Comparison of High-Flexion and Posterior Stabilized Tibial Inserts for Tibial Post and Articular Surface Damage: A Retrieval Study

S Schmitz CM, 2Klunklin K, 3Roy ME, 4Whiteside LA

1Biomedical Engineering, Texas A&M University, College Station, TX; 2Missouri Bone Joint Research Foundation, St. Louis, MO; 3Department of Orthopaedic Surgery, Chiang Mai University, Thailand; 4Signal Medical Corp., St. Louis, MO

Introduction: High flexion (HF) tibial inserts were designed to improve the outcome of TKA by allowing for a greater flexion arc. These components offer higher constraint of femoral component position on the tibial surface. The resulting differences in femoral and tibial component contact stresses may lead to increased wear for HF inserts relative to posterior stabilized (PS) inserts [9]. The purpose of this study was to determine whether HF inserts accumulate more (1) articular surface damage and (2) tibial post damage in vivo than PS inserts manufactured by the same company.

Materials and Methods: This IRB-approved study utilized all available retrieved Biomet HF (n = 8) and PS (n = 16) inserts implanted for at least 3 months (Table 1). HF insert styles included Maxim (1), Maxim Constrained (4), and Ascent (3), while PS insert styles included Vanguard (14) and PS Constrained (2). All but four were made by direct compression molding (DCM), which leaves no machining marks on the articular surfaces [6]. All inserts were sterilized by gamma irradiation in argon in a 2nd generation barrier film [2].

All inserts were examined under a dissection microscope for both articular surface and post damage, while backlash damage was evaluated as part of a different study [5]. Damage on each specimen was scored with a modified version of the scoring system used previously [4] that properly weighed the more severe damage patterns observed during evaluation. After sorting by design (PS vs. HF), inserts were compared by a two-sided heteroscedastic t-test for total articular surface and tibial post damage scores.

No differences in total tibial post damage were observed, with averages of 52.7% and 39.7% for HF and PS inserts respectively (p = 0.13); however, on average HF inserts were in vivo 2.2 times longer than PS inserts (p = 0.038). Articular surface damage increased with time in vivo among PS inserts (p = 0.0036), but no correlation was found for HF inserts (p = 0.16, Table 2A). Plots of articular damage vs. time in vivo for each insert type revealed no significant difference in damage rate (p = 0.62; Figure 1A).

No differences in total tibial post damage were observed, with averages of 43.5% and 35.0% for HF and PS inserts respectively (p = 0.34). Tibial post damage of HF inserts increased with time in vivo (p = 0.034), while post damage of PS inserts showed no correlation (p = 0.43; Table 2B). Plots of tibial post damage vs. time in vivo for each insert type revealed no significant difference in damage rate (p = 0.10); however, the damage accumulation rate of the HF inserts was 4.3 times higher than that of the PS inserts (Figure 1B).

Finally, a strong correlation was observed between total articular surface and tibial post damage at a rate that was 4.3 times higher than PS inserts made by the same manufacturer. A strong correlation between articular surface and tibial post damage for each insert was also observed. Thus, the potential for increased wear should be considered along with the potential for a greater flexion arc when choosing between HF and PS designs for clinical use.

Table 1. Summary of the tibial inserts analyzed in this study.

<table>
<thead>
<tr>
<th>Design Type (n)</th>
<th>DCM / Non-DCM</th>
<th>Time in vivo (years)</th>
</tr>
</thead>
<tbody>
<tr>
<td>HF (n = 8)</td>
<td>4/4</td>
<td>5.73</td>
</tr>
<tr>
<td>PS (n = 16)</td>
<td>16/0</td>
<td>2.62</td>
</tr>
</tbody>
</table>

Table 2. Summary of the linear regression data for A. articular surface damage and B. tibial post damage.

<table>
<thead>
<tr>
<th>A. Articular surface damage rate (max. damage score/yr)</th>
<th>B. Tibial post damage rate (max. damage score/yr)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Slope</td>
<td>p-value</td>
</tr>
<tr>
<td>-------</td>
<td>---------</td>
</tr>
<tr>
<td>3.43</td>
<td>0.16</td>
</tr>
<tr>
<td>2.43</td>
<td>0.0036</td>
</tr>
</tbody>
</table>

Figure 1. A. Articular surface damage and B. tibial post damage plotted vs. time in vivo for HF (dashed blue line) and PS (solid red line) inserts.

References:


Handout for Poster no. 1828 • 60th Annual Meeting of the Orthopaedic Research Society, March 15-18, 2014 • New Orleans, LA
**Comparison of High-Flexion and Posterior Stabilized Tibial Inserts for Tibial Post and Articular Surface Damage: A Retrieval Study**

Schmidt CM¹,³, Klunklin K²,³, Roy ME³, Whiteside LA³,⁴

¹Texas A&M University, College Station, TX; ²Department of Orthopaedic Surgery, Chiang Mai University, Thailand; ³Missouri Bone and Joint Research Foundation, St. Louis, MO; ⁴Signal Medical Corp., St. Louis, MO

**Introduction**

- High flexion (HF) tibial inserts were designed for a greater flexion arc, and they also created higher constraint of femoral component position on the tibial surface.
- The resulting differences in femoral and tibial component contact stresses may lead to increased wear for HF inserts relative to posterior stabilized (PS) inserts.
- The purpose of this study was to determine whether HF inserts accumulate more (1) articular surface damage and (2) tibial post damage in vivo than PS inserts manufactured by the same company.

**Materials and Methods**

- Inserts were examined under a dissection microscope by 3 observers for articular surface and post damage, and scored with a modified system based on Greulich et al. (2012).
- After sorting by design (PS vs. HF), damage scores were:
  - compared by a two-sided heteroscedastic t-test; and
  - correlated to time in vivo by linear regression, with the slope representing the rate of damage accumulation.
- Articular surface damage score was compared to tibial post damage score using a two-sided matched pair t-test.
- All statistical evaluations used p < 0.05 for significance.

**Results**

- A previous study that evaluated articular surface damage of HF and PS Genesis II inserts showed similar results.
- The similarities in articular damage of two inserts with similar articular conformity should be expected.
- The tibial post damage accumulation rate of HF inserts was 4.3 times higher than PS inserts (p = 0.10); however, the PS regression line showed no correlation to time in vivo.
- A previous study comparing Genesis II HF and PS inserts reported tibial post damage to be significantly higher among HF inserts.
- The average damage score was higher for HF inserts on all faces except the superior (p > 0.16).
- A significant correlation was observed between articular surface and post damage, agreeing with previous studies.

**Discussion**

- No difference in total articular surface damage and damage accumulation rates was observed among HF and PS inserts.
- A significant correlation was observed between articular surface and tibial post damage for each insert.
- A strong correlation between articular surface and tibial post damage for each insert was also observed.
- When choosing between HF and PS designs for clinical use, the potential for increased wear should be considered along with the potential for a greater flexion arc.

**Limitations:**

- Our sample size is small.
- Manufacturing method, such as Direct Compression Molding (DCM) vs non DCM, was not considered.
- The angle of flexion achieved after the original surgery and patient activity level could not be measured.

**Conclusions**

- HF inserts accumulated tibial post damage at a rate that was 4.3 times higher than PS inserts made by the same manufacturer.
- A strong correlation between articular surface and tibial post damage for each insert was also observed.
- When choosing between HF and PS designs for clinical use, the potential for increased wear should be considered along with the potential for a greater flexion arc.

**Table 1. Summary of the tibial inserts analyzed in this study.**

<table>
<thead>
<tr>
<th>Design Type (n)</th>
<th>DCM/Non-DCM</th>
<th>Time in vivo (years)</th>
</tr>
</thead>
<tbody>
<tr>
<td>HF (n = 8)</td>
<td>4/4</td>
<td>5.73 (1.10 - 9.74)</td>
</tr>
<tr>
<td>PS (n = 16)</td>
<td>16/0</td>
<td>2.96 (0.54 - 6.49)</td>
</tr>
</tbody>
</table>

- All Biomet HF and PS inserts >3 months in vivo included:
  - HF inserts: 1 Maxim, 4 Maxim Constrained, 3 Ascent
  - PS inserts: 14 Vanguard and 2 PS Constrained
- All inserts were γ-irradiated in Ar in a 2nd generation film.

**Table 2. Summary of the linear regression data for A. articular surface damage and B. tibial post damage.**

<table>
<thead>
<tr>
<th>Design Type</th>
<th>A. Articular surface damage</th>
<th>B. Tibial post damage</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Rate</td>
<td>p-value</td>
</tr>
<tr>
<td>HF</td>
<td>3.43</td>
<td>0.16</td>
</tr>
<tr>
<td>PS</td>
<td>2.43</td>
<td>0.0036</td>
</tr>
</tbody>
</table>

- Articular surface damage:
  - No difference in average score (52.7% for HF, 39.7% for PS; p = 0.13); however, HF inserts were in vivo 2.2 times longer on average (p = 0.038).
  - Increased with time in vivo for PS inserts, but no correlation was found for HF inserts.
  - Plots of articular damage vs. time in vivo for each insert type revealed no significant difference in the rate of damage accumulation (p = 0.62).

- Tibial post damage:
  - No difference in average score (43.5% for HF, 35.0% for PS; p = 0.34).
  - Increased with time in vivo for HF inserts, while PS inserts showed no correlation.
  - The rate of damage accumulation was 4.3 times higher for HF inserts (p = 0.10).
  - Articular surface and tibial post damage were strongly correlated (p = 0.0062), but the correlation was weaker when sorted by type (p = 0.06 for HF and PS inserts).