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SYMPOSIUM: RETRIEVAL STUDIES

In Vivo Oxidation and Surface Damage in Retrieved Ethylene Oxide-sterilized Total Knee Arthroplasties

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Abstract

Background Gas sterilization (eg, ethylene oxide [EtO] and gas plasma) was introduced for polyethylene to reduce oxidation due to free radicals occurring during radiation sterilization. Recently, oxidation has been observed in polyethylenes with undetectable levels of free radicals, which were expected to be oxidatively stable. It is unclear whether in vivo oxidation will occur in unirradiated inserts sterilized with EtO.

Questions/purposes We analyzed the oxidation, mechanical behavior, and surface damage mechanisms of tibial inserts of a single design sterilized using EtO.

Methods We collected 20 EtO-sterilized tibial inserts at revision surgeries. We assessed oxidative using Fourier transform infrared spectroscopy and mechanical properties using the small punch test. Surface damage was assessed using damage scoring techniques and micro-CT.

Results Oxidation indexes were low and uniform between the regions. The subtle changes did not affect the mechanical properties of the polymer. The dominant surface damage modes included burnishing, abrasion, and third-body wear. There was no evidence of delamination in the retrievals.

Conclusions The retrieved EtO-sterilized UHMWPE retrievals remained stable with respect to both oxidative and mechanical properties for up to 10 years in vivo. We did observe slight measurable amounts of oxidation in the

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Each author certifies that his or her institution approved the human protocol for this investigation, that all investigations were conducted in conformity with ethical principles of research, and that informed consent for participation in the study was obtained.
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inserts; however, it was far below levels that would be expected to compromise the strength of the polymer.
Clinical Relevance Due to the stable oxidative and mechanical properties, EtO-sterilized tibial components appear to be an effective alternative to gamma-sterilized inserts, at least in short-term implantations.

Introduction

UHMWPE has been successfully used as a bearing material in TKA since the late 1960s [16]. Oxidation after gamma irradiation sterilization in air can reduce the mechanical properties by 20% to 90% depending on the severity of the oxidation [16, 17]. The primary mechanism is thought to primarily rely on the residual free radicals introduced during gamma or electron beam sterilization [7, 16]. Thus, materials with higher levels of residual free radicals (ie, conventional gamma-sterilized polyethylene) are more susceptible to oxidative degradation. To combat this oxidative mechanism, in the 1990s, implant manufacturers began using gas sterilization [20, 28], gamma sterilizing in the absence of oxygen [22], or thermal treatments [29]. Gamma sterilization in the absence of oxygen reportedly improves oxidation resistance [16], but some studies suggest it merely delays the onset of oxidation until it is removed from the packaging [10, 18, 23, 25], at which point it will begin to oxidize and degrade. Gas sterilization and remelting thermal treatments both result in undetectable levels of free radicals [16] and have previously been thought to be oxidatively stable [31, 32]. However, two recent studies reported remelted highly crosslinked UHMWPE may also oxidize despite the fact that these materials initially contain undetectable levels of residual free radicals [11, 23]. It has been hypothesized that cyclic loading, lipid absorption, or some combination of the two are potential mechanisms that alter the stability of UHMWPE [27]. It is unclear at this time whether oxidation will occur in non-highly crosslinked, ethylene oxide (EtO)-sterilized UHMWPE.

UHMWPE that has been sterilized using EtO remains relatively oxidatively stable during in vitro testing [3, 4, 7, 28]. Additionally, EtO-sterilized UHMWPE has been reported to have 37% higher fatigue strength when compared to gamma-sterilized UHMWPE [28]. However, due to the lack of crosslinking, EtO-sterilized polyethylene does not exhibit the beneficial increase in wear resistance [12]. Due to these unique properties, several researchers proposed EtO-sterilized components are particularly suitable for TKA where fatigue damage is predominant as opposed to THA where abrasive/adhesive wear is a larger concern [3, 28, 34]. Several studies have demonstrated higher toughness values [33], no evidence of fatigue damage [34], and negligible levels of oxidation [8, 34] in EtO-sterilized TKA components; however, these studies are generally short-term retrievals or limited to nonconforming, unicompartmental designs [34]. Thus, it is unclear whether in vivo oxidation will occur in unirradiated inserts sterilized with EtO.

We investigated the in vivo oxidation, mechanical properties, and surface damage mechanisms for a single design of retrieved EtO-sterilized tibial inserts. For this implant design, we asked whether (1) the oxidation and oxidation potential of retrieved EtO-sterilized tibial inserts would be greater than those of unimplanted controls; (2) mechanical properties would degrade over time; and (3) the main damage modes would be consistent with abrasive and adhesive wear mechanisms (ie, burnishing, scratching, and abrasion), as opposed to fatigue wear mechanisms (ie, delamination and pitting).

Materials and Methods

We obtained 20 tibial inserts during revision surgery at a single institution. All of the inserts were of a single design (Proven^{TM} posterior-stabilized [PS]; StelKast, Inc, McMurray, PA, USA) and were sterilized using EtO gas. After removal, the implants were cleaned using institutional procedures and quickly stored in a −80°C freezer to prevent any further ex vivo degradation until testing could be performed. Eight never-implanted StelKast Proven^{TM} PS tibial inserts were removed from their packaging and served as controls throughout the experiment.

The retrieved tibial inserts were implanted on average for 5.0 years (range, 0.5–10.0 years) (Table 1). They were mainly revised for loosening (55%), infection (20%), and further degenerative changes to the patella (15%). In five of the patients, only the polyethylene insert was revised, whereas in the remaining 15 patients, the metallic femoral and tibial components, as well as the polyethylene insert, were revised. The average age of the patients at implantation was 60 years (range, 39–77 years) and 10 of the 20 patients were male. The average weight of the patients was 101 kg (range, 54–150 kg). The patients in this study were moderately to highly active as assessed using the UCLA Activity Level Scale (average maximum UCLA score, 6; range, 4–9).

To assess damage modes, we relied on microscopic and micro-CT inspection of all retrieved inserts. Two of us (DM, PS) assessed the damage modes on all of the retrieved inserts using the scoring method of Hood et al. [15]. When investigating interobserver variability of this method, Hood et al. [15] found the mean difference of the total damage scores between the two examiners was 1.1 (SD = 11.3) for the 10 components they examined [15].

Table 1. Clinical information for the retrieved inserts

Patient number	Sex	Age (years)	Weight (pounds)	UCLA activity score	Implantation time (years)	Revision reason
15	Male	56	305	9	1.9	Infection
37	Male	39	NA	4	1.7	Patellar DJD
71	Male	75	260	6	1.7	Loosening
95	Female	64	250	NA	2.2	Patellar DJD
98	Female	77	119	5	2.3	Patellar DJD
103	Female	59	248	5	4.2	Loosening
124	Female	59	210	NA	2.6	Loosening
145	Male	47	200	7	4.7	Loosening
165	Male	51	280	7	6.7	Loosening
184	Female	62	154	6	5.3	Loosening
211	Female	68	170	NA	4.5	Infection
214	Female	75	158	NA	5.3	Infection
278	Male	62	300	7	7.6	Loosening and osteolysis
297	Male	67	210	8	8.2	Loosening and instability
336	Male	58	245	8	8.5	Loosening
367	Male	58	245	8	9.3	Varus deformity
392	Male	49	330	8	9.3	Loosening
438	Female	73	129	4	0.5	Oversized components
440	Female	39	200	4	10.0	Infection
456	Female	55	224	4	2.7	Loosening and malalignment

NA = not available; DJD = degenerative joint disease.

The condyles, backside, and post of each insert were assessed on a scale of 0 to 3 for seven distinct wear mechanisms: abrasion, delamination, scratching, burnishing, embedded debris, plastic deformation, and pitting. A score of 0 was given when the damage mode was not present; 1 was given when the damage mode was present but less than 10% of the area; 2 was given when the damage mode covered 10% to 50% of the area; and 3 was given when the damage mode covered more than 50% of the area of a zone. To assist in identification and quantification of embedded debris that was not readily identifiable by visual inspection, we examined the micro-CT datasets. Embedded debris (bone cement, bone chips, etc) has a higher attenuation coefficient than polyethylene and can therefore be easily identified and measured using the three-dimensional datasets. Embedded debris volumes were calculated by summing the voxels associated with the identified embedded debris and multiplying the sum by the known voxel volume.

To assess oxidation and hydroperoxide content, we microtomed thin slices (200 μm thick) from the medial condyle and the central spine from each of the 28 inserts (Fig. 1) for analysis using Fourier transform infrared spectroscopy (FTIR). All of the slices were subsequently boiled for 6 hours in heptane to extract lipids, which may interfere with the oxidation analysis. The slices were subsequently air dried before FTIR analysis. The slices were then scanned in 100-μm increments (32 repeat scans/location; 4-cm^{-1} wavelength resolution) perpendicular from the surface at each region of interest. Regions of interest included the articulating surface, backside surface, post, and AP faces of the insert (Fig. 1). An oxidation index was calculated from the resulting scans in accordance with ASTM F2101-06 [1]. Slices were inspected before and after heptane extraction using dark-field microscopy for the presence of white bands, which are indicative of oxidation.

To assess oxidation potential, we used FTIR to measure the hydroperoxide content of the polyethylene. Hydroperoxides are intermediaries in the cascade of reactions during oxidation and therefore represent the potential to oxidize [6]. After oxidation analysis, all slices were subjected to nitric oxide for at least 16 hours to convert all of the hydroperoxides to nitrates, which are easily identifiable using FTIR. Slices were then scanned using the same protocol as used for the oxidation analysis. A hydroperoxide index was calculated as the ratio of areas under the 1637-cm^{-1} (integration limits: 1600–1670 cm^{-1}) and 1370-cm^{-1} (integration limits: 1330–1396 cm^{-1}) peaks. All FTIR measurements were performed using a Thermo Nicolet 6700 FTIR spectroscope with a Continuum microscope attachment (ThermoFisher Scientific, Waltham, MA, USA).

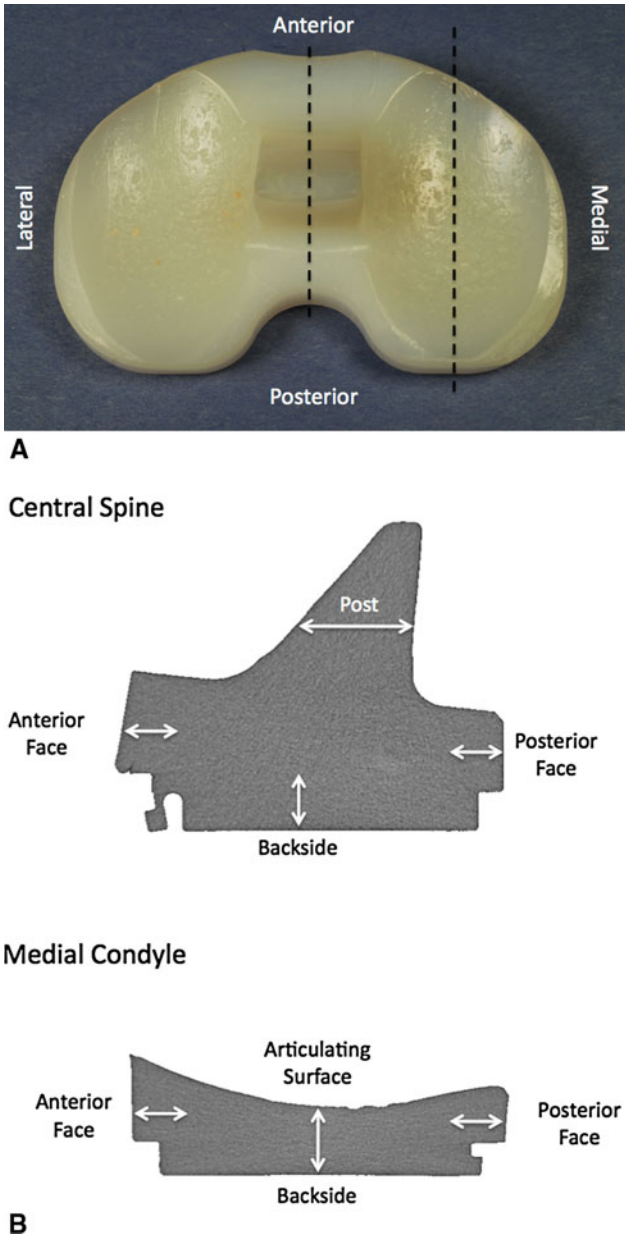

Fig. 1A–B (**A**) Tibial inserts were cut with a band saw along the dotted lines. Thin slices were then microtomed parallel to the newly exposed surfaces. (**B**) The areas of interest scanned using FTIR are shown.

There was insufficient material available for standard mechanical testing (ie, tensile testing bars); therefore, the small punch test was chosen to assess the mechanical behavior of the tibial inserts. We obtained four cores from the lateral condyle of each of the 28 inserts. Small disk specimens (6.4 mm in diameter and 0.5 mm thick) were machined at the surface (specimen depth, approximately 0–0.5 mm) and just beneath the surface of each core (specimen depth, approximately 1.0–1.5 mm), resulting in 224 small punch specimens. The specimens were then tested to failure using a standard mechanical testing system

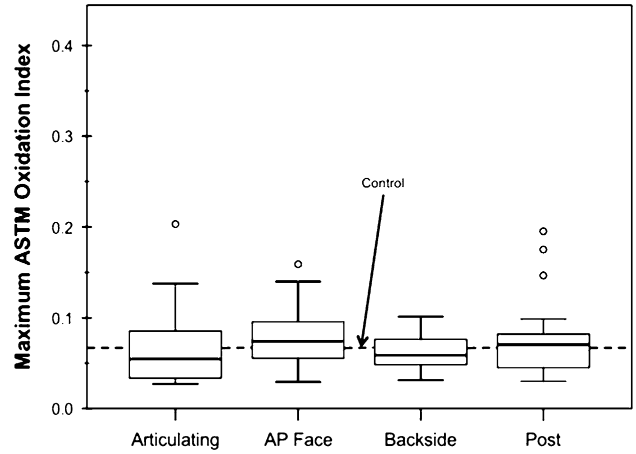

Fig. 2 Box and whisker plots show the oxidation indexes in the measured regions of the retrieved inserts. Box = the two middle quartiles of data; horizontal bar in box = median; whiskers extend to the highest and lowest values, excluding outliers (circles).

(MTS 858 Mini Bionix® II; MTS, Eden Prairie, MN, USA). Peak load, ultimate load, ultimate displacement, and work to failure were calculated in accordance with ASTM F2183 [2]. We chose the ultimate load and work to failure as important metrics as they provide insight into the ultimate strength and toughness of the material, respectively.

We assessed normality of the distributions of each continuous variable (oxidation index, hydroperoxide index, ultimate load, and work to failure) using the Shapiro-Wilk test of normality. Differences in the variables between the retrieved inserts and the control inserts were calculated using the Mann-Whitney U-test for those variables that were nonnormally distributed (oxidation and hydroperoxide indexes) and the t-test for those with normal distributions (ultimate load and work to failure). We used Friedman's ANOVA test to determine regional differences in oxidative properties within the inserts. Correlations between variables were assessed using the Spearman rank correlation test. All statistical tests were performed using PASW® Statistics 18 (SPSS, Inc, Chicago, IL, USA).

Results

In the retrieved components, oxidation indexes were low (maximum ASTM oxidation index, ~0.1) and uniform ($p = 0.075$) between the regions (Fig. 2). While we detected elevated oxidation indexes in the retrievals at the bearing surface, backside surface, and post ($p = 0.007$, $p = 0.008$, and $p = 0.025$, respectively) (Fig. 2) as compared to the controls, these differences were minute (mean difference, ≤ 0.05) (Table 2). Additionally, we observed no white banding on any of slices. The hydroperoxide indexes were low and we observed no differences between

Table 2. Maximum oxidation and hydroperoxide indexes for each region of the insert

Group	Maximum ASTM oxidation index				Maximum hydroperoxide index			
	Articulating	Backside	Post	AP face	Articulating	Backside	Post	AP face
Control (n = 8)	0.03 ± 0.01 (0.01–0.04)	0.04 ± 0.02 (0.02–0.08)	0.04 ± 0.01 (0.02–0.05)	0.06 ± 0.03 (0.03–0.10)	0.07 ± 0.04 (0.04–0.16)	0.08 ± 0.04 (0.05–0.18)	0.07 ± 0.02 (0.04–0.11)	0.10 ± 0.02 (0.08–0.14)
Retrieval (n = 20)	0.07 ± 0.04 (0.03–0.20)	0.06 ± 0.02 (0.03–0.10)	0.08 ± 0.05 (0.03–0.20)	0.08 ±0.03 (0.03–0.16)	0.10 ± 0.07 (0.03–0.28)	0.08 ± 0.04 (0.05–0.23)	0.09 ± 0.05 (0.04–0.28)	0.12 ± 0.06 (0.06–0.35)

Values are expressed as mean ± SD, with range in parentheses.

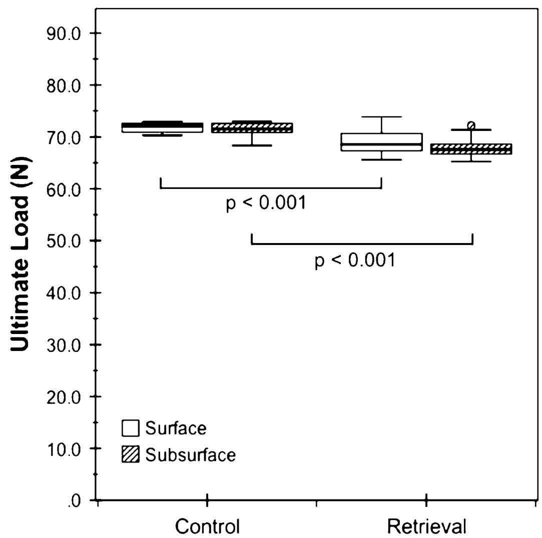

Fig. 3 Box and whisker plots show the ultimate load at the surface and the subsurface. Box = the two middle quartiles of data; horizontal bar in box = median; whiskers extend to the highest and lowest values, excluding outliers (circles).

Table 3. Mechanical properties of the inserts

Group	Ultimate load (N)		Work to failure (mJ)	
	Surface	Subsurface	Surface	Subsurface
Control (n = 8)	71.8 ± 1.0 (70.3–72.9)	71.4 ± 1.5 (68.3–72.9)	261 ± 8 (254–271)	260 ± 8 (250–275)
Retrieval (n = 20)	69.1 ± 2.4 (65.6–73.9)	67.8 ± 1.8 (65.2–72.2)	254 ± 8 (238–267)	250 ± 7 (239–263)

Values are expressed as mean ± SD, with range in parentheses.

Table 4. Summary of the surface damage mechanism scores

Mechanism	Mean score		
	Condyle	Backside	Post
Abrasion	2	0	2
Burnishing	6	1	3
Delamination	0	0	0
Embedded debris	2	0	0
Pitting	16	7	2
Scratching	14	3	3
Surface deformation	1	0	3

the retrieval and control samples at any location ($p = 0.542$, $p = 0.509$, $p = 0.799$, and $p = 0.203$ for the bearing, AP face, backside, and post, respectively). Neither the oxidation index nor the hydroperoxide index of the retrievals correlated with implantation time at any location.

At both the surface and the subsurface, the ultimate load of the retrievals was reduced when compared to the controls ($p < 0.001$ and $p < 0.001$, respectively) (Fig. 3). While the ultimate load dropped by approximately 5% in retrievals, there was no correlation with implantation time at the surface (Spearman's $\rho = 0.0120$; $p = 0.960$) or the subsurface (Spearman's $\rho = -0.429$; $p = 0.059$). We also observed a drop in the work to failure of the retrievals at the subsurface (mean difference = 10 mJ; $p = 0.001$) (Table 3) when compared to the control specimens, but this was not evident at the surface ($p = 0.054$). Similarly, at the subsurface, we were able to discern a negative correlation with implantation time and work to failure (Spearman's $\rho = -0.460$; $p = 0.048$). This correlation was not observed at the surface.

The main damage modes present on the condyles were scratching (mean score = 14 of 24), burnishing (mean score = 6 of 24), and what appeared to be pitting (mean score = 16 of 24) (Table 4). The medial condyle tended to have (statistically nonsignificant) higher damage scores than the lateral condyle. Under inspection of the micro-CT datasets, 18 of 20 of the inserts had evidence of embedded debris that could not be seen using only visual inspection (Fig. 4). Substantial amounts of embedded debris were identified on both the backside and condyles of the inserts (embedded debris mean volume = 0.04 mm^3 and 0.24 mm^3, respectively). The volume of embedded debris on the condyles was positively correlated with the total condyle pitting damage score (Spearman's $\rho = 0.666$, $p = 0.001$). Using the three-dimensional datasets, we also observed severe abrasion (abrasion depths up to 4.8 mm) on the medial and/or lateral edge of the tibial inserts on nine of 20 of the inserts. This was presumably due to bone or bone cement overhanging the femoral component, thus creating a new, rougher articulating surface against the polyethylene component. On the backside of the inserts, the main

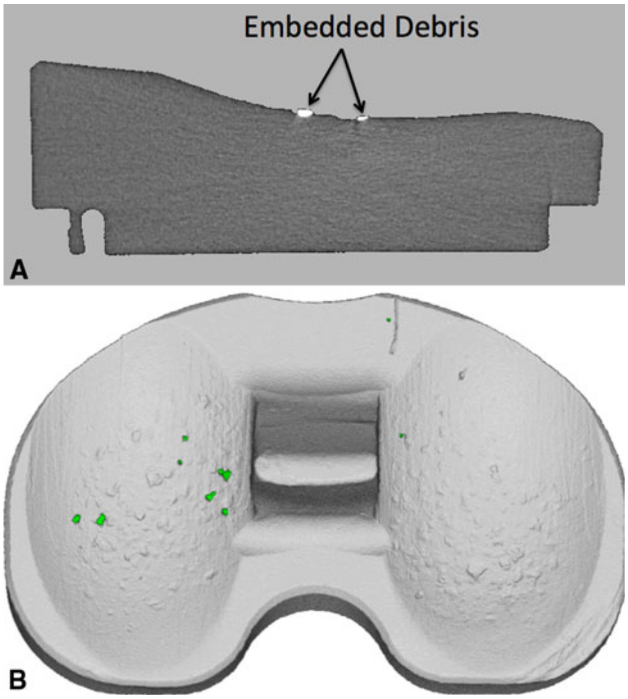

Fig. 4A–B (**A**) A micro-CT slice illustrates large pieces of embedded debris. (**B**) On a three-dimensional micro-CT reconstruction of a retrieved tibial insert implanted for 9.3 years, the green areas represent embedded debris.

damage modes were scratching and pitting. It is noteworthy that no delamination was observed anywhere on any of the inserts.

Discussion

Gas sterilization was introduced for polyethylene sterilization to reduce oxidation due to residual free radicals occurring during radiation sterilization. Recently, oxidation has been observed in polyethylenes with undetectable levels of free radicals, which were expected to be oxidatively stable. It is unclear whether in vivo oxidation will occur in unirradiated inserts sterilized with EtO. Therefore, we investigated the in vivo oxidation in unirradiated UHMWPE. Due to the lack of free radicals, these materials were presumed stable. We asked whether (1) the oxidation and oxidation potential of retrieved EtO-sterilized tibial inserts would be greater than those of unimplanted controls; (2) mechanical properties would degrade over time; and (3) the main damage modes would be consistent with abrasive and adhesive wear mechanisms, as opposed to fatigue wear mechanisms.

This study has several limitations. First, we only assessed damage modes and did not measure actual wear of the component. Since EtO-sterilized components are expected to wear more, this confounds the oxidation analysis as the wear process possibly occurs faster than the oxidation process. Evaluation of wear in TKA remains difficult due to the nonuniform geometries of the articulating surface. It is well understood that high damage scores do not always correlate with high volumes of wear. However, the focus of this investigation was to explore which damage modes were present to expand the knowledge of in vivo wear mechanisms of gas-sterilized UHMWPE. Second, we only inspected the oxidative properties of the medial condyle and central spine and the mechanical properties of the lateral condyle. While it is preferable to obtain the oxidative and mechanical properties of the entire insert, this was not possible due to the limited material of the inserts. Additionally, we did assess the damage modes on the entirety of all inserts. Finally, we analyzed retrieved components, which means this study was comprised of failed components. While we have no way of knowing how well-functioning inserts oxidize in vivo, we are aware of no mechanism in which well-functioning inserts would oxidize in a manner substantially different from that of retrieved components.

We found subtle increases in oxidation index in areas that undergo repeated loading (ie, the condyle, backside, and post). This is similar to the subtle increases seen in a recent study of highly crosslinked remelted polyethylenes [11]. The differences between the retrieved EtO-sterilized components and the control components in this study were low and not anticipated to have any adverse implications for the performance of the inserts. This is similar to previous reports where EtO-sterilized components exhibited little or negligible levels of oxidation [4, 6–8, 28, 30, 34]. These are mainly short-term retrieval studies or in vitro studies. The most comprehensive retrieval study found low levels oxidation of the EtO-sterilized inserts; however, oxidation analysis was limited to a nonconforming design [30]. The oxidation levels seen in these retrievals are substantially lower than those of historical and contemporary gamma-sterilized tibial inserts, as previously reported (Table 5) [25]. Similarly, previously reported [25] hydroperoxide indexes were higher in historical retrievals and conventional retrievals than in the EtO-sterilized components (Table 5). Therefore, at this time, there appears to be little clinical importance of this oxidation in the first decade of service for EtO-sterilized tibial inserts.

We detected a slight but statistically significant decrease in both the ultimate load and work to failure in our retrieved components as compared to the unimplanted controls. However, the reduction in both metrics was 5% or less of the exemplar values. Previous studies have suggested absorbed lipids have a plasticizing effect on UHMWPE [14, 16] and can slightly reduce the mechanical properties of the polymer. This effect reportedly decreased mechanical properties by as much as 7.9% [16], which is greater than what we observed in this study. While the

Table 5. Comparison of key variables in this study and from the literature

Study	Sterilization modality	Joint location	Average implantation time (years)	ASTM oxidation index*	Hydroperoxide index*	Surface ultimate load (N)	Surface work to failure (mJ)
Medel et al. [25]	Gamma in air	Knee	12.3	3.1	1.7	NA	NA
Medel et al. [25]	Gamma in inert gas	Knee	4.0	0.5	0.4	NA	NA
Williams et al. [34]	Ethylene oxide	Knee	12.2	0.02†	NA	NA	NA
Sutula et al. [30]	Ethylene oxide	Hip/knee	7.9	Negligible	Negligible	NA	NA
Kurtz et al. [17]	Gamma in air	Hip	11.5	2.1	NA	53.1	166
Current study	Ethylene oxide	Knee	5.0	0.08	0.12	69.1	254

* Maximum average index regardless of location; †calculated using ketone peak heights; an index of 0.02 calculated using this method is an oxidation index of approximately 0.04 when measured using the ASTM method; NA = not available.

subsurface work to failure was negatively correlated with implantation time, the work to failure of these retrievals was approximately 20% higher (even at 10 years) when compared to unaged gamma-sterilized control UHMWPE specimens in previous studies [13, 19]. In a study of 16 retrieved gamma-sterilized-in-air hip retrievals implanted on average for 11.5 years, the work to failure at the subsurface was extremely variable (range, 1–34 mJ) [17] and almost 30% lower, on average, than the components in this study.

The main damage modes we observed were scratching, burnishing, and pitting. Previously, one study found EtO-sterilized components had small amounts of burnishing abrasion, cold flow, and two cases of minor delamination, whereas 13 of 18 gamma-sterilized components had evidence of severe delamination [33]. In a study of 32 EtO-sterilized components, Williams et al. [34] found the EtO bearings showed no evidence of delamination or cracking, even at in vivo durations of up to 15 years. Pitting has traditionally been thought of as a fatigue wear mechanism [16, 21, 26], but it has more recently been thought to have two distinct etiologies. The second cause is thought to occur from third-body particulates entering the joint space and subsequently becoming embedded in and removed from the polyethylene during normal articulation [5, 9, 24, 26]. Given the prevalence of embedded debris in the polyethylene in this series of tibial inserts, we believe the pitting is due to the latter mechanism. This is a particular concern as this wear mode is anticipated to increase the volume of wear by as much as an order of magnitude [24].

In conclusion, the retrieved EtO-sterilized UHMWPE retrievals for the Proven™ knee remained stable with respect to both oxidative and mechanical properties for up to 10 years in vivo. We did observe slight measurable amounts of oxidation in the inserts; however, it was far below a level that would be expected to compromise the strength of the polymer. Additionally, the predominant damage modes were adhesive/abrasive and third body in etiology with no evidence of delamination. This is considered preferable in TKA where fatigue wear has been a concern due to the elevated contact stresses. Further research will be useful to track the progression of the Proven™ knee into its second decade of service.

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