

30 year wear performance of LEGION[◇] Primary knees with VERILAST[◇] Technology

Introduction

Partly due to recent evolutions in implant design, material improvements and changes in surgical technique, one of the often discussed topics in the field of total joint arthroplasty is the changing patient demographics. The continuing trend is towards younger, more active patients receiving total joint replacement than occurred even five years ago. The potential downside to these increased patient demands is the need for joints to have increased levels of wear performance so as to avoid the need for revision as a result of the many failure modes commonly attributed to polyethylene wear.

To address this need, Smith & Nephew has developed VERILAST Technology, which is comprised of two proprietary, advanced bearing technologies specifically engineered for total knee arthroplasty (TKA). Through extensive material and device-level testing, Smith & Nephew has developed a highly cross-linked UHMWPE (XLPE) for TKA and combines it with OXINIUM[◇] alloy to produce a bearing couple that has shown to exhibit low wear characteristics.

The purpose of this paper is to discuss the testing that was done to support the belief that VERILAST Technology used in the LEGION Primary knees will provide wear performance sufficient for 30 years of use under typical conditions in vivo.

Test rationale

Based on the literature reviews, a person receiving a total joint arthroplasty at a relatively young age of 45 years would undergo approximately 36 to 44 million cycles of loading on each knee over a period of 30 years (by the age of 75 years).¹⁻⁷ Hence, a wear test of at least 45 million cycles was considered as a high, but reasonable estimate for the amount of cycles that would occur during 30 years of typical in-vivo use. Consequently, components that demonstrate low wear throughout such a simulation should be sufficient for 30 years of implantation.

Materials and methods

LEGION CR (cruciate retaining) OXINIUM femoral components, LEGION CR XLPE tibial inserts and Ti-6Al-4V tibial trays were used during testing. Three component assemblies were tested on a knee simulator (AMTI, Watertown, MA) under displacement control for 45 million cycles. The test lubricant was Hyclone alpha calf fraction with sodium azide and EDTA added. Serum was diluted to 50% with filtered, deionized water to obtain an average protein concentration of 20 g/l. The following load/motion profiles were used at 1 Hz frequency during testing: axial load of 168N to 2600N, flexion of 0° to 58°, tibial rotation of 4.9° internal to 5.0° external and tibial translation of 8mm anterior to 0.8mm posterior.

Each of the inserts was weighed at regular intervals to determine mass changes, and soak controls were used to correct for fluid absorption. Roughness of the OXINIUM femoral components was measured, before and at interim cycle counts of wear testing, using a contact profilometer (Surfcom 1800D, Carl Zeiss, Brighton, MI). Roughness measurements were made in medial-lateral direction at pre-selected locations from 0 to 60° of flexion on each condyle of each femoral component.

Oxide thickness of the OXINIUM femoral components was measured at various intervals of wear testing using Fourier Transformed Infrared (FTIR) spectrometer (Nicolet Instrument Corp, Madison, WI) with an attached specular reflectance fiber optic probe. Measurements were made at pre-selected locations in the articulating areas from 0 to 60° of flexion on each condyle of each femoral component.

Results and discussion

All tibial inserts exhibited normal burnishing patterns consistent with adhesive and abrasive wear typically seen with clinical retrievals (Figure 1). Abnormal features such as cracking or other evidence of fatigue wear was not observed in any of the inserts.



Figure 1: Wear patterns of XLPE tibial inserts after simulating 30 years of use.

The mean volumetric wear rate (\pm standard deviation) of the XLPE inserts articulating against OXINIUM femoral components was 0.58 ± 0.17 mm³/Mcycle (Figure 2).

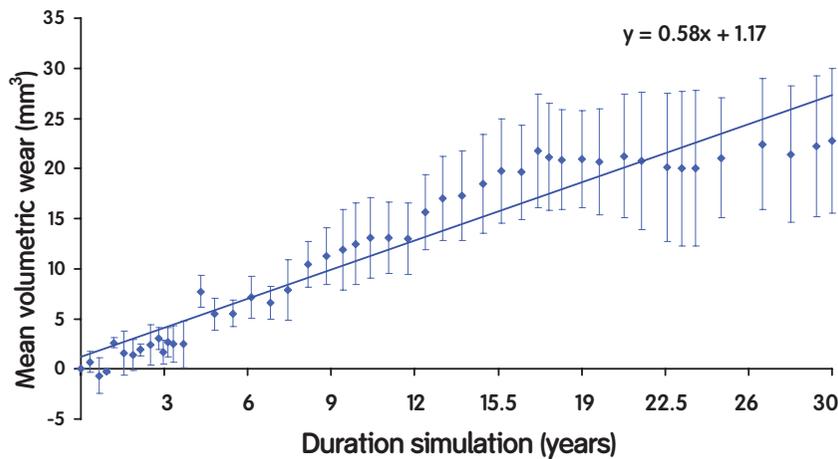


Figure 2: The mean volumetric wear of the XLPE inserts during wear testing.

In a previous wear test under substantially equivalent conditions for 5 million cycles simulating 3 years of use, the mean volumetric wear rate of 3 cobalt chrome and conventional UHMWPE (CPE) couples was 23.45 ± 2.36 mm³/Mcycle⁸. The mean volumetric wear rate of the VERILAST[®] couples was approximately 98% lower than that of the CoCr/CPE couples ($p < 0.01$).

After simulating 3 years of use, the mean volumetric wear of VERILAST couples (2.67 mm³) was approximately 98% lower than CoCr/CPE couples (120.42 mm³) (Figure 3a).

Moreover, after simulating 30 years of use, the mean volumetric wear of VERILAST couples (22.78 mm³) was approximately 81% lower than the CoCr/CPE couples after simulating 3 years of use (120.42 mm³) (Figure 3b).

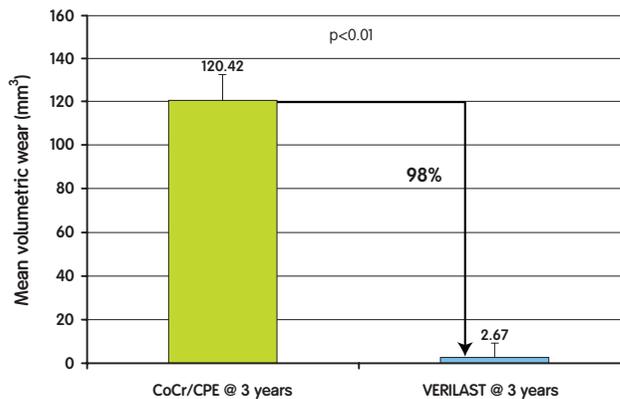


Figure 3a: Comparison of the mean volumetric wear of the CoCr/CPE and VERILAST couples after simulating 3 years of use.

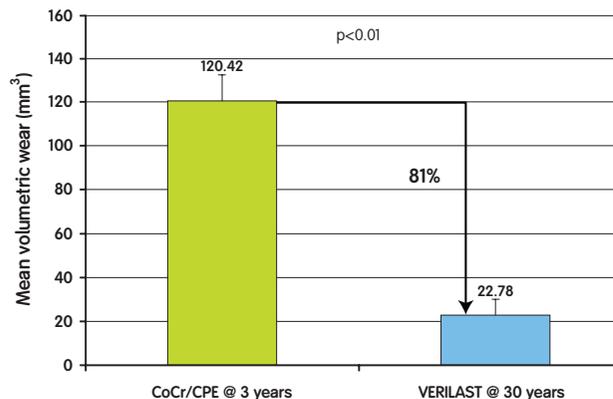


Figure 3b: Comparison of the mean volumetric wear of the CoCr/CPE after simulating 3 years of use and VERILAST after simulating 30 years of use.

An additional goal of this test was to validate that no changes to the ceramic oxide surface of the OXINIUM femoral components occurred during testing. After simulating 30 years of use, the femoral components exhibited virtually indiscernible wear.

No scratches were observed in the articulating areas, wear testing did not significantly change the roughness of the femoral components ($p>0.05$) and the femoral components showed no measurable loss of oxide surface within the measurement accuracy of $0.2 \mu\text{m}$ (Figure 4).

As demonstrated by the results of the extensive wear testing conducted, a LEGION[®] Primary knee with VERILAST[®] Technology is expected to provide wear performance sufficient for 30 years of actual use under typical conditions.

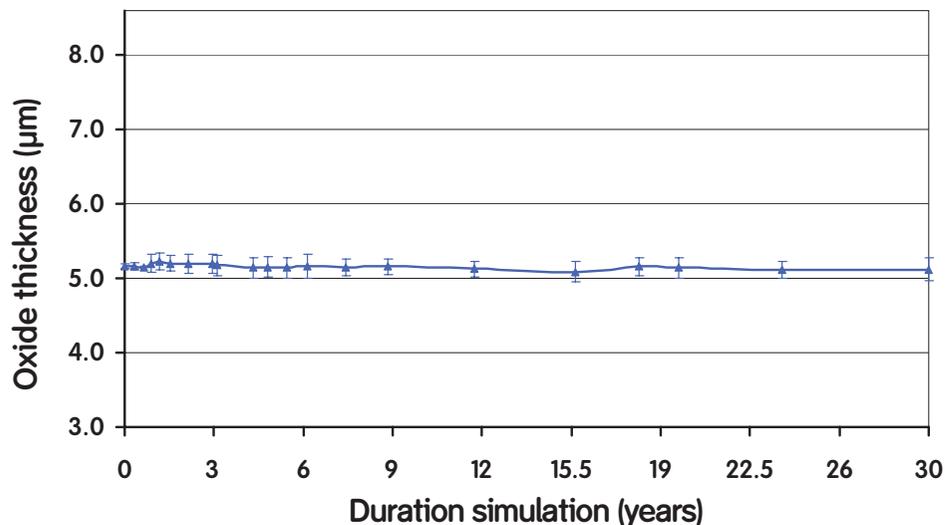


Figure 4: Mean oxide thickness of the OXINIUM[®] femoral components during wear testing.

References

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Laboratory wear testing on file at Smith & Nephew. The results of in-vitro wear simulation testing have not been proven to quantitatively predict clinical wear performance. Also, a reduction in total polyethylene wear volume or wear rate alone may not result in an improved clinical outcome as wear particle size and morphology are also critical factors in the evaluation of the potential for wear mediated osteolysis and associated aseptic implant loosening. Particle size and morphology were not evaluated as part of the testing.

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