of the cup. The Acetabular cup loss was significantly correlated to the inclination and version angles of its placement (r = 0.35 and 0.44). For the EI group The Cup loss was linked to the vertical offset (r = -0.701) and the Neck length (r = -0.596). The taper loss wasn’t linked to any variables in the NW group, but was linked to the bearing clearance (r = 0.316), but also to the height (r = 0.331), weight (r = 0.29) and taper angle (r = 0.314) in the EW group and Weight and Height (r = -0.756) in the EI group. While not showing any significance in correlation there was a visible effect of taper clearance angle on the taper failure with positive taper angles providing a higher level of loss than negative ones.

DISCUSSION: This is one of the few studies to have reported the assessment of the loss from well aligned MoM bearings and demonstrates that when aligned well these M2a-38mm™ joints were wearing at the rate expected and below that of other joints[1]. There was only one significant correlation for the NW joints which was a positive one with the bearing clearance. This shows that the lower clearance joints had a lower level of loss than their higher clearance counterparts. This can be attributed to both the higher running in wear experienced by high clearance joints but also the potential for enhanced lubrication of the bearings at lower clearances. The highest levels of loss shown in the EW group are expected given the nature of the bearing contact. The positive correlation with clearance was maintained in this group as well. The loss values were predominantly linked to the acetabular cup positioning, however the correlations were less than r = 0.45 suggesting other factors not assessed in this study were having an effect. It was also notable that a number of joints classified as edge wearing fell within the ‘safe zone’ (Figure 1.). The levels of material loss from the tapers are lower than other comparable MoM joint designs[1-3]. The negativecorrelatioonto bearing clearancein both the EW and the cohort as a whole offsets the benefits seen to the bearing wear and suggests a transfer of load or torque to the interface as a result of the lower clearance. Taper loss was the only variable which was linked to patient variable, with a weak but positive correlation to weight in the EW and whole cohort analysis. The positive taper angle effect is likely due to the production of a crevice environment and the more ready ability for the exchange of fluid and ions compared to the negative clearances. In conclusion, the NW joints showed levels of material loss which would be expected of these joints in vivo and levels of taper loss which is below that reported from other similar joint designs. The major issue was the number of joints which exhibited edge wear or interaction which exacerbated the loss from the bearings. However, the variable analysis suggests that positioning explains only a portion of the loss values, with well aligned joints exhibiting edge wear.

SIGNIFICANCE/CLINICAL RELEVANCE: This study is the largest single cohort analysis of this joint design. The control of the joint to a single design, size and stem design provided an opportunity to minimise the different variables between joints provided a unique ability to focus on those which are affecting their performance.


![Image](Image 353x76 to 546x246)

Table 1. Mean (range)/Volumetric loss values for the three sites of investigation based on bearing scar classification.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>NW</th>
<th>EI</th>
<th>EW</th>
</tr>
</thead>
<tbody>
<tr>
<td>Head</td>
<td>0.3 (0.156)</td>
<td>0.49 (0.04 – 1.73)</td>
<td>4.1 (0.25 – 46.1)</td>
</tr>
<tr>
<td>Cup</td>
<td>0.04 (0 – 0.35)</td>
<td>0.09 (0 – 0.38)</td>
<td>4.23 (0.02 – 35.1)</td>
</tr>
<tr>
<td>Taper</td>
<td>0.27 (0 – 0.8)</td>
<td>0.3 (0 – 0.7)</td>
<td>0.18 (0 – 1.1)</td>
</tr>
</tbody>
</table>

Figure 1. Inclination vs. version angle divided by bearing scar classification.