SIMULATOR-TESTING AND ACCELERATED AGING OF A HIGHLY CROSS-LINKED ACETABULAR LINER AFTER EIGHT YEARS IN VIVO

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Introduction
The first generation irradiated and melted highly cross-linked UHMWPE (HXLPE) acetabular components have been in clinical use for approximately eleven years. HXLPE was developed to improve wear resistance, in comparison to conventional UHMPE, and reduce particulate debris that could lead to osteolytic reactions.

Clinical midterm follow-up studies are showing substantially reduced wear rates with the highly cross-linked UHMWPE [1], which is in accordance with the predictive in vitro studies that subjected the liners to 27 million cycles on a hip simulator [2]. Additionally, retrieval studies have shown oxidative stability and wear resistance in HXLPE with in vivo durations of up to seven years [3]. Clinical studies and retrieval studies are highly time dependent. It is unknown whether or not long-term in vivo conditions, unable to be replicated pre-clinically, could adversely affect the oxidative stability and mechanical properties of the material.

To answer this question, we proposed subjecting a retrieved highly cross-linked and melted acetabular liner with long-term in vivo duration (92 months) to simulated normal gait for wear testing and subsequently to aging in an effort to predict its longevity beyond the initial implantation period. We investigated any changes to material properties of the retrieval, along with two fresh highly cross-linked and melted liners, after 5 million cycles on a hip simulator, and then again after accelerated aging.

Materials and Methods

Clinical Background: The highly cross-linked acetabular liner (32mm ID Durasul™, Warsaw, IN) was implanted on 10/30/2000 in the right hip as part of bilateral hip replacements in a 76-year-old male patient. After 92 months, the patient complained of stiffness and underwent repeat dislocations. On 6/20/2008, the acetabular liner was retrieved in a revision surgery along with the femoral head. Intraoperatively, the acetabular and femoral components showed no signs of damage or fracture due to the dislocations, however there was moderate heterotopic ossification. CT examination showed a large effusion with large fluid accumulation and a large acetabular cup deformity. CT examination showed a large effusion with large fluid accumulation. Intraoperatively, the acetabular and femoral heads, using a standard walking gait cycle with the peak load of 3000 N and performed at a rate of 2Hz. The lubricant used was 100% bovine serum, stabilized with 10.7 millimoles of ethylenediamine tetraacetate (EDTA, Fisher Scientific, Pittsburgh, PA) and 33 ml of penicillin-streptomycin solution (Sigma-Aldrich, St. Louis, MO) per 500 ml of serum. The simulator was interrupted in 0.5 million cycle (MC) intervals over 5 MC for gravimetric assessment of wear. After simulator testing, sections from the rim and acetabular surface of each liner were accelerated aged at 70°C for 2 weeks in a pressurized bomb at 5 atm under O2.

Analysis: A section of each liner near the rim was removed and microtomed (LKG Sledge, Sweden) into 150 µm thin films. The thin films were then placed in boiling hexanes for 16 hours to extract absorbed esterified fatty acids [4]. These thin films (n=3 from each component) were analyzed using Fourier Transform Infrared Spectroscopy (Bio-Rad FTS155/UMA500, Natick MA) as a function of depth from a non-articulating surface into the component. Oxidation index values were calculated by normalizing the carbonyl absorbance over 1680 cm⁻¹ - 1780 cm⁻¹ to the absorbance over 1330 cm⁻¹ - 1390 cm⁻¹, per ASTM F2102-01. The maximum oxidation indices from the thin films were averaged to determine an average maximum oxidation level for each component. Cross-link density was calculated as described previously [5] through gravimetric swelling analysis using xylene at 130°C for 2 hours. Crystallinity measurements were performed (Q1000 DSC, TA Instruments, Delaware, NJ) at 10°C/min. The crystallinity was calculated as the enthalpy between 20 and 160°C normalized with the heat of fusion of 100% crystalline PE (291 J/g). Statistical significance was determined using an unpaired, two-tailed student’s t-test.

Results and Discussion
The eight year-implanted acetabular liner, upon retrieval, showed yellow discoloration on the backside and articular surface. The articular surface and femoral head additionally bore scratching.

The 8-year retrieval showed an uncorrected wear rate of -1.087 mg/MC, while the fresh Durasul and Longevity had wear rates of -1.349 Mg/MC and -0.251 mg/MC respectively (negative values indicating weight gain). This confirms the absorption of lipids under cyclic loading in both fresh liners as well as the retrieval, which already contained lipids from the 8 years spent in vivo.

After simulator testing, there was no statistically significant difference in cross-link density between loaded and unloaded regions of the retrieved liner, with an overall average cross-link density of 0.180 ± 0.017. It showed an average crystallinity of 49.4 ± 3.00 and peak melt temperature of 139.9 ± 0.8, which shows no increase compared with fresh Durasul™. Oxidation was barely detectable after simulator-testing in the retrieved Durasul™ liner (0.016 ± 0.008) and fresh liner (0.012 ± 0.001), along with no regional variation between the surfaces and bulk of the material.

Once subjected to accelerated aging, all three liners, compared with an untested sample of fresh Durasul™ showed elevated oxidation levels at the surfaces (Fig 1). The cyclically-loaded articular surfaces show 3-5 times the oxidation of the rim on all liners. Surface oxidation in the retrieved liner reached a depth as far as 4mm in from the surface with an oxidation index of 0.76 ± 0.38. Fresh liners showed higher maximum surface oxidation with oxidation concentrated within the first 0.5mm (0.95 ± 0.55). This difference in oxidation depth and shape is likely attributed to the retrieved liner’s longer exposure to loading and lipids in vivo. Previous studies have shown that fresh highly cross-linked liners, when subjected to accelerated aging, showed no detectable oxidation [6]. This study indicates a clear change in oxidative resistance of the material after cyclic loading and lipid absorption; it also shows that the wear resistance as measured by a hip simulator is not altered after 92 months of in vivo service.

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References

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Figures
Figure 1. Oxidation profiles of highly-cross-linked acetabular liners (a) after simulator-testing, and (b) the rim and (c) articular surface of those same liners after simulator-testing and accelerated aging.