Material and Clinical Performance of Remelted Highly Crosslinked Polyethylene Used in Total Knee Arthroplasty

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Significance: Because elevated radiation crosslinking and remelting reduces the fracture toughness of PE, the use of HXLPE in the knee has been considered controversial. The purpose of this study was to investigate the damage mechanisms and oxidative stability of remelted polyethylenes in a consecutive series of retrieved tibial components.

Introduction: Remelted highly crosslinked polyethylene (HXLPEs) were introduced in total knee replacement (TKR) starting in 2001 to reduce wear, oxidation and particle-induced lysis [1]. Because elevated radiation crosslinking and remelting reduces the fracture toughness of PE, the use of HXLPE in the knee has been considered controversial [2,3]. Over time, HXLPE has gained acceptance as a candidate biomaterial for TKR [1]. However, few studies have reported on the clinical performance of HXLPE knees [4]. Now one decade following its introduction, knowledge regarding the in vivo damage mechanisms and oxidative stability of remelted HXLPEs in the knee remains incomplete.

Until recently, remelted highly crosslinked polyethylene has been considered oxidatively stable, presumably due to the lack of measurable free radicals [1]. Recently, researchers have observed elevated oxidation in retrieved HXLPE hip liners and knee insert components, particularly at the articulating surface [5,6]. The mechanisms of in vivo oxidation of remelted HXLPEs remains poorly understood, but in vivo loading and cyclic compression loads have been suggested as potential factors. Thus, due to different loading paradigms between hip and knee components, it is unclear if remelted highly crosslinked polyethylene will oxidize in total knee replacements to a greater extent than in hips.

The purpose of this study was to investigate the damage mechanisms and oxidative stability of remelted polyethylenes in a consecutive series of retrieved tibial components. We hypothesized that due to the relative lack of free radicals radiation crosslinked highly crosslinked polyethylenes would have lower oxidation levels than gamma inert-sterilized controls. Additionally, we hypothesized that the remelted components would remain oxidatively stable over time.

Methods: 186 posteriorly stabilized tibial components were retrieved at consecutive revision surgeries at 7 surgical centers. 69 components were identified as remelted highly crosslinked polyethylene (Prolong, Zimmer) while the remainder (n=117) were conventional gamma inert sterilized polyethylene. The sterilization method was confirmed by tracing the lot numbers with the manufacturer. The conventional inserts were implanted for 3.4±2.7 years (Range: 0.0 – 10.1 years), while the remelted components were implanted 1.4±1.2 years (Range: 0.0 – 4.2 years). Patient records were reviewed to determine the reason for revision, patient demographics, and activity scores.

Surface damage was assessed using the Hood method [7]. The condyles, post and backside were inspected for 7 damage mechanisms, including scratching, pitting, burning, abrasion, delamination, embedded debris, and surface deformation, as previously described [7].

For oxidation analysis, a subset of the implants was evaluated in accordance with ASTM 2102. Specifically, remelted components implanted for more than 1 year were analyzed as well as 14 inserts that were implanted for less than 1 year to serve as a baseline. Thus, 41 conventional and 41 remelted inserts were available for oxidation analysis. Thin slices (~200 µm) were taken from the medial condyle as well as the central spine and then boiled for 6 hours in heptane to extract any absorbed lipids. Lines scans were then taken at 100 µm increments (32 repeat scans per location) using FTIR spectroscopy. Regions of interest were the bearing surface, the backside surface, the anterior and posterior faces, and the post.

Results: The predominant reasons for revision were loosening, instability, and infection. None of the highly crosslinked tibial inserts were revised for osteolysis or component fracture.

Pitting, scratching, and burnishing were the predominant damage mechanisms within both material groups. Delamination was only present on one gamma inert, and was not present in the highly crosslinked group. The prevalence of condylar pitting was similar between the material groups (p = 0.269), however, pitting scores were greater at the backside surface in the HXLPE retrievals (p = 0.001).

References:

Figure 1: Stereomicrograph of the longest term highly crosslinked inserts (4y in vivo). Note the burnishing and extensive pitting on the condyles. This insert was revised for loosening of the tibial component.

Figure 2: Regional oxidation both cohorts of tibial inserts.

Discussion: This study evaluated the surface damage mechanisms, oxidative stability, and reasons of revision for 1st generation highly crosslinked polyethylenes in total knee replacement. Remelted highly crosslinked polyethylenes proved to have reduced oxidation indices as compared with conventional inserts. While we were able to detect oxidation levels (as high as 1) in the crosslinked group, we could not detect a correlation with implantation time. Additional long term highly crosslinked retrievals are necessary to ascertain the long term in vivo stability of these materials in total knee replacement.

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