The Effect of Varus-Valgus Rotation on Polyethylene Fatigue in Mobile Bearing Total Ankle Replacements

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INTRODUCTION:

Total ankle replacement (TAR) has become an effective means of treating end-stage ankle osteoarthritis. Studies demonstrate that multiple factors affect the survivorship of a TAR, including patient factors, surgical technique, coronal plane alignment, and bearing surfaces. Optimizing polyethylene fatigue is also essential to improve the outcomes of TARs. This study had two aims: first, to establish a loading protocol to reliably replicate polyethylene fatigue fracture in vitro, and second, to assess the impact of oxidation and antioxidant stabilization on polyethylene fatigue in a mobile bearing TAR device. We hypothesize that varus-valgus rotation and oxidation will decrease polyethylene fatigue life, and antioxidant stabilization will increase fatigue life.

METHODS:

Ultra-high-molecular-weight polyethylene (UHMWPE) 25kGy GUR 1020 inserts as well as UHMWPE inserts made from 75kGy GUR 1020-E (vitamin-E polyethylene) underwent accelerated aging for 4 weeks per ASTM F2003. The oxidation index (OI) was determined by Fourier-transform infrared spectroscopy (FTIR) analysis. Inserts were then evaluated using a six degree-of-freedom servohydraulic wear tester to impart varied amounts of flexion-extension, axial rotation, varus-valgus rotation, and axial loading. Two loading methods were used: 1) fixed flexion and fixed varus-valgus angles with cyclic axial loading and 2) -4/+8° flexion-extension, ±5° axial rotation, 1500-3000N axial loading, with ±3° of varus-valgus rotation. Samples were run to either fracture or runout (>1 million cycles). Conventional non-aged UHMWPE samples subjected to the second testing protocol served as a control. Fractured polyethylene inserts were then studied with fractography.

RESULTS:

Conventional 4-week aged UHMWPE demonstrated plastic deformation and no fatigue failure after 1 million cycles using the first testing protocol (OI=2.59±1.11). Conventional non-oxidized UHMWPE demonstrated no fatigue failure after 3 million cycles using the second testing protocol (OI=0.14±0.04). Conventional 4-week aged UHMWPE demonstrated fatigue fracture in <1 million cycles using the second testing protocol that included varus-valgus rotation (OI=2.59±1.11) ($p<0.001$). Vitamin-E 4-week aged UHMWPE demonstrated no fatigue failure after 3 million cycles using the first and second testing protocol that included varus-valgus rotation (OI=0.23±0.02) (Figure 1). Fractography performed on the broken inserts suggests that fractures initiate primarily at the trough, then propagate due to cyclic loading (Figure 2).

DISCUSSION AND CONCLUSION:

Polyethylene fatigue and fracture is a subject of research for all total joint replacements. It is a known fact that oxidation of polyethylene leads to decreased fatigue life. Packaging and handling of the polyethylene is of utmost importance to prevent oxidation. Other advancements, such as antioxidant stabilization, are being used in efforts to increase polyethylene fatigue life. In this study, fracture of the polyethylene inserts only occurred in conventional oxidized UHMWPE with +/-3° of varus-valgus rotation during loading. Fractography of the fractured oxidized polyethylene inserts showed a fracture pattern similar to fractured inserts retrieved from surgical cases. The OI also fell within the range of OI from retrievals (1≤OI≤3). This supports the literature that coronal plane rotation as well as oxidation lead to increased risk of polyethylene fracture. Interestingly, no fractures were produced in the 75kGy GUR 1020-E. Vitamin-E polyethylene hip and knee prostheses have demonstrated promising clinical performance. More research is necessary to see if this will translate to TAR, but it is encouraging that under in vitro conditions, the material is resistant to oxidization and stress. Furthermore, this study establishes a reliable protocol for future adverse testing of polyethylene components.

There are limitations to this study. Despite the cycles to failure produced, it is unknown how many significant varus-valgus cycles a device may experience under normal activities of daily living, and given the severe loading regime applied in the second testing protocol, how similar this setup would be to the clinical experience of patients. Also, varus-valgus rotation does not necessarily replicate varus-valgus alignment of a device. In conclusion, the testing methods proposed here show that observed fractures can be reproduced in the preclinical setting due to combined varus-valgus rotation and oxidation. These methods can be used to assess the safety of alternate materials with antioxidant properties.

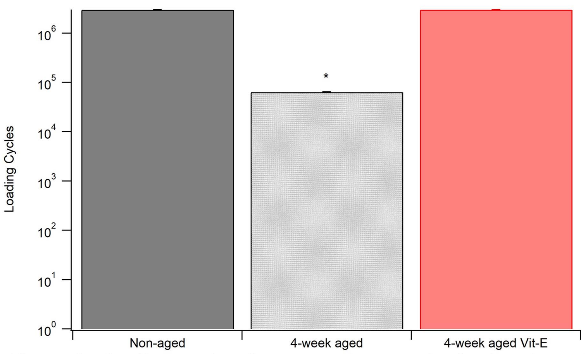

Figure 1. Loading cycles for non-aged conventional, 4-week aged conventional, and 4-week aged Vitamin-E UHMWPE from second testing protocol. ($p<0.001$, *)

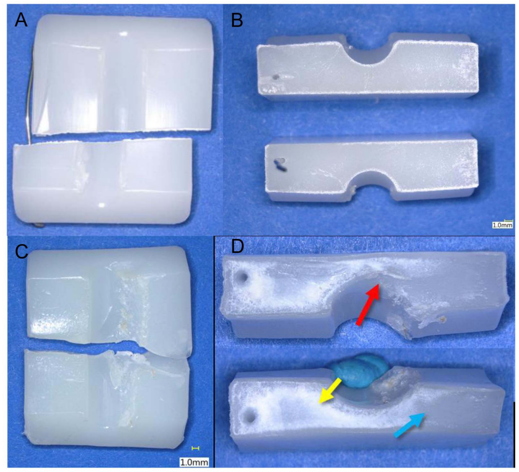

Figure 2. (A, B) Conventional aged UHMWPE insert fracture from current second testing protocol. (C, D) Conventional UHMWPE insert retrieved from surgical case.