Material Performance and Reasons for Revision of 1st and 2nd Generation Highly Crosslinked Polyethylenes Used in Total Hip Arthroplasty

Significance: The oxidative stability of highly crosslinked polyethylenes and the influence of mechanical behavior on THA remains unclear. This study assesses the oxidative properties, mechanical behavior and reasons for revision of 2nd generation highly crosslinked polyethylenes in total hip arthroplasty.

Introduction: Highly crosslinked polyethylenes (HXLPEs) have been in use in total hip replacement for more than a decade [1]. There is consensus in the literature that these materials show improved wear in vivo and significantly reduce osteolysis [2]. However, questions remain regarding the long-term oxidative stability of HXLPEs and the influence of mechanical behavior on THA clinical performance. Starting in 2005, 2nd generation HXLPEs were developed to improve the clinical performance of HXLPE. Examples of 2nd generation HXLPEs include sequentially annealed [3] and vitamin E diffused HXLPEs [4].

The purpose of this multicenter study was to assess the oxidative stability, mechanical behavior, wear and reasons for revision of 2nd generation HXLPEs and compare them to our ongoing retrieval collection of 1st generation annealed and remelted HXLPEs [5, 6]. We hypothesized that sequentially annealed components would exhibit wear rates similar to 1st generation HXLPEs. We also hypothesized that 2nd generation HXLPEs would be more oxidatively stable than 1st generation HXLPEs.

Methods: 431 hip liners were consecutively retrieved during revision surgeries at 9 surgical centers and continuously analyzed over the past 10 years in a prospective, multicenter study of THA revision outcomes and retrieval analysis. 27 liners were sterilized using non-irradiating methods (Gas Sterilized; Implanted 8.4±3.7 years), 47 liners were sterilized in an inert environment (Gamma Inert; Implanted 6.2±3.8 years), 218 were highly crosslinked and remelted (A-Class, Durasul, Longevity, Marathon, XLPE: Remelted; Implanted 1.9±2.3 years), 84 were highly crosslinked and annealed (Crossfire: Annealed 1; Implanted 3.8±2.9 years), 52 were highly crosslinked and annealed in 3 sequential steps (X3: Annealed 2; Implanted 1.2±0.9 years), and 3 were highly crosslinked and stabilized with vitamin E (E1: Vitamin E; Implanted 1.2±0.7 years).

The analytical methods have been described previously [5, 6], and are briefly summarized. Oxidation was characterized in accordance with ASTM 2102 using transmission FTIR performed on thin sections (~200µm) from the superior/inferior axis. Lipids were extracted from the slices prior to analysis by 6 hours in boiling hexane. Sections were then exposed to NO for 16 hours and rescanned using an FTIR spectrometer to assess hydroperoxide content, a metric of oxidation potential. Mechanical behavior was assessed via the small punch test (ASTM 2183). Small cylindrical samples were taken from the superior and inferior regions of the inserts both at the surface and below the surface.

Results: The predominant reasons for revision were loosening, instability, and infection. Thus far, three Vitamin E-diffused components have been revised in the study after 1.2 years on average (Range: 0.7 – 2.0 years) for instability (n=1), femoral loosening (n=1), and cup migration (n=1; Fig. 1).

Oxidation and oxidation potential were higher in the Gamma Inert and both annealed groups than the Remelted, Gas Sterilization, and Vitamin E groups (p<0.001; Kruskal-Wallis Test), particularly at the rim (Fig. 2). Oxidation was significantly correlated with implantation time only at the rim of the Annealed 1 liners (Rho=0.68; p<0.001) and the bearing surface of the Remelted (Rho=0.27; p<0.001) and Annealed 2 liners (Rho=0.45; p<0.001). The oxidation index was low and uniform in the Vitamin E-diffused liners (Average Max Oxidation Index = 0.09), as was the oxidation potential (Average Maximum Hydroperoxide Index = 0.13).

At the superior bearing surface, the ultimate load was negatively correlated with implantation time in the Annealed 1 liners (Rho=0.27; p=0.017) and Gamma Inert liners (Rho=0.31; p=0.04), but not with any other cohort (p>0.05). The Annealed groups had the highest ultimate load at the bearing surface (Kruskal-Wallis Test; p<0.001). The Gas Sterilized liners had the lowest superior surface ultimate load (p<0.020).

Conclusions: This ongoing study continues to evaluate chemical and mechanical properties and reasons for revision among clinically relevant HXLPEs used in total hip replacement, including 2nd generation HXLPEs. The oxidative stability and mechanical behavior of these materials, however, is formulation dependent. With respect to oxidation, sequential annealing appears to have effectively reduced oxidation when compared with first-generation annealing. Additional Vitamin E retrievals are needed to compare with the existing collection of thermally stabilized HXLPEs that have been characterized up until now.

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References: