Dynamic Fatigue Testing of Cement Mantle Integrity Around a Tibial Tray

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INTRODUCTION
Clinical studies have shown that cementation of keel tibial trays enhance the mechanical stability and prevent aseptic loosening [1]. Therefore, it is important the cement mantle associated with a tibial tray maintains its integrity throughout the lifetime of the tibial implant. A tibial tray with a design used in minimally invasive surgery with a shorter keel was selected.

The purpose of this test was to provide consistent and reproducible information about the structural integrity of the cement mantle around the tibial baseplate keel.

METHODS

Specimen Preparation
Three Triathlon® MIS Tibial Trays (Stryker Orthopaedics®, NJ), size 1, were cemented (Simplex®, Stryker Orthopaedics®, NJ) into aluminum blocks to mimic the in vivo tray/bone cement interface. To simulate a worst-case scenario, size 1 trays were chosen because their narrow keel has the potential to produce the most severe induced stresses on the bone cement. The aluminum blocks were machined with the appropriate bone cuts to replicate the cavity that the tibial keel punch would create in the bone. The bone cement was prepared by hand mixing. It was then applied to the keel cavity and superior surface of the holding block. The tray was then mounted to the block using thumb pressure and the excess cement was removed. The cement was allowed to fully cure for 24 hours. Three Triathlon® PS Tibial Insert (Stryker Orthopaedics®, NJ), size 1, 19mm were then inserted into the tray. To further support a worst-case testing scenario, a 19mm tibial insert was chosen because it is the thickest insert and therefore generates the greatest amount of moment at the tray/cement interface.

Testing Procedure
Fatigue testing was performed on the tibial products to test the structural integrity of the mantle around the keel. Physiological loading was used which simulated stair ascent/descent activity. The assembled tibial component was rigidly mounted at a 0º flexion angle to an MTS Bionix system (MTS Corp., MN). A corresponding femoral component was oriented at a 60º flexion angle to simulate stair ascent/descent. Testing was performed to evaluate the structural integrity of the cement mantle around the tibial tray keel. In all cases, the trays remained rigidly fixed to the blocks, and the cement mantles showed no sign of degradation. After testing was completed. It is believed that fracture of the cement mantle in samples 2 and 3 occurred during separation of the implants from the anterior portion of the holding blocks when force was applied for removal. Signs of cement mantle degradation were not found on any surfaces of the cement mantle, displaying that the testing forces incurred by the implant were not over the fatigue limits of the cement mantle.

RESULTS
All components completed 1x10⁶ cycles of loading. All tibial trays remained rigidly affixed to the aluminum blocks. The aluminum blocks were then disassembled and to visually examine the cement mantle around the keel and inferior surface of the plate. Upon inspection it was found that sample 1 (Figure 3) showed no signs of cement mantle degradation while samples 2 and 3 were removed from the holding blocks with complications. A considerable amount of force was used to cantilever the implants out of the fixture. While being removed, small fragments of bone cement adhered to the anterior rib section of the holding block and made it difficult to remove the tray from the anterior portion of the block.

DISCUSSION
No motion of the implant could be detected either during testing or after testing was completed. It is believed that fracture of the cement mantle in samples 2 and 3 occurred during separation of the implants from the anterior portion of the holding blocks when force was applied for removal. Signs of cement mantle degradation were not found on any surfaces of the cement mantle, displaying that the testing forces incurred by the implant were not over the fatigue limits of the cement mantle.

Multi-axis dynamic fatigue testing of the Triathlon® MIS Tibial Tray was performed to evaluate the structural integrity of the cement mantle around the tibial tray keel. In all cases, the trays remained rigidly fixed to the blocks, and the cement mantles showed no sign of degradation. These results support the potential success of these tibial trays in a clinical setting with a tibial tray typically used for minimally invasive surgery.

SIGNIFICANCE
The abstract highlights bench-top testing for a tibia product and verification in a clinical setting will need to be determined.

REFERENCES