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Mechanical Properties of Retrieved Highly Crosslinked (Crossfire) Liners after Short-Term Implantation

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Abstract

This study reports on detailed analyses of retrieved, annealed crosslinked liners. Twelve crosslinked liners (Crossfire, Stryker Orthopaedics, Mahwah, NJ) of the same Omnifit design were retrieved at revision surgery by one institution after an average 1.9 years (0.02 to 4.8 years) *in vivo*. In each case, the revision surgery was performed for reasons unrelated to wear. The mechanical properties and extent of oxidation of all inserts were characterized using a standard small punch test and measurement of the oxidation index. Results indicated that there was no association between implantation time and either mechanical properties or extent of oxidation for the inserts near the worn bearing surface. Slight variation in properties was observed as a function of sampling location, with the properties near the unworn surface displaying the greatest relative variability. We conclude that the variability in polyethylene properties observed in this small study was not clinically significant for these short term-implanted, annealed crosslinked liners.

Keywords

Mechanical properties; oxidation; wear; hip arthroplasty; highly crosslinked ultra-high molecular weight polyethylene

Introduction

Short-term clinical trials of both annealed and remelted highly crosslinked polyethylene materials have reported encouraging results with substantial reductions in wear compared to conventional polyethylene [1–5]. Although radiographic wear assessments for highly crosslinked polyethylenes have thus far proven favorable, clinical studies that rely on diagnostic imaging have insufficient resolution to discriminate between wear or damage mechanisms and to quantify changes in the properties of the polyethylene. Consequently, direct analysis of retrieved polyethylene components provides a crucial validation of *in vivo* performance of the biomaterial.

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Thus far, retrieval analyses of highly crosslinked polyethylene materials have focused on assessments of microscopic wear and surface roughness [6], surface cracking [7], and plastic deformation [8] of the articulating surface. However, the implantation time associated with these previous retrieval studies was less than 24 months. Cases of highly crosslinked polyethylene short-term revision have also been reported [9–11], but in only one of these isolated studies, involving rim fracture of the liner in a vertically malpositioned shell [11], did the mechanical performance of the liner contribute to the reason for revision. Overall, six years after their clinical introduction, the retrieval experience with highly crosslinked polyethylene materials remains extremely limited. Nevertheless, despite the paucity of available data, it appears that highly crosslinked polyethylenes share many of the same wear and damage mechanisms as conventional UHMWPE during the two years following implantation [6–8]. Because of their recent introduction, the long-term *in vivo* stability of both annealed and remelted highly crosslinked UHMWPE remains unknown.

Unlike remelted polyethylenes, annealed materials are often gamma sterilized and therefore contain residual free radicals that may be susceptible to long-term oxidation *in vivo*, either from molecular oxygen or from reactive oxygen species dissolved in the joint fluid [12]. Previous work has shown that conventional gamma sterilized liners undergo *in vivo* oxidation and degradation of mechanical properties, especially in unworn bearing surface regions and the superior and inferior faces of the rim [12,13]. It is unknown whether an *in vivo* oxidation mechanism exists in annealed highly crosslinked polyethylene materials, and if so, whether *in vivo* degradation influences the clinical performance of the hip bearing.

In conventional gamma sterilized liners, access to joint fluid appears to influence the local magnitude of oxidation [12]. Because wear and *in vivo* oxidation take place concurrently, it has thus far proven difficult to determine whether *in vivo* oxidation is reduced at the bearing surface, or if previous evidence of severe oxidation has merely been erased by wear processes. We hypothesized that annealed highly crosslinked liners, like conventional polyethylene liners, would exhibit region-specific degradation *in vivo*. To evaluate the clinical performance of the polyethylene, we evaluated the magnitude of femoral head penetration into the liner, as well as the penetration rate. We also treated the two liners with the longest implantation times (3.9 and 4.8y *in vivo*) as case studies, as they were expected to show the greatest evidence of *in vivo* oxidation.

Materials and Methods

Twenty-four annealed, highly crosslinked liners (Crossfire, Stryker Orthopaedics, Mahwah, NJ) were retrieved from constrained (21%, 5/24) and unconstrained (79%, 19/24) acetabular components during consecutive revision surgeries at a single, high-volume urban surgical center, in collaboration with a regional retrieval center. The index procedures were performed between May 1999 and April 2003, and the retrieved components were implanted between 0 to 4.8y (avg: 1.5y). The implants were collected and analyzed continuously throughout a five-year period.

As soon as the implants were catalogued and cleaned using a standard detoxification protocol at our institution, a process which normally takes between one and two weeks, they were expeditiously stored in a subzero freezer to minimize oxidative changes to the liners *ex vivo* prior to testing. Five new liners (four unconstrained, 1 constrained) were used as controls. The shelf life was traceable by the manufacturer from the lot codes in 23/24 (96%) retrieved liners and in 5/5 (100%) of the control liners. The average shelf life of the retrievals and controls was 0.5y (range: 0 to 3.4y), during which the Crossfire components were stored in a polymeric barrier blister package with a metallic foil barrier cover, which was filled with nitrogen (N₂-Vac; Stryker Orthopaedics, Mahwah, NJ).

Forty-six percent (11/24) of the patients were female, and their average age was 62y (range: 37 to 85y). 54% (13/24) of the revised components were used in patients that had a history of previous revision surgeries. The implants in this study were revised for reasons unrelated to wear, which included aseptic loosening, n=9; instability and recurrent dislocation, n=7; malpositioning, n=2; infection, n=2; acetabular component dislodgement, n=1; subsidence of femoral stem, n=1; leg length discrepancy, n=1; and constrained liner separation, n=1. There was no evidence of osteolysis in any of the revisions.

In a preliminary analysis, data from all Crossfire retrievals were considered, regardless of implant design (e.g., including both constrained and unconstrained liner designs). Information from the manufacturer indicated that the constrained Crossfire liners were produced only on a custom basis, and not released for the general population. Although this was the most complete and inclusive analysis, the results were biased by multiple designs as well as by a large proportion of liners with short implantation times. Consequently, for this study we focused our analyses on 12 unconstrained, Crossfire liners produced with the Omnifit design (Series II). Not only did this liner design represent the largest group in our retrieval collection, but it also the first to be introduced clinically in the fall of 1998. In a second series of analyses, we evaluated the two longest-implanted Omnifit liners (3.9y and 4.8y *in vivo*) as individual case studies, because they were expected to show the greatest changes in polyethylene properties from exposure to the *in vivo* environment.

Clinical data for the 12 cases in the Omnifit cohort are detailed in Table 1. For the Omnifit cohort, 66% (8/12) of the patients were female, and their average age was 58y (range: 37 to 78y). 42% of the patients (5/12) had a history of previous revisions. The average implantation time was 1.9y (range: 0.02 to 4.8 y) (Table 1). Traceable in 92% (11/12) of the cases, the average shelf life was 0.3y (range: 0.1 to 2.4 y) (Table 1).

Patient activity level was assessed using the UCLA activity scale ranging from 1 to 10. Patients were asked in a questionnaire to assess their activity level prior to the onset of symptoms leading to revision surgery. For the 12 Omnifit retrieval cases, the average patient activity score was 4 (range: 2 to 8), corresponding to regular participation in mild activities, such as walking and limited housework or shopping (Table 1).

All of the Omnifit liners had a 28 mm inner diameter. The head material was CoCr alloy in 58% (7/12) of the cases; zirconia ceramic in 25% (4/12) of the cases; and unknown in 1 case (Table 1). The measured thickness of the liners, in unworn locations, ranged from 7.2 to 14.2 mm, and the outer diameter of the acetabular shells varied between 48 to 62 mm (Table 1).

Mechanical properties, including ultimate load (strength), and extent of oxidation of all inserts were characterized using the standard small punch test (ASTM F2183) and oxidation index (ASTM 2102), as described previously [12]. In both worn and unworn locations, small punch specimens were sampled near the surface (0 to 0.5 mm) and below the surface (1.5 to 2 mm) of the retrieved liners, consistent with previous sampling schemes [12] to facilitate comparison with data collected from conventional polyethylene liners. The 0.5 mm thick specimens obtained near the surface were prepared with one face starting between 0 and 25 micrometers from the articulating surface. Thus, the “surface” measurements using the small punch test should be interpreted as an assessment of the mechanical properties between 0 and 0.5 of the articulating surface, consistent with the thickness of the specimen.

The worn and unworn locations were identified by examining the articulating surface under a stereomicroscope for the presence of contact damage, such as the presence of scratches and the removal of machining marks. This classification system worked well for the majority of Crossfire retrievals in our collection (10/12, 83%). For one implant, retrieved after 0.02 years, no worn region of the liner surface could be detected due to its extremely short implantation

time. Another implant, retrieved after 1.55y *in vivo*, had evidence of wear processes occurring across the entire articulating surface, such that no measurements could be performed in an unworn location.

A total of 104 small punch tests were performed on the 12 retrievals, and 28 tests were performed on the four control liners, corresponding to an average of 8 tests per implant. For statistical analysis, the properties of the retrievals were averaged at each sampling location. The regional properties of the retrievals were compared with the controls using Mann Whitney two sample rank tests. Among the retrievals, regional comparisons in the ultimate load were evaluated with paired t-tests. At each location, the average mechanical properties of the retrieved liners, including the average data from the controls, were analyzed as a function of implantation time and shelf life using linear regression.

Thin sections (200 μm) created using a microtome were also prepared in worn and unworn locations and boiled in heptane for 6h to remove absorbed lipids [14]. The oxidation index through the thickness of the liners was then analyzed following ASTM 2102. Regional differences in the maximum oxidation index were evaluated with paired t-tests. All statistical tests were performed using JMP software (SAS Institute, Cary, NC).

The thickness of the liners was measured in the loaded and unloaded regions using a calibrated digital micrometer. Femoral head penetration into the liner was calculated by subtracting the thickness of the liner in worn and unworn regions. During the 12 months following implantation, dimensional changes in the Crossfire inserts of this design are a combination of creep and wear [1]. Consequently, an average femoral head penetration rate was calculated for liners that were implanted for longer than a year, by dividing the measured head penetration by the implantation time, as described previously [15]. There were six liners with *in vivo* durations of greater than one year that were amenable to analysis of head penetration using this method. An insufficient quality of consecutive radiographs precluded reliable radiographic head penetration measurement for the majority of these retrieved inserts. However, measurements were made for two case studies, detailed below, using the Martell technique (Hip32 Software, version 3.0) [16].

Results

Cohort of Omnifit Retrievals

Variability was observed in the ultimate properties of both the control and the retrieved liners. The ultimate load of the control Crossfire liners ranged between 77.4 and 98.9 N (mean $\pm$ SD: 92.3 ± 10.1 N). Among the retrieved liners, the ultimate properties varied as a function of sampling location, with the unworn surface locations displaying the greatest relative variability in mechanical properties (Fig. 1). Figure 1 shows the distribution in ultimate properties measured for the individual small punch tests carried out on the 12 retrieved Crossfire liners. In the box and whiskers plot, the top and bottom horizontal margins of the box correspond to the 25th and 75th percentiles in the data set, whereas the horizontal line corresponds to the median. The bottom and top “whiskers” span the 10th and 90th percentiles. Outliers, below the 10th percentile and above the 90th percentile, are plotted individually as open circles on the plot.

The average ultimate properties of the retrieved liners at the four sampling locations are summarized in Table 2. Among the retrieved components, the properties of the unworn surface were significantly lower than the worn surface in pair-wise comparisons (mean difference: 11.0 N, $p = 0.01$). Similarly, the subsurface properties tended to be lower in the unworn regions as compared with the worn regions of the liners (mean difference: 6.0 N, $p = 0.02$). The difference in properties between the worn surface and worn subsurface regions was not

statistically significant. The properties measured at the unworn surface and unworn subsurface locations of the retrievals were lower than the control Crossfire liners, but the difference was not significant ($p = 0.19$ and 0.26 for the unworn surface and subsurface, respectively).

There was no correlation between implantation time and the ultimate load of the polyethylene at the worn surface ($r^2 = 0.00$, $p = 0.86$). At the unworn surface and subsurface locations, only weak associations between ultimate load and implantation time were observed ($r^2 = 0.14$ and 0.21 , respectively), but neither of these correlations were significant ($p = 0.16$ and 0.08 , respectively).

Ketones, with a characteristic absorbance around 1718 cm^{-1} , were found to be the primary carbonyl species present in both the worn and unworn bearing regions of Crossfire (Fig. 2). The oxidation profiles of all the samples were similar in shape and typically displayed a peak near the bearing surfaces, with a lower peak at the backside surface (Fig. 2). The maximum oxidation occurred near the unloaded bearing surface at an average depth of $0.9 \pm 0.9\text{ mm}$ (range: 0.2 to 3.0 mm).

Considerable variation was noted in the magnitude of oxidation in the retrievals (Figs. 3–4, Table 3), with the greatest range (between 0.34 and 1.64 a.u.) apparent near the surface of the unloaded bearing surface. The average peak oxidation index was lower near the worn bearing surface ($0.50 \pm 0.28\text{ a.u.}$) than near unworn surface of the liners ($0.95 \pm 0.45\text{ a.u.}$) (mean difference: 0.42 units , $p = 0.02$).

A correlation was observed between implantation time and the oxidation at the unworn surface ($r^2 = 0.41$, $p = 0.03$), but not at the worn surface ($r^2 = 0.03$, $p = 0.64$). The shelf life of the implants was not correlated with the peak oxidation at either the unworn surface ($r^2 = 0.10$, $p = 0.37$) or the worn surface ($r^2 = 0.00$, $p = 0.91$).

With one exception (see Case Study #1), the retrieved liners in this study generally showed minimal evidence of creep and wear, which was not evident without dimensional measurement. The average depth of femoral head penetration was 0.16 mm (range: 0.02 to 0.31 mm). For six components that were implanted at least one year, the average rate of femoral head penetration was $0.06 \pm 0.03\text{ mm/y}$ (range: 0.02 to 0.09 mm/y).

Case Studies

Case Study #1.—The patient in this case was a moderately active 62-year-old woman, with a UCLA activity score of 7 out of a maximum 10. She was 170 lbs, corresponding to a BMI of 30 kg/m^2 (clinically obese). This was a primary cementless total hip replacement performed in 1999 involving “mixed and matched” components, including Crossfire acetabular component and a Taperloc femoral stem with a zirconia femoral head (Biomet, Inc.; Warsaw IN). The liner had a shelf life of 2 months.

It is noteworthy that a 28 mm diameter, zirconia ceramic femoral head, fabricated by Desmarquest, was used in this case. Certain batches of zirconia femoral heads produced by Desmarquest were the subject of an international recall, due to *in vivo* phase transformations which could result in head fracture [17]. According to Biomet, none of the zirconia heads used with its Taperloc stem were included in the recall. Nevertheless, Clarke has reported that *in vivo* phase transformation may lead to surface roughening of the femoral head, with potentially adverse ramifications for clinical wear of the polyethylene [17].

The patient subsequently experienced recurring dislocations. At the time of revision, after 3.9y of implantation, the liner appeared severely worn anteriorly around the equator. However, there was no evidence of osteolysis in this case. The equatorial aspect of the wear also precluded

repeatable thickness-based wear measurements for this liner. It was also not possible to reliably measure wear for this patient using the Martell method, because the wear vector was directed superiorly and laterally, in an equatorial direction out of the cup, based on the radiographs. However, analysis of the radiographs did demonstrate that the cup was malpositioned (Inclination of $59^\circ \pm 3^\circ$) (Figure 5).

Using scanning electron microscopy (SEM), we were able to determine that the equatorial damage to the liner represented wear, not fracture. Other observations in this case included apparent failure of the locking mechanism (apparent on radiographs, Fig. 5) and surface roughening of the zirconia femoral head (average surface roughness, R_a of 85 nm), probably due to localized phase transformations, verified by white light interferometry. The initial R_a of zirconia femoral heads has been reported to range between 5 and 6 nm [17]. Moderate oxidation was observed on the unworn side of the liner (peak oxidation index = 1.6 units), but oxidation was negligible in the worn region (Fig. 6A). Small punch testing of the liner in worn regions resulted in a mean ultimate load of 96.6 N at the worn surface vs. 72.6 N at the unworn surface. Consequently, we judged that a number of factors, unrelated to the liner properties, contributed to the early revision in this complex case: malpositioning of the cup; equatorial loading of insert, with concomitant hip joint instability; failure of the insert locking mechanism; and surface roughening of the femoral head.

Case Study #2.—The second patient was a very active 56-year-old woman, with a UCLA activity score of 8. She weighed 138 lbs., corresponding to a BMI of 26 kg/m^2 . She received her primary total hip replacement in 1990, which was revised in 1999 by one of the authors (WH) using a Crossfire Omnifit liner with a 28 mm diameter, CoCr alloy femoral head. The Crossfire liner had a shelf life of 2 months. After four years, the patient presented with complaints of severe groin pain and the acetabular component was judged to have loosened. At revision surgery, after 4.8y *in vivo*, the Crossfire liner was removed. The acetabular shell was found to be grossly loose upon revision.

The cup was well-positioned with an inclination angle of $41^\circ \pm 1^\circ$. The wear surface of the liner was burnished and macroscopically indistinguishable in appearance from a conventional polyethylene liner. The penetration of the femoral head into the liner was estimated to range between 0.17 and 0.27 mm, based on thickness and radiographic measurements, respectively, corresponding to an average femoral head penetration rate of 0.04 to 0.06 mm/y.

When viewed under dark field microscopy, thin sections taken perpendicular to the worn and unworn bearing surfaces showed no evidence of white band formation. The oxidation profiles differed on both the worn and unworn sides, with moderate oxidation evident beneath the unworn bearing surface (peak oxidation index = 1.6 units, Fig. 6B). Small punch testing of the liner resulted in a mean ultimate load of 88.5 N at the worn surface vs. 85.3 N at the unworn surface. The revision of this liner for loosening was thus judged unrelated to the oxidation of the polyethylene.

Discussion

Variation in the mechanical properties and oxidation levels was observed in this series of annealed highly crosslinked liners, but the reasons underlying the variability remain unclear. We did not find evidence at the worn surface of the liners to support our hypothesis of *in vivo* degradation at that location. Nevertheless, systematically lower mechanical properties and greater oxidation was observed in unworn regions when compared with the worn locations of the liners, supporting the main hypothesis of our study. Thus, the Crossfire data collected from this study confirms our previous finding, that the femoral head partially protects the bearing surface from *in vivo* oxidative degradation [12,13]. Notably, only a small fraction of the

variability in Crossfire mechanical properties and oxidation near the unworn surface was explained by implantation time. In addition, our data did not support shelf life as a factor associated with the property variation. Because property variation was observed in control liners, as well as in liners that had been implanted for less than 1 year, our data suggest that manufacturing factors may be responsible for some of the variability in polyethylene properties in these components.

Crossfire has been shown to be wear-resistant in hip simulator studies [18] as well as clinical trials [1]. The majority of our retrieved Crossfire liners also showed evidence of reduced femoral head penetration (on average, 0.16 mm), which is a combination of wear and creep. These penetration findings were limited, however, to six retrievals from our collection with an implantation time of greater than one year.

In the two case studies, we have highlighted our “worst case scenarios” with this material over the past five years. Between 1999 and 2003, an estimated 4,220 primary procedures incorporating a Crossfire liner have been performed at our institution. An estimated eight hundred of these primary procedures were performed in 1999. As with conventional polyethylene and other formulations of highly crosslinked polyethylene [11], Crossfire is not impervious to adverse equatorial loading conditions, such as those that occurred in Case Study #1. However, although rim wear was noted, fatigue failure similar to that reported for remelted components implanted vertically [11] did not occur. Both Case Study #1 and Halley’s case involved female patients with large body mass (30 and 36 kg/m², respectively), malpositioned liners (60° and 70° inclination, respectively), and unstable hips with histories of recurring subluxations and/or dislocations. However, there were several noteworthy differences between the rim fracture reported by Halley et al. [11] and the equatorial wear observed with Case Study #1. In Halley’s case study, the CoCr femoral head diameter was 40 mm, and an extended lip liner, with an equatorial thickness of 3 mm, was used. In Case Study #1, the femoral head diameter was 28 mm, and a low profile liner was implanted. Case Study #1 had further extenuating circumstances, such as the *in vivo* phase-transformed zirconia head, and incomplete seating of the liner. Notwithstanding the differences between Halley’s report and Case Study #1, it appears that proper placement of the acetabular shell may be just as important for Crossfire Omnifit liners as it is for other polyethylene formulations and liner designs.

While the negative clinical implications of suboptimal alignment are straightforward, assessing the clinical ramifications of *in vivo* oxidation is complicated by the competing processes of wear and oxidation at the bearing surface. With conventional polyethylene liners, the worn surface may be located several millimeters deeper than the initial reference surface of the liner after ten years of implantation, complicating the interpretation of oxidation measurements. Such complications were not evident for the liners in this study, which generally exhibited reduced penetration. Consequently, the differences in oxidation and mechanical properties of Crossfire in the worn and unworn locations resulted from factors other than material removal.

Analysis of the FTIR spectra demonstrates that the ketone carbonyl groups present in Crossfire (Fig. 2) are the same primary oxidation species as is encountered in conventional gamma sterilized polyethylene [12]. The regional differences in oxidation (Figs. 2–4, and 6) suggest that the femoral head limits access of oxidizing species to the wear surface. Such a theory would explain the systematically lower oxidation in worn regions. The scenario of *in vivo* oxidation suppression by the femoral head contact is best illustrated in the retrieved liner from Case Study #2, which after 4.8 years of implantation, showed minimal wear and markedly lower oxidation profiles in worn versus unworn regions of the bearing surface (Fig 6B). In contrast with one case mentioned in a conference abstract [19], we found no evidence of severe oxidation or “white bands” in any of the regions we examined in this study.

Furthermore, our small punch test data indicate that the mechanical properties of Crossfire are insensitive to *in vivo* exposure at the bearing surface, at least for the components we evaluated in our study. We focused our analysis on the ultimate load, which in previous studies involving conventional polyethylene has been the mechanical property most sensitive to oxidation and molecular weight [12,13,20]. In components that are gamma irradiated in air, for example, severe oxidation can result in over a 90% reduction in ultimate load after ten years *in vivo* [13]. In contrast, the average ultimate load of the Crossfire liners near the unworn surface remained within 10% of their initial ultimate strength after on average 1.9 years *in vivo* (92.3 N for control vs. 83.4 N for unworn surface). However, the variability in the material properties, coupled with the relatively small sample of components that were implanted for over 1 year, underscore the importance of continuing to monitor retrieved implants fabricated from Crossfire. Many of the retrievals analyzed in this study were revised due to complications following a previous surgery, resulting in a preponderance of short-term revisions in our collection. Additional retrieval studies are necessary to quantify changes near the worn bearing surface that may occur with Crossfire liners after intermediate- and long-term implantation.

This study captured consecutively retrieved Crossfire liners at a single high volume teaching institution over a five-year period, and thus provides some insight into the early failure modes for liners of various designs fabricated from annealed highly crosslinked polyethylene. None of the liners in our series were revised for wear or osteolysis. The most common reasons for revision (aseptic loosening and instability) are typical with conventional polyethylene. In light of the positive short-term performance observed at our institution, as well as in published clinical trials, we conclude that some of the variability in polyethylene properties exhibited by annealed crosslinked liners in our study was inherent, and likely related to the manufacturing process of the liners.

The variation we observed in the properties of Crossfire was not clinically significant for any of our short-term cases, which were evaluated within 5 years of implantation. As with all novel highly crosslinked polyethylenes, the long-term clinical performance of Crossfire remains unknown. We continue to evaluate the properties of retrieved Crossfire components at our institutions and anticipate providing an update of our findings after additional components with longer implantation times have been collected and analyzed.

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Figure 1. Ultimate load measured in the small punch test at four sampling locations in the retrieved Crossfire liners.

Figure 2. Fourier transform infrared spectra in the carbonyl region of polyethylene, associated with oxidation. (A) Unworn bearing region; (B) Worn bearing region.

Figure 3.

Maximum oxidation index measured at four sampling locations in the retrieved crossfire liners. The average peak oxidation index was lower at the worn bearing surface than at unworn surface of the liners (mean difference: 0.42 units, $p = 0.02$).

Figure 4.

Average ($\pm$ SD) oxidation index profiles near the bearing surface of the retrieved Crossfire liners. The maximum oxidation index was lower at the worn bearing surface than at unworn surface of the liners (mean difference: 0.42 units, $p = 0.02$).

Figure 5.

Anterior-posterior radiographs for Case Study #1, revised after 3.9y. The shell is at an inclination angle of 59°. (A) Index radiograph and (B) 3 years post-operative. Note the fractured locking ring fragments (B), near the inferior distal aspect of the femoral neck (indicated by the arrow).

Figure 6. Oxidation index profiles for the liners retrieved in (A) Case Study #1 and (B) Case Study #2. The raw spectra for Case Study #2 are shown in Figure 2.

Table 1
Summary of Clinical and Implant Data for 12 Crossfire Retrievals (Omnifit Series II Liner Design)

Study #	Gender	Age	Weight (lbs)	BMI (kg/m ²)	UCLA Activity Score	Previous Revision	Revision Reason	Implantation Time (y)	Head Size (mm)	Head Material	Shell Size (mm)	Liner Shelf Life (y)	Liner Thickness (mm)
24	M	64	190	26	4	0	Recurrent Dislocation	0.02	28	CoCr Alloy	66	0.08	14.0
31	M	46	247	45	3	1	Recurrent Dislocation	0.29	28	CoCr Alloy	52	0.13	9.1
71	F	53	160	26	3	1	Recurrent Dislocation	0.92	28	Zirconia	52	0.09	8.5
73	M	37	205	29	4	1	Recurrent Dislocation	0.46	28	Zirconia	50	0.10	8.7
206	F	68	160	26	2	0	Recurrent Dislocation	0.67	28	N/A	52	N/A	8.9
222	M	68	250	34	4	0	Loosening	1.6	28	Zirconia	56	0.25	10.8
250	F	62	160	28	7	0	Cup Malposition, Recurring Subluxations, Eccentric Wear	3.9	28	Zirconia	48	0.17	7.5
291	F	51	149	29	4	1	Loosening of Femoral Component	2.7	28	CoCr Alloy	52	0.10	8.8
297	F	46	148	25	2	0	Loosening of Acetabular Component	1.6	28	CoCr Alloy	52	0.23	11.0
343	F	61	127	27	3	0	Acetabular Component Dislodged	3.1	28	CoCr Alloy	46	2.42	7.2
345	F	78	210	33	4	0	Recurrent Dislocation	3.3	28	CoCr Alloy	62	0.08	14.2
346	F	56	138	26	8	1	Loosening	4.8	28	CoCr Alloy	52	0.17	8.8

N/A: Not available.

Table 2 Average ultimate load ($\pm$ SD) measured by the small punch test at four

Study #	Implantation time (y)	Worn Surface	Worn Subsurface	Ultimate Load (N)	
				Unworn Surface	Unworn Subsurface
24	0.02	N/A	N/A	88.2	74.6
31	0.29	106	102.6	97	94.7
71	0.92	83.4	89.5	81.4	89.6
73	0.46	101.4	96	105	100.9
206	0.67	87.5	91.4	58.8	91.4
222	1.6	90.9	96.3	83.8	90.7
250	3.9	96.6	86.8	72.7	87.2
291	2.7	105.2	99.9	86.3	84.4
297	1.6	92.6	98.6	N/A	N/A
343	3.1	79.8	101.1	84.9	96.6
345	3.3	100.1	94.5	74.5	84.4
346	4.8	88.5	85	85.3	63.5
AVERAGE	1.9	93.8	94.7	83.4	87.1
SD	1.6	8.8	5.9	12.2	10.5

* Note: Worn or unworn regions were not observed in two retrievals

Table 3

Maximum oxidation index (OI) measured at four locations near the surface of retrieved Crossfire liners.

Study #	Implantation time (y)	Maximum OI (A.U.) Unworn Bearing	Maximum OI (A.U.) Unworn Backside	Maximum OI (A.U.) Worn Bearing	Maximum OI (A.U.) Worn Backside
24	0.02	1.05	1.42	N/A *	N/A *
31	0.29	0.34	0.49	0.75	0.27
71	0.92	1.04	0.67	0.26	0.20
73	0.46	0.37	0.94	0.48	0.35
206	0.67	1.05	0.49	0.76	0.48
222	1.57	0.66	1.06	0.41	0.38
250	3.93	1.60	0.27	0.21	0.17
291	2.72	0.89	0.26	0.29	0.24
297	1.55	N/A *	N/A *	0.24	0.76
343	3.07	0.51	0.64	0.44	0.52
345	3.26	1.32	0.24	0.54	0.15
346	4.78	1.64	0.37	1.12	0.42

* Note: Worn or unworn regions were not observed in two retrievals