Reasons for Revision, Surface Damage, and In Vivo Oxidation for Retrieved Sequentially Annealed HXLPE in Total Knee Arthroplasty

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Introduction: Highly crosslinked and thermally treated polyethylene (HXLPE) was introduced in total hip arthroplasty (THA) more than 15 years ago to decrease wear and osteolysis [1]. However, the adoption of HXLPE has been slower in total knee arthroplasty (TKA) due to concerns regarding the tradeoff in reduced fatigue and fracture resistance that accompanies radiation crosslinking [2]. In 2005, sequentially irradiated and annealed HXLPE (X3, Stryker Orthopaedics, Mahwah, New Jersey) was introduced to improve the wear, mechanical properties, and oxidative stability of first generation, annealed HXLPE. The short-term clinical performance of sequentially annealed HXLPE has been encouraging in hip arthroplasty [3,4]. However less is known regarding the clinical performance of sequentially annealed HXLPE in knee arthroplasty. The purpose of this retrieval study was to investigate the revision reasons, oxidation, and surface damage mechanisms of sequentially annealed HXLPE as compared with gamma inert UHMWPE in TKA.

Methods: Between 2006 and 2014, 217 sequentially annealed HXLPE tibial inserts were collected at routine revision surgery as part of a multi-institutional orthopaedic implant retrieval program. Because in vivo oxidation is typically correlated with implantation time [5], our control cohort only included
inserts with an implantation time less than the longest implanted sequentially annealed HXLPE inserts (6.5 years in vivo). Thus, 95 gamma inert inserts were collected and served as control specimens for this study. Fifty-two percent of the X3 inserts had stabilizing posts, whereas, 87% of the gamma inert inserts had posts. The sequentially annealed and gamma inert cohorts were implanted for 1.6 ± 1.5 years (Range: 0 to 6.5 years) and 2.4 ± 2.0 years (Range: 0 to 6.5 years), respectively. Patient demographics for both cohorts are summarized in Table 1.

To assess oxidation, thin slices (~200μm) were taken from the medial condyle and central eminence. The slices were analyzed for oxidation using FTIR according ASTM 2102 after they were submerged in boiling heptane for 6 hours to remove absorbed lipids. Three millimeter line scans were taken perpendicular to the surface of the regions of interest. These included the anterior-posterior faces (AP Faces), the bearing surface, backside surface, and stabilizing post, when available. Oxidation was assessed in 190 of 217 of sequentially annealed inserts and 80 of 95 of controls. Damage mechanisms were assessed using a semi-quantitative 4-point scale as previously described by Hood et al. [6]. The inserts were inspected for 7 damage mechanisms: abrasion, burnishing, delamination, embedded debris, pitting, scratching, and surface deformation.

**Results:** Inserts from both cohorts were revised primarily for loosening, infection, instability, and stiffness (see Figure 1). Sequentially annealed inserts without stabilizing posts had a higher percentage of inserts revised for instability than inserts with posts (p = 0.005).
Oxidation indices were similar between the two groups at the articulating surface (p = 0.87), AP Face (p = 0.84), and post (p = 0.67) (see Figure 2). At the backside, sequentially annealed HXLPE had slightly lower oxidation indices compared to the gamma inert cohort (Mean Difference = 0.015; p = 0.003, see Figure 2). For the sequentially annealed inserts, oxidation was correlated with implantation time at the bearing surface (Spearman’s Rho = 0.56; p<0.0001), backside surface (Spearman’s Rho = 0.39; p<0.0001), AP Face (Spearman’s Rho = 0.38; p<0.0001), and post (Spearman’s Rho = 0.36; p<0.07). The predominant damage mechanisms for both cohorts were pitting, burnishing, and scratching. One sequentially annealed and 2 gamma inert inserts had evidence of delamination and/or subsurface whitening. There were 2 cases in the sequentially annealed cohort of posterior condylar fractures; these were associated with chronic posterior loading secondary to instability in CR inserts.
Discussion: This study investigated the clinical performance of a collection of consecutively retrieved sequentially annealed HXLPE knee inserts and compared them with an implantation time-matched cohort of gamma inert-sterilized controls. Our results suggest that in short-to-intermediate term, sequentially annealed tibial inserts exhibit similar reasons for revision, oxidation levels and surface damage mechanisms as gamma inert inserts. The strengths of this study include a large sample size from a multi-center retrieval program. The study is limited due to the short implantation time for the majority of the explants. Longer-term retrievals are still necessary to fully assess the oxidative stability and damage in sequentially annealed HXLPE used in TKA.

Significance: This study investigated the revision reasons and oxidation of sequentially annealed HXLPE in total knee arthroplasty. Our results suggest that in short-to-intermediate term, sequentially annealed tibial inserts exhibit similar reasons for revision, oxidation levels and surface damage mechanisms as gamma inert inserts.

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