Patient-specific Wear Testing For TKR: The Influence Of Gait And Implant Alignment On Wear Scar Size And Location

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Introduction: The clinical lifespan of TKR devices is about 10-15 years,1 after which long term failure due to polyethylene wear occurs.2 It is the goal of the orthopaedic research community to develop new designs and materials with extended service lifetime. It is therefore necessary to evaluate implant performance in vitro, which is usually conducted using a knee simulator. This testing apparatus replicates the environment, kinematics, and loading that a prosthesis will experience in vivo. There are currently standardized input parameters used to simulate average walking (ISO 14243-1, ISO 14243-3), however, the wear scars produced by ISO standard profiles do not fully replicate the spectrum of wear scar patterns seen in vivo.3 It is unclear whether gait mechanics or component alignment cause these divergences. The aim of this study is to replicate a wear pattern observed on a particular implant in vivo using a knee wear simulator with patient specific input. It was our hypothesis that both gait style and rotational alignment of the tibial plateau will have an impact on the size and location of wear scars on the medial and lateral tibial liner articulating surfaces.

Methods: One tibial liner retrieval (MGII, Zimmer Inc.) with complete clinical information and gait data has been available. Lower limb kinematic and kinetic gait data were measured using the point cluster technique (PCT)4 with the patient walking at a self-selected “normal” speed. A four camera optoelectronic system was used to record 3D knee motions, and a force plate was used to record foot-ground reaction forces. Three walking trials were collected, and the average of these was used as simulator input. Internal contact forces and motions during stance phase were calculated using an earlier established mathematical model.5 This computational model balances external knee forces, which are the ground reaction force and limb inertial properties, and the internal knee forces, which are muscle forces, soft tissue forces, and contact (i.e. axial) forces. Kinematic simulator inputs included flexion/extension, anterior/posterior translation, and internal/external rotation. Implant alignment was also investigated as a factor contributing to wear scar area and location. A full-length a/p radiograph of the lower limb was examined in order to assess implant alignment. Using implant landmarks, the tibial tray rotational alignment was approximated.

Knee simulator tests of 1800 cycles were conducted on a displacement controlled Endolab knee simulator. Three test conditions were used: gait test with no rotational offset, gait test with 7° (internal) rotational offset, and ISO. Surfaces were marked with a black marker to visualize wear scars during short term tests. Wear scars were outlined using the optical mode of a coordinate measuring machine (CMM) (Smartscope, OGP). The wear scar was also measured on the retrieval using the CMM. Wear scar area, location, and overlap were assessed when comparing simulator tests to the retrieval outline.

Results: The simulator inputs generated from the gait data were compared with ISO 14243. The first contact force peak of the patient (1791 N) was significantly lower than ISO (2598 N), while second contact force peak was similar. There were minimal differences in the flexion/extension profiles. For
stance phase, the anterior/posterior translation and internal/external rotation kinematics did not show similar patterns, but they did fall within similar ranges from zero. There was little similarity for the swing phase.

The total wear scar area of the retrieval was measured to be 919.8 mm², and the angle between the medial and lateral wear scar centroids was 14.2°. The outcome values of the tested components compared to the retrieval are shown in Table 1. Wear scars on the retrieved component had 81% larger areas than that of the ISO simulation, 44% larger area than patient-specific gait simulation, 27% larger area than the 7° offset simulation. The wear scars on the 7° offset simulation showed most similar outcome values to the retrieval with a total area of 724.2 mm² and a centroid offset angle of 11.2°. The ISO standard simulation produced the least similar outcome values with a total area of 552.6 mm² and centroid offset angle of -1.2°. Qualitative analysis of the wear scars indicated that the 7° offset simulation and the retrieval matched very well, including a smaller scar close to the intercondylar eminence on the medial side (Figure 1b). Also, percent overlap of the retrieval was greatest for the 7° offset simulation and lowest for ISO (Figure 2).

Discussion: The approach of this study requires a unique set of information and equipment including gait data, retrieval, clinical information, radiographs, computational knee model, knee simulator, etc. Case specific analyses allow the cross-validation of pre-clinical wear testing procedures and help to understand the impact of certain parameters. Results of this study support the hypothesis that patient-specific gait and implant alignment have an impact on wear scar area and location. In this case, the patient-specific gait style simulation had a smaller effect on wear scar patterns than the patient-specific rotational offset simulation. However, outcome values were still improved for the patient-specific gait style simulation compared to ISO. Tibial tray rotational alignment had a significant impact on the location and area of the simulated wear scars. In terms of wear volume this effect may be even greater for TKRs with more conforming contact conditions than the flat MGII design. Retrieval contact areas were larger than all simulator tested components, which suggests that activities other than gait may have significant impact prosthesis damage in vivo. Limitations for this study are that only one patient has been simulated thus far, although tests for a second patient are currently being conducted. Also, no full wear test was conducted. Future work will use other patient’s information to simulate wear scars, as well as a wear test to investigate rotational alignment as a parameter.

Significance: Both gait style and rotational alignment have been rarely discussed in the context of wear of the tibial plateau and should be further investigated. Understanding the impact of these parameters will provide insight on improving current preclinical testing methods.

<table>
<thead>
<tr>
<th>Wear scar area (mm²)</th>
<th>Lateral</th>
<th>0°</th>
<th>7°</th>
<th>ISO</th>
</tr>
</thead>
<tbody>
<tr>
<td>Retrieval</td>
<td>445.2</td>
<td>323.5</td>
<td>369.3</td>
<td>279.1</td>
</tr>
<tr>
<td></td>
<td>474.7</td>
<td>313.9</td>
<td>354.9</td>
<td>228.6</td>
</tr>
<tr>
<td>Medial</td>
<td>919.8</td>
<td>637.4</td>
<td>724.2</td>
<td>507.7</td>
</tr>
<tr>
<td>Total</td>
<td>0</td>
<td>-282.4</td>
<td>-195.6</td>
<td>-412.0</td>
</tr>
<tr>
<td>Centroid offset (°)</td>
<td>14.2</td>
<td>1.3</td>
<td>11.2</td>
<td>-1.2</td>
</tr>
</tbody>
</table>

Table 1: Outcome values of retrieved and simulated (0° offset, 7° offset, and ISO) TKR liners.
Figure 1: Comparison of retrieved and simulated (a) 0° offset, (b) 7° offset, and (c) ISO components.

Figure 2: Percent overlap of simulated wear scars on retrieved wear scars (all scales in mm²)

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