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## Lock and PS-Post Fatigue Strengths of Highly Crosslinked Polyethylene Tibial Inserts

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### Summary

A posterior-stabilized (PS) tibial insert must be able to resist the combined compressive and anteroposterior (A/P) shear loading that is predicted to occur in vivo without either disassociation of the tibial insert from the tibial tray or failure of the PS post. The purpose of this study was to evaluate both the lock strength and the PS-post fatigue strength of virgin and highly crosslinked tibial inserts from the posterior-stabilized,

high-flexion (PSHF) knee system in a functional, device-level test. The failure mechanisms were identified and compared between the materials. This data was compared to the test results generated using the clinically successful GENESIS<sup>®</sup> knee system, which has not had any known reports of either lock failure or PS-post fatigue failure using currently employed EtO sterilization practices.

### Materials and Methods

The LEGION<sup>®</sup>/GENESIS II PSHF knee system was evaluated in this study. Tibial inserts (Size 1-2, 25 mm) were manufactured from compression-molded GUR1020 UHMWPE that was in either the unirradiated (virgin) or highly crosslinked, re-melted (7.5-XLPE) conditions. This size and thickness were selected for evaluation as they would put the greatest stresses on the post and locking detail and provide the most aggressive evaluation of the parameters tested (i.e., the worst-case scenario). There was no difference in the designs of tibial inserts between the virgin and 7.5-XLPE materials.

Tibial trays were cemented into a mounting fixture and each tibial insert was placed into the tibial tray as described in the standard surgical technique for the device. The mounting fixture was secured to an angled plate to achieve 30° of simulated flexion. The femoral component was mounted to the cross-head of the load frame on a linear translation fixture that allowed movement in the A/P direction (Figure 1). At 30° of flexion, the cam of the femoral component contacts the PS post of the

tibial insert at the most superior point. Consequently, this test configuration maximizes the moment arm in a severe loading condition that would be most likely to cause disengagement of the insert from the tray and/or deformation of the tibial post.

First, lock-strength testing was conducted by increasing the load at a given rate to determine the maximum load required to either deform the PS post or disengage the tibial insert from the tibial tray.

Next, fatigue testing was conducted on a servo-hydraulic load frame under load-control. A cyclic fatigue load was applied through the femoral component and translated to the tibial insert at 10 Hz for 10 million cycles (Mc) or until the tibial insert disengaged from the tibial tray or until the PS post deformed/failed such that it no longer sustained load. The fatigue-endurance limit, or fatigue strength, was defined as the load at which at least three components survived for 10 Mc without any failures.

Finally, lock-strength testing was conducted again after fatigue testing with the inserts that ran-out to 10 Mc in the fatigue test to determine if either the lock strength or the ultimate failure mode were altered by the fatigue testing. To assess the clinical relevance of the resultant data, these results were compared to the test results for the clinically successful GENESIS<sup>®</sup> design with virgin UHMWPE, which has not had any known reports of either lock failure or PS-post fatigue failure using currently employed EtO sterilization practices.

## Results

Lock-strength testing of virgin UHMWPE and 7.5-XLPE in the LEGION<sup>®</sup> PSHF design showed both materials result in similar lock strengths before fatigue testing (Figure 2). In addition, these lock strengths are at least 66% greater than that found for the clinically successful, virgin GENESIS PS components evaluated by the same method.

In the fatigue tests, three virgin, LEGION PSHF inserts completed 10 million cycles without failure at a maximum load that was 78% higher than the fatigue strength of the GENESIS PS design (Figure 3). Subsequently, five 7.5-XLPE components were tested at the same maximum load, and all of them completed 10 million cycles without failure. As a result, it was concluded that the fatigue strength of the 7.5-XLPE inserts was at least as high as, if not greater than, that of the virgin LEGION PSHF inserts (Figure 3). Brittle fracture of the

PS posts as reported in the literature for other polyethylene formulations and knee designs was not observed in this study [1].

Finally, lock-strength testing of virgin UHMWPE and 7.5-XLPE in the LEGION PSHF design as conducted again after fatigue testing. Both materials exhibited small increases in the lock strengths compared to those found before fatigue testing (Figure 2). Thus, it can be concluded that fatigue testing for 10 Mc had no detrimental effect on the lock strengths of these inserts. Again, these lock strengths were higher than the lock strength for virgin GENESIS PS components after fatigue testing.

## Discussion

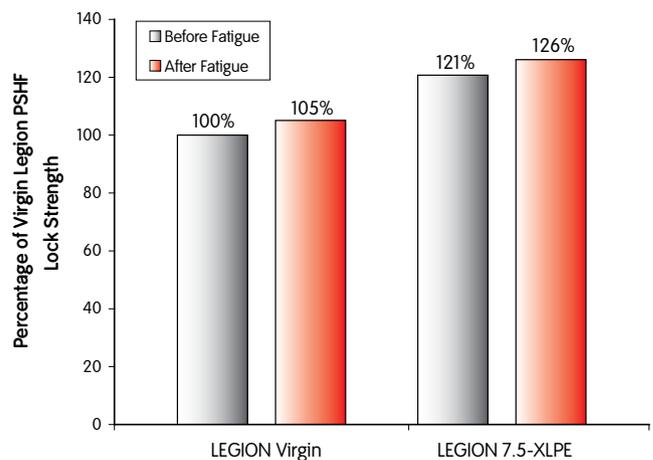
This device-level testing demonstrated that there was no degradation in the lock strength or PS-post fatigue performance of highly crosslinked tibial inserts compared to virgin UHMWPE in the LEGION PSHF design. Brittle fracture of the PS posts as reported in the literature for other polyethylene formulations and knee designs was not observed in this study with either material. For clinical relevance, these results were compared to those from earlier in-vitro testing of the clinically successful GENESIS design. In all cases, the performance of the LEGION inserts was superior to that of the GENESIS inserts.

Figure 1: Photograph of the set-up



Photograph of the set-up for lock-strength and fatigue tests of posterior-stabilized (PS) tibial inserts.

Figure 2: Bar plot of the lock strengths



Bar plot of the lock strengths of virgin and 7.5-XLPE LEGION PSHF tibial inserts before and after fatigue testing expressed as a percentage of the virgin lock strength before fatigue testing.

In the LEGION PS knee system, the cam is designed to contact the post at flexion angles greater than 57°. Walking is the most common activity performed by TKA patients during which the knee is rarely flexed beyond 60° [2]. The other common daily activities performed by TKA patients include stair climbing/descending, sitting/chair rise, moving from standing to reclining, moving from lying to standing, single limb stance with the other knee flexed, and running [3]. During these activities knees flex greater than 90°[3], and the femoral cam is expected to be in contact with the post.

In a study of TKA patients, Huddleston et al. reported that the patients performed walking activity for 80% of the total data collection time, and had an estimated 1.2 million total cycles per year [3]. Additionally, the knees flexed over 90° an average of 5% of the total data collection time [3]. Based on this relationship between walking data collection time and a slightly higher 1.5 million cycles per year, TKA patients would exceed 90° of flexion an estimated 75,000 cycles per year, or an estimated 2.25 million cycles over a period of 30 years. Therefore, the post-fatigue testing conducted in this study for 10 million cycles is well above the number of cycles estimated to be experienced in vivo and would represent a worst-case scenario.

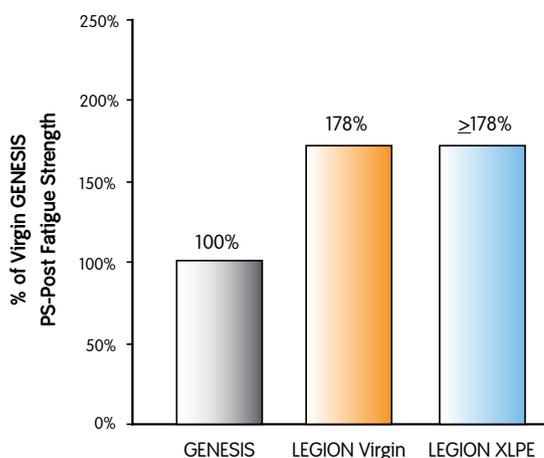
## Conclusion

In-vitro lock-strength and PS-post fatigue testing has demonstrated that the use of highly crosslinked tibial inserts in the LEGION® PSHF system does not result in decreases in the lock or PS-post fatigue strengths. In addition, fatigue testing for 10 million cycles did not result in any decreases in the lock. Comparison of this data to that of virgin GENESIS® PS inserts shows that both virgin and highly crosslinked materials provide greater lock and PS-post fatigue strengths in the LEGION PSHF design. More importantly, clinical failures of the GENESIS PS locks and PS posts have not been observed outside of oxidized, gamma-air-sterilized components. Thus, the strength improvements shown by LEGION PSHF inserts made from either virgin or highly crosslinked materials relative to the GENESIS design suggest that either material should be able to withstand the increasing demands being placed upon the inserts by younger, more active patients.

## References

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2. CM Myles et al., "Knee joint functional range of movement prior to and following total knee arthroplasty measured using flexible goniometry," Gait and Posture, 2002, 16:46-54.
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Figure 3: Bar plot of the PS-post fatigue



Bar plot of the PS-post fatigue strengths of unirradiated (virgin CPE) and highly crosslinked, re-melted (7.5-XLPE) UHMWPE in the same LEGION design relative to the results from the clinically successful GENESIS PS design.

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