Adverse MOM Wear-rates Resulting from Abrasive Metal Particulates - A 3rd-body Simulator Model

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Introduction: Recent metal-on-metal (MOM) studies have have brought a focus to perceived risks in CoCr cup design concepts with “edge loading”. However the effect of 3rd-body wear appear to have been neglected.\cite{1} Indeed, laboratory simulation of in-vivo effects is fraught with difficulty given the many variables, only a few known, and most unpredictable.\cite{2} Abrasive wear models in the hip have included, a) inserting debris between bearings and b) adding particulates to the lubricant. In one simulator study with metal debris, titanium particles (Ti) were introduced to surfaces of two 28mm diameter MOM.\cite{3} The resulting wear results increased 3-orders of magnitude compared to controls. In a later study, hydroxyapatite (HAP) particles were introduced to surfaces of three 36mm MOM (5-Mc test duration).\cite{4} Resulting maximum wear-rates remained quite low, indeed would be considered typical for a standard MOM test without debris. Given such a dichotomy in data representing 3rd-body wear effects, this simulator study investigated MOM abrasion using 3 types of debris. The effects of metal debris (CoCr and Ti6Al4V) were compared to polymerized bone-cement particles (PMMA), all using 36mm MOM bearings run synchronously in a hip simulator.

Methods: The nine 38mm MOM were wrought high-carbon Co-Cr-Mo alloy (donated by DJ Orthopedics, Austin). The cups were mounted anatomically in an orbital hip simulator and run under standard guidelines (ISO-14242-3). Commercially available cobalt chrome (CoCr: F75) spheres and irregularly-shaped titanium alloy particles (Ti64: F136) were used as analog metal debris. Custom cement debris (PMMA) was created by shaving particles of polymerized cement from a retrieved cemented knee joint. SEM and EDS imaging provided constituents, shape and size in 50--200µm size range (Fig. 1). The 5mg debris allotments representing each dose contained approximately #232, 344 and 1,296 particles for CoCr, Ti64 and PMMA, respectively. The debris was positioned on femoral heads wetted with bovine serum and then cup-loading applied. Debris was added at each new test interval, beginning at 0.8Mc. There were no other additives in the 400ml volume of lubricant (protein: 17mg/ml). Each test interval was approximately 500,000 cycles duration and wear analysis was by gravimetric method. The data was reviewed statistically by linear regression and box-plot analyses.

Results: Within one hour of test, the six lubricant chambers with metal debris had turned the serum lubricant quite black in color (Fig. 2) and this was maintained through all test intervals to 5Mc duration. In contrast, the PMMA tests did not affect the yellow lubricant color (Fig. 2: flask #7). All MOM wear trending was satisfactorily linear and consistent to 5Mc duration (Fig. 3). Box plot comparisons for overall MOM wear rates showed statistically significant differences in wear rates (Fig. 3d). The linear-regression trends (0.8-5Mc) with PMMA, CoCr and Ti64 debris challenges provided MOM wear-rates of 0.3, 4.1 and 6.4mm3/Mc respectively (Table 3).

Discussion: This appears to be the first comparative study of debris effects in a hip simulator model. Prior simulator studies used either titanium (Ti)\cite{3} alone or hydroxyapatite4 particles alone.\cite{4} The consistently black coloration of the serum lubricants was visual evidence of adverse MOM wear-rates due to metal debris (range 4-6.4mm3/Mc). Clearly the Ti64 debris created the greatest adverse effect, with MOM wear achieving 58% higher than with CoCr debris, and representing 20-fold increase over controls. A wear-rate of 6.4mm3/Mc (Table 1) represented 26.6mg of CoCr debris released over 500,000 cycles. Thus, the 0.5mg allotment of Ti64 debris produced 53-times that weight of CoCr debris as a result of 3rd body abrasive wear. There were many limitations in this type of simulator study. We basically followed earlier Ti-debris protocols (0.5mg per interval)\cite{3} and introduced debris at every interval over 5Mc duration.\cite{4} In addition, the debris sizes and shapes are likely limitless in vivo\cite{2}; here the chosen size range (50-200um) represented our prior experiences with MOM explants.\cite{1} It is also unknown whether introducing #200-300 metal particles into a MOM interface at each new simulator event has clinical relevance. Nevertheless this simulator debris study did confirm, (i) effect of cement particles appeared innocuous, (ii) both CoCr and Ti64 particles were capable of provoking adverse wear in MOM bearings, and (iii) this test method was consistent and fairly precise over the 5Mc duration.\cite{4}

Significance: It is recognized that 3rd-body particles migrating into the joint space can create an adverse wear risk with any material combination in artificial hip joints. Various studies have indicated that bone cement, Ti6Al4V, CoCr and hydroxyapatite particulate types are all capable of damaging CoCr surfaces. However two MOM simulator studies produced contrary results
with 3rd-body wear (Ti vs HAP debris). The present simulator study compared three likely debris candidates (PMMA, Ti6Al4V, CoCr), producing consistent results over 5-million cycles duration and illustrated for 1st time that bone cement produced no visible effect while Ti6Al4V and CoCr debris clearly showed adverse wear in MOM bearings.

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**References:**

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<th>Particulates</th>
<th>Regression Coeff (Min values)</th>
<th>MOM Wear-rates (mm3/Mc)</th>
<th>MOM Wear Ratios</th>
<th>Wear-ratio Cup/MOM</th>
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</thead>
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<tr>
<td>CoCr debris</td>
<td>0.992</td>
<td>4.07</td>
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<td>Ti6Al4V debris</td>
<td>0.986</td>
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<td>PMMA debris</td>
<td>0.941</td>
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</table>
a) CoCr Cup (CoCr Debris)

b) CoCr Cup (Ti64 Debris)

c) CoCr Cup (PMMA Debris)

d) MOM wear rates