Less Midterm Damage and Oxidation Are Seen in Retrieved Highly Crosslinked Ultrahigh-Molecular-Weight Polyethylene Tibial Inserts than in Direct Compression Molded Polyethylene Inserts

Alexandra Stavarakis, MD · Lydia Weitzler, MS · Timothy Wright, PhD · Douglas E. Padgett, MD

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Abstract *Background:* Highly crosslinked ultrahigh-molecular-weight polyethylene (XLPE) shows reduced wear in total hip arthroplasty compared to direct compression-molded polyethylene (compPE); however, minimal research evaluating polyethylene damage in XLPE tibial inserts in total knee arthroplasty exists. *Questions/Purposes:* We evaluated damage and material properties in retrieved XLPE components at midterm (≥ 2.5 years) follow-up. *Methods:* We identified 19 XLPE tibial inserts with ≥ 30 months in vivo using our institutional review board-approved implant retrieval system; 19 compPE retrieved inserts were matched based on age at index surgery, body mass index, sex, and length of implantation. Articular surface damage was assessed using a subjective grading system. Swell ratio testing and Fourier-transform infrared spectroscopy were used to measure crosslink density (XLPE) and oxidation (XLPE, compPE), respectively, at loaded and unloaded surface and subsurface regions. *Results:* CompPE inserts had higher overall damage than XLPE inserts, specifically at the post of posterior-stabilized inserts. The XLPE inserts had lower crosslink density at the loaded surface (0.159 mol/dm^3) than either unloaded region (0.183 mol/dm^3). CompPE peak oxidation index (OI) was greater than XLPE peak OI in the loaded and unloaded surface regions (1.67 vs. 0.61 and 1.38 vs. 0.46, respectively). *Conclusions:* Surface damage and oxidation are reduced in XLPE inserts compared to compPE at midterm follow-up. Peak OI greater than 1.0 in

the compPE group suggests that mechanical-property degradation had occurred, a likely cause for increased damage. Longer-term retrievals will determine whether these trends continue. Based on midterm results, XLPE shows an advantage over compression molded PE in total knee arthroplasty.

Keywords Crosslink density · Oxidation analysis · Polyethylene degradation · Surface damage · Total knee arthroplasty

Introduction

Polyethylene wear-associated osteolysis leading to aseptic loosening remains a concern in both total hip arthroplasty (THA) and total knee arthroplasty (TKA). Highly crosslinked ultrahigh-molecular-weight polyethylene (XLPE) and direct compression-molded polyethylene (compPE) were both developed to provide improved wear characteristics compared to conventional polyethylene [5, 10, 19]. XLPE's superior wear characteristics have been linked to a reduced incidence of osteolysis following THA [4, 5, 9].

XLPE has also been used in TKA, following evidence that it provides improved wear resistance when compared to conventional polyethylene in knee-simulator studies. However, the advantage of XLPE in TKA in a clinical setting remains unclear. Furthermore, concern exists that XLPE may be associated with increased oxidation, reduced mechanical strength, decreased yield strength, and decreased toughness. These drawbacks are of particular concern in posterior-stabilized designs, given the risk of fracture of the polyethylene tibial post [4, 8, 12, 14, 15, 17].

Liu et al. recently evaluated surface damage in XLPE in comparison to compPE at short-term follow-up (mean, 15 months; range, 1 to 44 months) [15]. No differences in the severity or presence of polyethylene damage observed on the articular surfaces or of the percentage of the articular surface that showed damage were found between the two

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A. Stavarakis, MD · L. Weitzler, MS (✉) · T. Wright, PhD ·
D. E. Padgett, MD
Hospital for Special Surgery,
535 E. 70th St.,
New York, NY 10021, USA
e-mail: weitzlerl@hss.edu

Table 1 Patient characteristics

Variable	XLPE	compPE	<i>p</i> value
Number	19	19	N/A
Number of females (%)	12 (63%)	11 (58%)	0.99
Length of implantation (months)	63 ± 27 (range 32–129)	81 ± 29 (range 30–127)	0.06
BMI (kg/m ²)	30 ± 7 (range 20–48)	30 ± 8 (range 20–48)	0.9
Age at index (years)	58 ± 9 (range: 31–70)	58 ± 10 (range 25–74)	0.94

XLPE highly crosslinked ultrahigh-molecular-weight polyethylene, *compPE* compression-molded polyethylene

materials. They also showed that XLPE crosslink density decreased with time, particularly in the loaded surface region. Similarly, peak oxidation levels were higher in loaded regions when compared to unloaded regions. However, because of the short-term nature of the retrieved components, the long-term clinical importance of these findings could not be discerned.

The purpose of this study was to compare surface damage, oxidation, and crosslink density of XLPE compared to compPE at midterm follow-up (≥ 30 months). The goal was to see if the results from the short-term retrieval study conducted by Liu et al. [15] were consistent with longer-term follow-up.

Methods

XLPE tibial inserts with a minimum 30 months of in vivo use were considered for this study. Our institutional review board-approved implant retrieval system was used to identify 270 frozen XLPE tibial inserts retrieved between January 2012 and October 2016 and 92 frozen compression-molded tibial inserts retrieved between January 2015 and December 2016. Tibial inserts were only included if they had been placed in a −18°C freezer within 6 months of revision surgery to avoid the confounding effects of continued ex vivo oxidation after component retrieval [7].

Nineteen XLPE inserts fulfilled all of the criteria. They were matched to 19 of the 92 frozen compPE inserts based on sex, age at index surgery, body mass index (BMI), and length of implantation. Matching resulted in no significant differences in mean age (XLPE, 58 years; compPE, 58 years; $p = 0.94$), mean BMI (XLPE, 30.4 kg/m²; compPE, 30.1 kg/m²; $p = 0.9$), sex (XLPE, 63% female; compPE, 58% female; $p = 0.99$), or mean length of implantation (XLPE, 63 months; compPE, 81 months; $p = 0.06$) between the two groups (Table 1). Other demographic and clinical data identified from the patients' medical records included reason for revision and implant manufacturer and design.

Of the 19 XLPE inserts, eight were Smith & Nephew (London, UK) Legion™ implants, including six posterior stabilized (PS) and two cruciate retaining (CR); seven were Zimmer (Warsaw, IN, USA) implants, including five NexGen® LPS and two Natural Knee® CR; two were Sigma® PS (DePuy, Warsaw, IN, USA) implants; and two were Scorpio® (Stryker, Kalamazoo, MI, USA) implants, including one Scorpio PS and one Scorpio CR. All 19 of the compPE tibial inserts were manufactured by Exactech

Inc. (Gainesville, FL, USA), including eight Optetrak® PS, eight Optetrak Logic PS, and one Optetrak High Flex.

Five XLPE inserts and only one of the compPE inserts had been revised for aseptic loosening (Table 2). Other reasons for revision surgery were instability (three XLPE, two compPE), infection (zero XLPE, two compPE), stiffness (three XLPE, one compPE), and others (eight XLPE, 13 compPE). None of the reasons for revision differed significantly between the two groups.

A sample size calculation determined that a sample size of 18 was needed to detect a 20% difference in outcome measures.

Surface damage to the articular surfaces of the retrieved inserts, including damage to the tibial posts in PS designs, was assessed using a previously established subjective scoring system [11]. Each insert was divided into ten regions for a CR design and into 14 regions for a PS design (Fig. 1). The backside of all inserts was divided into four regions. Each region was scored for burnishing, pitting, scratching, third-body debris, abrasion, deformation, and delamination, with a score between 0 and 3, depending on the extent and severity of each damage mode in each region. Each tibial insert was evaluated by two independent observers (AS, LW), blinded to the demographic or clinical data, using a light stereomicroscope at × 10 magnification. If the difference in total damage scores between the two graders was more than 10 points, a third independent observer (CE) also scored the insert. The average of both or all three scores was used.

Crosslink density was measured for the XLPE group of inserts using a gravimetric swell ratio test according to ASTM standards D2765 and F2214 [1, 2, 6, 7]. A razor blade and hammer were used to cut cubes (3 × 3 × 3 mm) from four regions in the medial plateau of each tibial insert: loaded surface, loaded subsurface, unloaded surface, and unloaded subsurface regions (Fig. 2a). The cubes were immersed in 25 mL of xylene (Fisher Scientific, Pittsburgh,

Table 2 Indication for revision

Indication for revision	XLPE	compPE	<i>p</i> value
Aseptic loosening	5	1	0.08
Instability	3	2	0.63
Infection	0	2	0.15
Stiffness	3	1	0.29
Other	8	13	0.1

XLPE highly crosslinked ultrahigh-molecular-weight polyethylene, *compPE* compression-molded polyethylene

Fig. 1. Regions for damage scoring of a cruciate-retaining knee (a) and a posterior-stabilized knee (b).

PA, USA) for 2 h at 135°C. Swell ratio and crosslink density were calculated from the mass of each cube before and after immersion. Swell ratio is used to assess the degree of crosslinking, which effectively helps the material maintain its shape. When crosslinking decreases, the polyethylene cube swells and thus loses its shape. Due to the lack of high amounts of crosslinking in the compPE inserts, crosslink density testing was not performed on this group.

Oxidation index (OI) was measured using Fourier-transform infrared (FTIR) spectroscopy, following ASTM standard F2102 [3]. A Leica SM2500 sliding microtome (Leica Microsystems, Wetzlar, Germany) was used to create 100- μ m-thick sagittal slices directly adjacent to the region where the cubes had been cut for the crosslink density measurements. A Spectrum™ 100 spectrometer and a Spotlight™ 300 FTIR microscope (PerkinElmer, Shelton, CT, USA) were used to perform FTIR analyses on each PE slice starting at the articular surface and scanning to a depth of 6 mm below the surface, using an aperture of $200 \times 200 \mu\text{m}$, with 32 scans per 200- μ m interval. Thus, OI measurements were obtained from the loaded and unloaded surface and subsurface regions (Fig. 2b). OI was calculated from the spectrum as the ratio of the carbonyl peak area to the methylene vibration peak area, centered at 1720 and

1370 cm^{-1} , respectively, using Bio-Rad software (Hercules, CA, USA). Polyethylene is made up of only carbon and hydrogen. The carbonyl group contains oxygen, carbon, and hydrogen, while the methylene group contains only carbon and hydrogen; therefore, an increase of oxidation is typically indicated by a larger carbonyl peak area.

Statistical Analyses

Patient age at index surgery, patient BMI, and length of implantation were compared using paired Student's *t* tests to assure appropriate matching of the XLPE and compPE retrieved tibial inserts. Patient sex and reason for revision were compared using a χ -square test for matching of these two factors. XLPE and compPE damage scores, crosslink densities, and oxidation indices were compared using paired Student's *t* tests.

Results

The XLPE group had a significantly lower overall surface damage score than the compPE group ($p = 0.002$) (Table 3). When each of the seven damage modes was analyzed

Fig. 2. A retrieved tibial insert, showing where samples were collected for crosslink density analysis (a) and oxidation analysis (b). **a** A sagittal view of a tibial insert from which polyethylene cubes were cut at different regions for crosslink density analysis: the loaded surface (red square 1), loaded subsurface (red square 2), unloaded surface (blue square 3), and unloaded subsurface (blue square 4). **b** To measure peak oxidation, a 200- μ m slice of polyethylene was cut from the medial compartment of the tibial insert immediately adjacent to sagittal section of the tibial component. A fourier-transform infrared spectroscopy microscope took 30 scans ($200 \times 200 \mu\text{m}$) from the articular surface to 6-mm depth to analyze the surface and subsurface of both loaded and unloaded regions. The red arrow shows where 30 scans were taken from the surface to the subsurface of the loaded regions (the location of the red arrow corresponds to the location of the red cubes 1 and 2 shown in a), and the blue arrow shows where 30 scans were taken from the surface to the subsurface of the unloaded regions (the location of the blue arrow corresponds to the location of the blue cubes 3 and 4 shown in a) [16]. Permission to reprint from Springer

Table 3 Mean articular surface damage scores

	Articular surface			Post region			Total		
	XLPE	compPE	<i>p</i> value	XLPE	compPE	<i>p</i> value	XLPE	compPE	<i>p</i> value
Burnishing	12 ± 5	6 ± 6	0.001	0.5 ± 6	0.4 ± 0.8	0.6	14 ± 5	8 ± 6	0.003
Pitting	10 ± 6	14 ± 6	0.06	0.9 ± 1	3 ± 2	0.001	13 ± 8	19 ± 8	0.04
Scratching	9 ± 4	11 ± 5	0.3	0.8 ± 1	1 ± 2	0.3	11 ± 5	13 ± 6	0.1
Third-body debris	0.04 ± 0.1	0.09 ± 1	0.001	0.02 ± 0.08	0.2 ± 0.4	0.1	0.05 ± 0.2	1 ± 1	0.003
Abrasion	0.37 ± 0.5	0.06 ± 0.9	0.4	0.3 ± 0.6	1 ± 1	0.03	0.7 ± 0.7	2 ± 2	0.03
Deformation	1 ± 2	2 ± 3	0.08	0.5 ± 0.8	4 ± 3	0.001	2 ± 3	6 ± 5	0.002
Delamination	0.3 ± 1	4 ± 5	0.02	0.07 ± 0.2	2 ± 3	0.002	0.4 ± 1	6 ± 7	0.005
Total	33 ± 8	33 ± 8	0.06	3 ± 3	12 ± 6	<0.001	41 ± 11	54 ± 14	0.002

XLPE highly crosslinked ultrahigh-molecular-weight polyethylene, compPE compression-molded polyethylene

individually, the XLPE group had greater total burnishing ($p = 0.003$) but less pitting ($p = 0.04$), third-body debris ($p = 0.003$), abrasion ($p = 0.03$), deformation ($p = 0.002$), and delamination ($p = 0.005$). No difference was found in the scores for scratching between the two groups. The difference in overall visual damage score was influenced by the damage to the tibial post in the PS retrieved inserts. Less overall damage was noted on the articulating surfaces of the posts in the XLPE group than in the compPE group ($p < 0.001$), most notably on the posterior surface of the post, consistent with articulation against the metallic cam on the femoral component. The XLPE group had lower pitting ($p < 0.001$), abrasion ($p = 0.03$), deformation ($p = 0.001$), and delamination ($p = 0.002$) scores in the post regions, with no difference in burnishing, scratching, and third-body debris scores between the two groups. After isolating the total damage scores for the articular surfaces, a trend toward lower scores in the XLPE group was found, but the difference was not significant. Burnishing scores in the XLPE group were larger than those in the compPE group ($p = 0.001$), while the XLPE group had lower third-body debris ($p = 0.001$) and delamination ($p = 0.02$) scores. No differences were found for the

other damage modes between the two groups at the articular surface (Table 3).

Crosslink densities for the XLPE inserts (Fig. 3) were lowest at the loaded surface region (0.159 ± 0.04 mol/dm³) and highest at the unloaded surface and subsurface regions (0.183 ± 0.04 mol/dm³) ($p < 0.05$). At the loaded subsurface region, the crosslink density was 0.177 ± 0.04 mol/dm³ (no significant differences existed between the crosslink density of the loaded subsurface region and that of any other region).

Oxidation was highest within 3 mm of the articular surface in both groups (Fig. 4). The mean OI closest to the articular surface was greater for the compPE group in both loaded and unloaded regions (loaded mean: compPE OI, 0.90 ± 0.57 vs. XLPE OI, 0.22 ± 0.11 ; unloaded mean: compPE OI, 0.84 ± 0.58 vs. XLPE OI, 0.15 ± 0.06) ($p < 0.0001$). Furthermore, subsurface OI was also greater for the compPE group in both loaded and unloaded regions (loaded compPE subsurface mean: OI, 0.22 ± 0.18 vs. 0.06 ± 0.03 in XLPE; unloaded compPE subsurface mean: OI, 0.22 ± 0.12 vs. 0.07 ± 0.04 in XLPE) ($p < 0.0001$) (Fig. 4).

Discussion

Our goal was to compare the performance of XLPE and compPE retrieved tibial inserts at midterm (≥ 2.5 years) follow-up on the basis of damage to the polyethylene surfaces and oxidation indices and to examine crosslink density for the XLPE inserts. The intention was to extend previously published results of XLPE from our group obtained after short implantation times [15] to results from longer implantation times and to include a control group of compression molded (non-highly crosslinked) inserts. Our findings show that at midterm follow-up, XLPE had less evidence of surface damage compared to compPE, driven primarily by less damage caused at the cam-post interface; this may be of importance, given prior concerns of possible gross post failure in inserts fabricated from XLPE [20].

Our study has limitations. First, this study is retrospective and involves the analysis of PE inserts that were retrieved from failed TKAs; therefore, the inserts may not reflect the performance of inserts from well-functioning TKAs. The failure mode of individual cases could have influenced the mode or severity of surface damage and the

Fig. 3 Crosslink density results for the highly crosslinked ultrahigh-molecular-weight polyethylene (XLPE) group showed significant differences between the loaded surface region and each of the unloaded regions. * $p < 0.05$

Fig. 4. Oxidation index results showed less degradation for highly crosslinked ultrahigh-molecular-weight polyethylene (XLPE, black) compared to compression-molded polyethylene (compPE, gray) groups for all four regions. * $p < 0.0001$

changes in crosslink density and oxidation. Second, the method of crosslinking varied among the differing manufacturers and may have an impact on the results. Unfortunately, due to the small number of retrievals, comparison among the different methods of crosslinking could not be performed. The major difference in manufacturing technique is that Stryker polyethylenes are annealed after crosslinking, as opposed to being remelted, as is done by DePuy, Smith & Nephew, and Zimmer. As only two Stryker inserts were included in this study, we do not feel that it is a major

concern. A final limitation is that we did not attempt to perform mechanical property measurements to relate to the changes in crosslink density and OI. But because of the destructive nature of the swell ratio and FTIR measurements, mechanical property tests at the same location were impossible. Instead, we can rely on relationships in the literature [13] to infer that the properties we measured relate to adverse changes in mechanical properties.

At midterm follow-up, XLPE had reduced crosslink density when compared to the short-term retrievals on which we

Fig. 5. Peak oxidation index greater than 1 leads to variability in mechanical properties. XLPE highly crosslinked ultrahigh-molecular-weight polyethylene, compPE compression-molded polyethylene

previously reported; however, the same trend was found as in the shorter-term retrieved inserts—namely, the largest reduction in crosslink density occurred at the loaded surface region [15]. Decreased crosslink density with implantation time has been postulated to be caused either by mechanical means with tensile stresses near the surface reaching sufficient magnitudes to break crosslinks between the polyethylene chains or by chemical means through the absorption of lipids into the polyethylene, which could also be greater in highly stressed regions of the material [18].

CompPE had greater overall oxidation when compared to XLPE in both loaded and unloaded surface and subsurface regions. CompPE inserts also had a greater peak OI than those in the XLPE group. Peak OI was significantly greater ($p < 0.001$) in the compPE group in both loaded (compPE OI, 1.673; XLPE OI, 0.605) and unloaded (compPE OI, 1.380; XLPE OI, 0.458) surface regions (Fig. 5). A peak OI above 1.0 has been associated with decreases in key mechanical properties of polyethylene [13]. Our findings suggest that compPE may be more susceptible to oxidative degradation, and the accompanying alterations in mechanical properties may explain the greater damage seen in the compPE group than in the XLPE group.

Nonetheless, we strengthened our comparison of highly crosslinked to compression molded polyethylene by matching the inserts in terms of the patients' ages and BMIs and the length of implantation, thus accounting for potential confounding variables. While we used retrieved inserts from different manufacturers and of different designs—and thus other variabilities existed in manufacturing and sterilization processes besides whether the polyethylene was crosslinked or compression molded—these two cohorts provide information on implant performance and material properties of currently used devices at medium-term follow-up.

In conclusion, after analyzing XLPE retrieved inserts at longer follow-up than our previous report [15], it still appears that the use of XLPE in TKA, despite its increased cost, results in reduced surface damage and decreased oxidation, which may lead to a reduction of polymeric wear with decreased osteolysis and, it is hoped, a lower incidence of aseptic loosening.

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Compliance with Ethical Standards

Conflict of Interest: Alexandra Stavrakis, MD, and Lydia Weitzler, MS, declare that they have no conflicts of interest. Timothy Wright, PhD, reports receiving royalties from and owning stock in Exactech and having a research contract with Stryker, both related to this work; he also reports owning stock in OrthoBond, having a research contract with Lima, and acting as education committee member for the Knee Society, outside the current work. Douglas E. Padgett, MD, reports acting as a paid consultant to DJO Global and a board or committee member for the Hip Society and the Journal of Arthroplasty, outside the current work.

Human/Animal Rights: All procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2013.

Informed Consent: N/A

Required Author Forms Disclosure forms provided by the authors are available with the online version of this article.

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