In-vitro Wear Simulation of Different Materials for Total Hip Replacement under Stop-Dwell-Start Conditions

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Disclosures:
M. Hadley: 3A; DePuy Synthes. 4; Johnson & Johnson. C. Hardaker: 3A; DePuy Synthes. G. Isaac: 3A; DePuy Synthes. J. Fisher: 3B; DePuy Synthes.

Introduction: The total hip arthroplasty (THA), is a widely used solution to help restore hip function following arthritic disease. Pre-clinical in vitro evaluation of new designs, in particular wear behaviour, is an important aspect of the development of joint replacements to better understand devices and more accurately predict performance in vivo.

Hip wear simulation is commonly used for pre-clinical testing of bearings, where the ball and socket are subjected to typical loads and motions to which they would be exposed in vivo (1). Current standards for in vitro wear simulation of THA applies kinetics and kinematics characteristic of normal walking to the joint for millions of cycles during which components are periodically examined to evaluate the degree of wear and change in geometry. This has been shown in many studies to be a highly accurate method for comparing different types of implants and predicting their performance once in a patient (2), however this approach does not account for the varying walking patterns of patients throughout a typical day. Clinical studies have shown that an average THA patient typically walks in bursts of around 10 steps before pausing or changing to another activity such as stair climbing or sitting (3). When pausing during walking, the most frequent duration of pause was shown to be 2-5s (4).

The effect of interrupting a walking simulation with dwell periods on the tribology of a metal-on-metal joint has been studied previously 5. Significant increases in wear were observed in the worst case condition when the number of cycles between dwell periods was reduced to one or two cycles due to deterioration of the lubricating film during the pause, and insufficient cycles between pauses to re-establish optimal lubrication. The present study sought to test the hypothesis that other bearing materials would also exhibit similar characteristics of an increase in wear under the demanding stop-dwell-start (SDS) conditions.

Methods: Test Specimens: Four bearing material combinations were evaluated for this study: metal-on-metal (MOM) (n=10), metal-on-polyethylene (MOP) (n=5), ceramic-on-polyethylene (COP) (n=5) and ceramic-on-ceramic (COC) (n=5). All were 36mm diameter Pinnacle® bearings; the metal implant components were wrought CoCrMo (ASTM F1537), ceramic components were Ceramax™ Ceramic, Biolox® Delta and polyethylene components were Marathon™ Cross-Linked Polyethylene (All DePuy Synthes, Leeds, UK).

General Methodology: Samples were tested on a ten station ProSim Deep Flexion Hip Wear Simulator (Simulation Solutions, UK). Newborn bovine serum 25% (v/v) (SeraLabs, UK), equivalent to a minimum of 17g/L of protein was used as a lubricant. Sodium azide (0.1% w/v) and ethylenediaminetetraacetic acid (EDTA) (0.02% w/v) were added to retard bacterial and excessive protein growth. Serum was changed every 0.5 million cycles (mc) and the tests were run for a total of 2mc.

Walking Simulation: The kinematic and kinetic inputs described above were applied continuously at a frequency of 1Hz. Samples were gravimetrically analysed every 0.5 million cycles (mc) and the tests were run for a total of 2mc.

Stop-dwell-start (SDS) simulation: The load and motion cycle described above was applied once followed by a ten second dwell period with a constant load of 1250N, representing bi-lateral stance load. This was repeated continuously for a total of 0.5mc, with gravimetric analysis every 50,000 cycles. In the SDS test only cycles with motion were counted for the purposes of calculating wear rates and describing the duration of the test; it was assumed that no wear would occur during the dwell when no relative motion between the surfaces was occurring. The shorter test length for the SDS studies was due to the significantly longer period of time required to run these tests.

Results: Volumetric wear rates were calculated over 2mc for the samples in the walking test, and over 0.5mc for the samples in the SDS tests. Significant increases in wear rate were observed for all material types under SDS conditions when compared with the continuous walking condition. Mean wear results are presented in Table 1 and Figure 1.

The percentage increase in wear rate from walking to SDS simulation was calculated for each bearing material. For MOM bearings this increase was 1436%, MOP 490%, COP 322% and COC 3500%.

Discussion: The results of this study support the hypothesis that MOP, COP and COC bearings demonstrate a significant increase in wear rate under in vitro SDS simulation compared with normal walking, as has been demonstrated previously on MOM devices. This is believed to be due to deterioration of the lubrication within the bearing interface during the dwell phase. Following the dwell a small number of motion cycles are needed to re-establish the lubricant film through entraining motion at
the bearing interface. If, as in this study, only one motion cycle occurs between dwell phases, there was insufficient entraining motion to re-establish the lubricant mechanism, therefore the wear rate increased. This has been demonstrated both experimentally and theoretically (5,6).

It is generally accepted that the bearing materials examined in this study operate under different lubrication regimes; MOM functions largely in the mixed regime, while MOP and COP are closer to the boundary lubrication end of the mixed zone, and COC tends towards the fluid film end of the mixed zone (7). The results of this study demonstrate a larger absolute increase in wear for the hard-on-soft (MOP and COP) bearings from normal walking to adverse SDS conditions compared with the hard-on-hard (COC and MOM) bearings, however the relative increase in wear rate from walking to SDS is greater for the hard-on-hard bearings. This is to be expected, since a lack of lubricant induced by adverse conditions will have a more significant effect on a bearing operating in the mixed or fluid zone under normal conditions, as the bearing relies more on fluid load support during normal walking, thus is more susceptible to depletion of that load support under the worst case test scenario. In contrast, a hard-on-soft bearing operating closer to the boundary regime under normal conditions will experience a lesser effect of depletion of the fluid lubrication under adverse conditions, therefore a relatively smaller increase in wear will occur.

The simulator inputs used in the SDS study, where the ‘patient’ takes a single step before pausing, are a worst case scenario for this type of wear simulation, however this could be representative of an elderly or very infirm patient, or one in the early stages of recovery. Testing under these conditions allows improved understanding of the function of the bearing under the extremes of in service use.

Significance: This work demonstrates the importance of continued refinement of in vitro wear simulation in the development of THA and illustrates the significantly higher wear rates which can present in all commonly used bearings under typical patient activity conditions.

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<table>
<thead>
<tr>
<th>Volumetric Wear Rate (mm3/mc)</th>
<th>Test</th>
<th>MOM (n=10)</th>
<th>MOP (n=5)</th>
<th>COP (n=5)</th>
<th>COC (n=5)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Walking</td>
<td>0.11±0.08</td>
<td>6.48±1.24</td>
<td>4.65±0.79</td>
<td>0.01±0.04</td>
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<tr>
<td>SDS</td>
<td>1.69±0.33</td>
<td>38.2±20.49</td>
<td>19.64±2.61</td>
<td>0.36±0.2</td>
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<td>P</td>
<td>0.000</td>
<td>0.001</td>
<td>0.000</td>
<td>0.002</td>
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