Oxidation and Rim Damage of Sequentially Annealed HXLPE in Total Hip Arthroplasty

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Disclosures:
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Introduction: In the late 1990’s, highly crosslinked polyethylenes (HXLPEs) were clinically introduced in total hip arthroplasty (THA) to improve wear resistance of the polyethylene liner and thus, reduce the incidence of polyethylene wear debris induced osteolysis. Over the past 15 years, several studies have reported that annealed HXLPE liners have resulted in reduced wear in THA, however, this improvement came at the expense of oxidative properties, particularly at the exposed rim surface [1-3]. This oxidation at the rim leads to embrittlement of the polymer that may ultimately result in rim damage. One proposed solution to the in vivo oxidation observed with annealed HXLPE, known as sequential annealing, was to perform the annealing process in three sequential steps. Clinically introduced in 2005, the sequential annealed HXLPE formulation allows for more free radical mobility and thus more effectively quenches free radicals as compared to single step annealing. However, it remains unclear how the oxidative properties and rim damage in sequentially annealed HXLPE compare with first generation, annealed HXLPE.

The purpose of this multicenter study was to assess oxidation and rim damage of 2nd generation sequentially annealed HXLPE. We hypothesized that sequentially annealed liners would exhibit lower oxidation than first generation annealed HXLPE.

Methods: Acetabular liners that were consecutively retrieved during revision surgeries at 7 surgical centers and continuously analyzed between 2000 and 2013 in a prospective, multi-institutional study of total hip arthroplasty material properties and outcomes. The study cohort consisted of 127 Sequentially Annealed liners (X3, Stryker; Implanted 1.2±1.2 years; max: 5 years). We matched our control cohort to the study cohort by including only those control liners with an implantation time that did not exceed the maximum implantation time (5 years) in the study cohort. Sixty-six (66) annealed HXLPE liners (Crossfire, Stryker; Implanted 2.2±1.4 years, max: 4.9 years) met the inclusion criterion for the study. Oxidation was assessed on thin slices (~200 μm) from the superior/inferior axis using transmission FTIR according to ASTM 2012. Liners were inspected using optical microscopy for evidence of rim damage, subsurface delamination, and cracking consistent with previous studies [1,2].

Results: The liners from both cohorts were revised predominantly for loosening, instability, and infection. None of the liners in either cohort were revised for wear, osteolysis, or mechanical failure of the polyethylene. Oxidation levels of the Sequentially Annealed liners were lower than the Annealed liners at all measured locations (p<0.001; Wilcoxon Test; Figure 1). Regional variation was observed in both cohorts, particularly at the rim of the liners, which had the highest oxidation. However, rim oxidation was more severe in the Annealed group. In both cohorts, oxidation was positively correlated with implantation time at the rim (Rho = 0.70, p<0.001 and Rho = 0.27, p = 0.007, for the Annealed and Sequentially Annealed cohorts, respectively). Rim damage (burnishing, delamination, etc.) was observed on 12/123 (10%) of Sequentially Annealed and 7/64 (11%) of the Annealed cohorts. While the prevalence of rim damage was similar between the 2 cohorts (p = 0.80), the severity of the damage varied between the cohorts. For the Sequentially Annealed cohort, the damage primarily appeared in the form of burnishing as a result of femoral neck impingement or from articulation with the femoral head during dislocation (Figure 2). Whereas the damage in the Annealed cohort was primarily in the form of delamination subsequent to femoral neck impingement or from articulation with the femoral head during dislocation (Figure 2).
Discussion: In this study we compared the oxidation and rim damage among first and second generation annealed HXLPEs used in total hip arthroplasty. It was clear that Sequentially Annealed (X3) liners had lower oxidation levels than the 1st generation Annealed (Crossfire) HXLPE liners. We found that rim damage was present at approximately the same rate (~10%) in both material cohorts. However, Sequentially Annealed liners appeared to resist severe rim damage better than the Annealed cohort (at least out to 5 years in vivo) which had cases of severe delamination. Despite this, we did not find evidence to support an association between oxidation or rim damage observed and the clinical outcome. More and longer-term retrievals are necessary to fully assess oxidation and rim damage in Sequentially Annealed HXLPE used in THA.

Significance: Sequentially annealed highly crosslinked polyethylenes (HXLPEs) were introduced in total hip arthroplasty (THA) to reduce the oxidation observed in 1st generation annealed HXLPEs. This study compares 127 retrieved sequentially annealed HXPLE liners to 1st generation annealed HXLPE liners, revealing a lower incidence of oxidation and rim damage in devices with the newer polyethylene formulation.

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