LOAD SCENARIOS INFLUENCE FLUID ABSORPTION OF POLYETHYLENE

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ABSTRACT
Wear of total joint replacements is determined gravimetrically in simulator studies. A mix of bovine serum, distilled water, and additives is intended to replicate the lubrication conditions in-vivo. Weight gain due to fluid absorption during testing of UHMWPE components is corrected using a load soak station. In this study six sets of UHMWPE pins were tested for their fluid soak behavior. The samples were subjected to three different loading scenarios while being submersed in two types of commonly used lubricants. After two million cycles or 23.1 days, respectively, the different fluids lead to significantly different soaking results. Test groups that were dynamically loaded gained more weight than unloaded or statically loaded samples. The results suggest that dynamically loaded soak control stations are required during wear testing of UHMWPE components. Otherwise the fluid uptake masks the wear measurement, especially for new polyethylene materials with low wear rates. Furthermore, an agreement on detailed lubricant specifications is desirable.

1. INTRODUCTION
Wear testing has become an important tool in the preclinical evaluation of new implant designs. The wear of total joint replacement devices (hip, knee, and spine) is typically determined gravimetrically using multi-degree-of-freedom simulators. Replicating the physiological environment is fundamental, and a mix of bovine serum, distilled water, and additives is intended to represent the lubrication conditions in-vivo. In the case of ultra-high molecular weight polyethylene (UHMWPE) components, fluid absorption (i.e. weight gain) can mask the weight loss due to wear. Therefore, applicable standards recommend (but do not require) a load soak sample to correct for fluid uptake. Also, the specific loading conditions for the load soak sample are not further regulated. Thus, a wide range of possible loading scenarios are applied in the testing community ranging from load-free soak over static load to an exact replication of the dynamically applied contact force. In this study, we examined the effect of the load scenario on the fluid uptake of UHMWPE samples on two commonly used testing fluids.

2. MATERIALS & METHODS
Three different load scenarios were chosen: no load, static, and dynamic load. Each of the load scenarios was tested on four pins, and two different fluids were used (Tab. 1). The two testing fluids were based on the same bovine serum. Both were diluted with reverse osmosis treated water to the same protein content (30 g/l). However, different additives were admixed to stabilize the lubricant (Tab. 2).

<table>
<thead>
<tr>
<th>Load Scenario</th>
<th>Fluid 1</th>
<th>Fluid 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>No Load</td>
<td>Group 1</td>
<td>Group 4</td>
</tr>
<tr>
<td>Static (1000N)</td>
<td>Group 2</td>
<td>Group 5</td>
</tr>
<tr>
<td>Dynamic (0…1000N)</td>
<td>Group 3</td>
<td>Group 6</td>
</tr>
</tbody>
</table>

Table 1: Test matrix, based on three loading scenarios and two fluids.

<table>
<thead>
<tr>
<th>Additive</th>
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<tbody>
<tr>
<td>Fluid 1</td>
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<tr>
<td>Fluid 2</td>
</tr>
</tbody>
</table>

Table 2: Fluid Mixtures.

Fluid 1 was prepared by mixing 59 parts of bovine serum in 41 parts of reverse osmosis treated water, 200 mg/l of Ethylene-diaminetetraacetic acid (EDTA) and 27 g/l of Tris-(hydroxymethyl)-aminomethan (Tris) were added to the mix. Fluid 2 used the same ratio of bovine serum and water, adding 9 g/l Sodium Chloride (NaCl), 15 ml/l 1-Phenoxyl-2-Propanol (Phenoxetol), and 27 g/l Tris. The Hydrochloric Acid (HCl) was used to set the pH-value of the final solution to 7.4, using about 25 ml/l HCl (5N).

All test samples were machined out of compression molded UHMWPE bar rod (GUR 1050). The raw material was gamma sterilized in nitrogen. Samples were of cylindrical shape (diameter and length: 12mm), with one flat and one concave end to fit a 28 mm ceramic ball with a clinically relevant clearance as used in total hip arthroplasty. The pins had a nominal weight of 1.2 g. Mounted into sample holders they were pressed with their conforming side against the ceramic hip balls. The samples were submersed in either testing fluid and kept at 37°C body temperature.

While the static load was applied through dead weights, the dynamic loading was applied with pneumatic actuators at 1Hz.
cycle frequency in a saw tooth pattern. Each test lasted for 2 million cycles or 23.1 days, respectively. The samples were cleaned, dried, weighed, and visually inspected every 250k cycles.

Independent samples t-tests (2-tailed) with a significance level of 0.05 were used to identify differences between specimen groups.

3. RESULTS

All samples experienced asymptotic weight gain due to fluid soak (Fig. 1). The three specimen groups submersed in Fluid 2 showed significantly more weight gain than samples exposed to Fluid 1 (p<0.001).

The dynamically loaded specimens experienced significantly higher weight gain than the unloaded and statically loaded specimens, independent of the fluid (p<0.001). In Fluid 1, the unloaded and statically loaded samples experienced an almost identical weight gain. The unloaded samples of Fluid 2 had a 1.5-fold weight increase compared with the statically loaded samples.

Visual observation revealed no surface contamination, adhering particles, or discoloration.

4. DISCUSSION

The load soak behavior of UHMWPE samples in physiological testing fluid highly depends on the applied load profile and fluid composition. Dynamic loading significantly increases the amount of absorbed fluid. The additives in testing lubricants play a major role in fluid absorption.

While standard techniques for wear tests of total joint prosthesis have been established over recent years [1], most studies looked at the effect of protein amount in the testing fluid on wear rate [2]. However, the results of this study suggest that the type and amount of additives in the fluid, as well as the loading scenario, will alter the weight change of UHMWPE specimens and thus mask the wear assessment.

Wear tests using novel polyethylene materials and the same setup as in this study have been conducted earlier [3]. Wear rates were typically in the range of 1 to 3 mg per million cycles. Thus, based on the results of this study, it is evident that the applied soak model has impact on the results. Wear tests that rely on gravimetric measurements to assess and compare the wear behavior of UHMWPE implants should therefore incorporate dynamic loaded soak control stations to minimize the error due to fluid absorption. The type of fluid, including a detailed list of additives, would need to be provided if absolute test results are compared. Ideally, the research community agrees on one single fluid recipe to eliminate the described side-effects.

ACKNOWLEDGMENTS

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REFERENCES


![Figure 1](image-url): Weight gain for samples tested in Fluid 1 (top) and Fluid 2 (bottom). Plotted are the averages of four samples within each group and the standard deviations. Loading details are listed in Tab. 1.