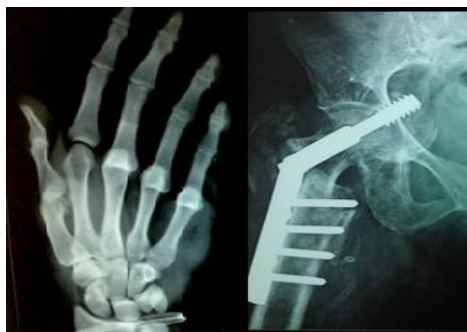




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Clinical performance of sequentially irradiated and annealed highly cross-linked polyethylene tibial bearings: A retrieval analysis of 439 devices

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Abstract

Background: Ultra-high-molecular-weight polyethylene (UHMWPE) remains the bearing surface of choice in total knee arthroplasty (TKA), yet oxidation and wear can lead to failure. Highly crosslinked, sequentially annealed polyethylene (X3, Stryker) was designed to resist oxidation, but its long-term *in vivo* performance remains debated.

Methods: We analysed 439 retrieved X3 tibial inserts (mean time in situ [TIS] 4.35 years; range 0-15.2). Surgeons provided patient and implant data at revision. Bearings underwent visual inspection, white banding assessment, Fourier transform infrared spectroscopy (FTIR; ketone index, KI), and small punch testing (SPT). Logistic regression evaluated associations between patient/implant factors and failure modes.

Results: Pain (36.9%), infection (29.1%), and instability (26.4%) were the main revision reasons. Infection was associated with male sex and higher weight ($p < 0.001$, $p = 0.04$). Instability was more frequent in women (odds ratio [OR] 2.49; 95% CI 1.55-3.86; $p < 0.001$). Thirty-nine bearings fractured (10.1%); women had a markedly increased fracture risk (OR 4.94; 95% CI 1.9-12.7; $p < 0.001$). Longer TIS raised fracture odds by 32.1% per year (95% CI 19.8-45.7; $p < 0.001$). SPT showed progressive decline in work to failure, dropping below 200 mJ after approximately 7 years. KI rose with TIS ($p < 0.001$), and each additional year increased odds of visual oxidation by 66.8% (95% CI 49.3-86.3).

Conclusion: Sequentially annealed, non-remelted UHMWPE (X3) shows progressive *in vivo* oxidation with mechanical deterioration after approximately 7 years. Fracture risk is significantly higher in women and with longer implantation time. Retrieval analysis can identify patient groups at risk for early polyethylene failure and inform strategies to reduce revision rates.

Keywords: X3 polyethylene, knee arthroplasty, sequentially cross-linked and annealed polyethylene, revision arthroplasty, retrievals

Introduction

Ultra-high molecular weight polyethylene (UHMWPE) has been used as a bearing surface in joint arthroplasty since 1962 because of its high mechanical strength and excellent wear resistance [1]. Despite this, the generation of wear debris over time can provoke adverse biological responses, most notably osteolysis and aseptic loosening, ultimately resulting in revision surgery [2]. With the increasing demand for total knee arthroplasty (TKA), particularly in younger and more active patients, reducing polyethylene wear has remained a key priority for researchers and orthopaedic manufacturers [3].

The introduction of first-generation highly crosslinked UHMWPE in the late 1990s led to significant reductions in wear. Crosslinking, typically achieved through gamma irradiation at doses of 50-100 kGy, creates carbon-carbon bonds between polyethylene chains, increasing wear resistance [4, 5]. However, the irradiation process also generates free radicals primarily through the breaking of C-H bonds which can drive oxidative degradation of the material. Early sterilisation methods involving gamma irradiation in air exacerbated this issue, with shelf ageing and mechanical embrittlement observed in numerous retrievals [6, 7]. As a result, manufacturers shifted toward thermal treatments to mitigate oxidation by reducing free radical content.

Two approaches: annealing and remelting are commonly used, each offering trade-offs between oxidative stability and mechanical performance^[8].

While highly crosslinked UHMWPE was rapidly adopted in hip arthroplasty, its use in TKA was initially limited due to concerns regarding its reduced ductility and fatigue resistance under the complex loading patterns of the knee^[9]. To address these concerns, Stryker Orthopaedics (Michigan, USA) introduced a second-generation crosslinked polyethylene known as X3 in 2005. X3 is produced by three sequential cycles of gamma irradiation (30 kGy per cycle, total 90 kGy), each followed by annealing at 130 °C for 8 hours. This sequential treatment aims to maximize crosslinking while more effectively eliminating free radicals, thus producing a material with both high oxidative resistance and improved mechanical performance. Sterilisation is performed using gas plasma, eliminating the risk of further radical generation^[10, 11]. Accelerated ageing tests have demonstrated the oxidative stability of X3. However, our earlier retrieval study in 2015, involving 15 X3 tibial bearings, raised concerns about potential early oxidative degradation of the material *in vivo*^[12]. We hypothesised that early *in vivo* oxidation of the X3 material may be occurring because of retained free radicals and that the UHMWPE specification, combined with patient-related variables, contributes to the observed oxidative degradation. The present work was designed based on the principle that retrieval analysis gains meaning through cumulative evidence, with our first publication leading to the working hypothesis. This present study seeks to determine if there is a systematic failure mode for a larger number of retrievals presenting over a longer predetermined time, thus confirming or refuting the working hypothesis. The potential outcomes of such investigations are that recurring trends across small well-described cohorts can reveal clinically relevant material or design issues or potentially patient cohorts at risk. In this follow-up multicentre study, we examine 439 retrieved X3 tibial inserts collected from 2008 to 2022.

Materials and Methods

A total of 439 Stryker X3 tibial bearings were collected over a 14-year period (2008-2022). At the time of revision surgery, a surgeon-generated retrieval report including patient and implant characteristics was completed. The implant retrievals were collected from 63 surgeons from nine institutions across Western Australia. According to the Australian National Joint Replacement Registry, 4055 Triathlons have been revised. The 439 X3 tibial bearings collected in our centre represent roughly 10% of the total Triathlon retrievals in Australia, corresponding to the approximate size of the population of Western Australia compared to Australia^[13]. The high number of retrievals we have received is due to the high compliance of the surgeons in retrieval analysis. The following predetermined methodology for analysis was carried out.

Visual Assessment

All bearings underwent prospective visual inspection and stereomicroscopic macroanalysis (Leitz MZ80, Leitz, Germany). Wear was graded using the Hood method^[14]. Evidence of oxidation, such as white banding, cracking, subsurface delamination, or fracture was documented.

Based on initial visual oxidative assessment, 92 retrieved bearings were further evaluated by: (1) white banding (WB) assessment, (2) Fourier Transform Infrared spectroscopy

(FTIR), and (3) small punch testing (SPT). The FTIR and SPT were calculated according to the American Society for Testing and Materials: ASTM F2102-01 and ASTM F2183-02, respectively. This number represented a minimum of 3 devices for each 2-year period starting at 1 year and not including the final year, which strikes a pragmatic balance between achieving significance and managing available resources. Specimens were received in a sealed container, processed in the laboratory and then stored in the dark in a -18°C freezer until testing was performed.

White Banding Assessment and Fourier Transform Infrared Spectroscopy

A sagittal cut was made through the bearings using a Buhler Saw (Buehler, Lake Bluff, IL, USA). Thin sections (200 µm), were then obtained using new, sharp microtome blades (Polycut S, Reichert Jung, Germany). Thin sections were utilized for both WB and FTIR analyses.

The oxidation level in each bearing, determined through absorbance spectra, was measured with FTIR (Thermo Scientific, Nicolet iN10 Mx, Thermo Fischer, USA). Oxidation assessments were conducted as a function of depth on a cross-section of each tibial bearing. 64 scans per 50-µm depth interval, with a wavelength interval of 8 cm⁻¹ and an aperture of 150 µm² were taken. The analysis of oxidation in the X3 samples was carried out based on ASTM F2102-01. The oxidation index (OI) is defined as the ratio of the area of the carbonyl absorption peak (s) centred near 1720 cm⁻¹ to the area of the absorption peak (s) near 1370 cm⁻¹. However, this method has faced criticism due to potential overestimation of OI from absorbed lipids during component implantation, hence, the oxidation of each sample was determined by ketone peak height rather than OI as specified in the standard^[15]. The reported oxidation level of each thin section was defined as the measured ketone (1718 cm⁻¹) peak height (KI) normalized to the 1368 cm⁻¹ peak height; a KI value above 1.2 is considered an indicator of oxidation^[16, 17]. This approach enables a separate evaluation of absorbed species (ester, 1738 cm⁻¹) and oxidation products in assessing bearing oxidation.

Small Punch Testing

Small punch testing was conducted to evaluate the natural mechanical characteristics of the retrieved UHMWPE bearings. Preparations of disc-shaped specimens measuring 6.35mm in diameter and 0.50mm in thickness were obtained from core samples taken perpendicular to the articular surface. These specimens were subjected to testing in accordance with ASTM F2183 using an Instron 5566 (Instron, Massachusetts, USA) materials testing machine. Among the properties assessed, work to failure is deemed a reliable measure to evaluate oxidative degradation, reflecting the intrinsic toughness of the polymer^[18]. Testing in our Laboratory involving 100 samples, in conjunction with visual inspection and oxidation readings, indicates that work to failure values below 200mJ are suggestive of significant oxidative degradation. It is important to note that this test may potentially overstate the actual mechanical attributes in a retrieved device because sections cannot be obtained in regions of delamination or white banding^[12].

Data Analyses

Data were summarized using mean and standard deviation (SD), median and first to third quartiles (Q1, Q3), or counts and proportions as appropriate. Infection, loosening, and

brittle fracture were analysed as binary outcomes. Associations of those outcomes with patient and implant characteristics were assessed with logistic regression models using robust error estimation to account for multiple units within the same patient. Age at implantation was treated as a confounder, particularly with weight, and models adjusted for age at implantation.

For the subsample of units where mechanical testing was conducted, consistency of work till failure measurements within units was assessed with the Intra Class Correlation coefficient from a random intercept model. A linear mixed model with a breakpoint was fit to the measurements to estimate the time in situ at which the work till failure plateaus. All analyses were performed using R Statistical Software (v4.3.1; R Core Team 2023) and statistical significance was set at $P < 0.05$.

Results

The presented results and analysis are based solely on retrievals, meaning it includes only those implants that were revised and subsequently available for examination. As such, all percentages and trends noted reflect the subset of patients who experienced failure, not the broader population of all patients who underwent knee replacement. As such, the findings represent the relative frequency of failure modes among failed implants, not the absolute risk of failure in the general arthroplasty population. However, the data does provide an insight into the complications and damage patterns that are most common when failure occurs.

Patient Demographics

Table 1 summarizes patient characteristics. Of the total 439 X3 tibial bearings, 192 were retrieved from men and 204 from women with an average implantation age of 4.35 years (range 0.1-15.2 years). Some patients underwent bilateral TKA and contributed more than one retrieval. The average patient age was 67.9 years. Male weight was on average 14.47 kg more than female weight (95%CI:19.35,9.59; $p < 0.001$). BMI was almost identical. Pain (36.7%) was the most common reason for removal, followed by infection (28.9%) and joint instability (26.2%).

A negative association was detected between age at implantation and loosening ($p = 0.047$); with every 5 years, the odds of loosening decrease by 11.4% (95%CI: 0.2,21.3). Sex was also strongly associated ($p < 0.001$) with infection; men had 2.63 times higher odds of infection compared to women (95%CI:1.65,4.19). A strong association was detected between joint instability and sex ($p < 0.001$); women were associated with 2.49 times higher odds of joint instability compared to men (95%CI:1.58,3.92). After adjusting for age at implantation, an association with weight was detected ($p = 0.029$); with every 5 kg of increase in weight, the odds of infection increased by 8.7% (95%CI:0.9,17.2).

Implant factors

Table 2 summarizes implant characteristics. The average age of implantation was 4.35 years (range 0.1-15.2 years). No association was detected between fixation and infection ($p = 0.052$). A strong association was detected between the knee type and loosening. Relative to Cruciate Retaining, Posterior Stabilized knees had 3.79 times higher odds of loosening (95%CI:1.97,6.35; $p < 0.001$) in the retrieval group. Table 3 summarizes patient characteristics by fracture status. A multivariable model for fractures was used (Table 4). Women were associated with a 4.94-fold increase in the odds

of a fracture (95%CI:1.9,12.7; $p < 0.001$). No association was detected between fracture and activity level ($p > 0.05$).

Mechanical Properties

A total of 92 samples were tested using the small punch test to determine the average work to failure. Fig. 1 shows the data fitted with a lowess curve, revealing a strong decreasing trend up to 7 years. Beyond this point that, work to failure did not significantly further decrease. The consistency of the repeated measurements was evaluated using a null linear mixed model and intra-class correlation coefficient. Up to 7.57 years, work till failure decreased by 9.09 mJ per year (95%CI:-12.0,-6.18; $p < 0.001$). Thereafter, no significant association with time in situ (TIS) was detected ($p = 0.572$).

Fig. 2 depicts a positive relationship between TIS and the ketone index (KI). A KI value above 1.2 is considered an indicator of oxidation (12). Regarding visual oxidation and patients' characteristics (table 5), only TIS was strongly positively associated ($p < 0.001$) with visual oxidation. On average, with each year of TIS, the odds of Visual Oxidation increased by 66.8% (95%CI:49.3,86.3).

Discussion

Over several decades, manufacturers have strived to improve implant materials and designs in order to enhance knee implant performance and reduce implant failures. The tibial insert is the component at most risk of failure due to its inherent material [19]. In 2005, a second-generation material, X3, was introduced in knee arthroplasty by Stryker Orthopaedics. This material, which is sequentially irradiated and annealed, has been reported to have a reduction in wear of 58% compared to single-stage irradiated and annealed materials [11, 20]. Despite several reports having demonstrated that the X3 material exhibited significantly less oxidation than first-generation materials, there continues to be controversy regarding the long-term oxidation and hence performance of this material [5, 12, 21].

This study was instigated in response to our earlier investigation in 2015, which suggested early oxidative degradation of the X3 material may be occurring. Our retrieval laboratory has continued to receive revised X3 tibial implants, including a significant number that have fractured ($N = 39$). Having collected data over 14 years from 439 X3 tibial retrievals along with patient and implant data with an average time *in vivo* of 4.35 years (range 0.1-15.2 years), it was aimed to further elucidate the long-term performance and the effects of patient and materials specification on the X3 material.

According to the 2023 Australian Orthopaedic Association National Joint Replacement Registry Report, triathlon CR has been the most used knee since 2019 and has a cumulative revision rate of just 4.7 (4.2,5.2), which underlies its excellent clinical performance (13). Our data did however, indicate a strong association between TIS and visual oxidation ($p < 0.001$), with an increase in the odds of visual oxidation of 66.8% (95%CI:49.3,86.3) with each year of implantation for retrieved devices. Oxidative degradation of the UHMWPE represents one of the main failure reasons for total knee implants [22, 23]. The average life span of UHMWPE tibial inserts is estimated at 15-20 years, being strongly influenced by its deterioration grade. FTIR represents the experimental method of choice for the oxidation process identification in polymeric materials [24]. Currier *et al.* have also shown that a KI value of 1.2 reduces mechanical properties in gamma irradiated polyethylene and therefore is considered the point

at which oxidation has a clinical consequence ^[17]. Oxidation can also be measured as OI and can be calculated as KI x 1.9, according to the UHMWPE Biomaterials Handbook ^[25].

We observed a positive relationship with TIS and KI ($p<0.001$), Table 5. On average, with each additional year, the odds of visual oxidation increased by 66.8% (95%CI:49.3,86.3). Fracture was observed in 39 tibial components. We observed, longer TIS was associated with higher risk of fracture ($p<0.001$); with each additional year, the odds of fracture increased by 32.1% (95%CI:19.8,45.7; $p<0.001$). Analysis of the patient cohort highlighted a 4.94-fold increased risk of PE fracture for heavier women (95%CI:1.9,12.7; $p<0.001$). MacDonald *et al.* analysed 345 X3 tibial implants and found 6 posterior fractures of the tibial insert. In their Gama Inert control group of 111 tibial retrievals, no fractures were found. Patient sex and characteristics were not included ^[26]. Sonn *et al.* and Teeter *et al.* have also observed posterior fractures of the X3 tibial insert. In these cases, patient characteristics were indeed provided, with both cases occurring in female patients with BMI>30 ^[27, 28].

Our results depict a decreasing trend of work to failure up until approximately 7 years. Hereafter, the average work to failure was below 200 mJ, which is indicative of oxidation ^[12].

Given the overall excellent performance of X3 tibial inserts reported in national joint registries, we hypothesized that failures may be more prevalent in specific patient subgroups. Although *in vivo* oxidation of the X3 material has been documented, its effect on implant performance remains unclear ^[26]. Our retrieval analysis demonstrated a strong association between joint instability and sex, with women exhibiting significantly higher odds of instability compared to men. Increased joint instability is likely to result in elevated localized contact stresses on the posterior bearing surface, contributing to cumulative fatigue damage on the posterior condyles. In the presence of oxidative degradation, this damage may predispose the material to fracture.

The combined results from the retrieval analysis indicate that non-remelted polyethylene's, such as the X3 material, may undergo oxidation *in vivo* which is likely attributed to the retention of free radicals post the annealing heat treatment. The exact role of applied load, the *in vivo* environment and its effect on oxidation however remains to be fully understood. Clinically relevant degradation of the X3 tibial bearings was observed and is thus a cause for concern, whilst the working hypothesis of a susceptibility of the material to *in vivo* oxidation appears confirmed.

Limitations of this study include the lack of complete patient data associated with the retrieved implants and the absence of a control group. In spite of these limitations, analysing retrieved components remains the primary method to gain insight into the failure mechanism of implants in clinical settings.

Due to the predicted substantial worldwide increase in the demand for TKA, implant retrieval appears the gold standard for elucidating material causes for revision and in doing so, it is hoped to reduce the burden on patients, reduce revision rates and health care costs. In addition to demand, patient demographics are changing, with increasing numbers of young, active, and more obese patients receiving TKA ^[3]. This study demonstrates that retrieval data can be useful to identify commonality in failure modes which may be useful in predicting if a patient cohort is at risk of early failure, which

ultimately may reduce revision rates.

Table 1: Summary of patient characteristics

	W (N=204)	M (N=192)	Overall (N=396)
Age			
Mean (SD)	68.1 (10.4)	67.6 (9.14)	67.9 (9.78)
Median [Q1, Q3]	68.0 [61.0, 76.0]	68.0 [61.0, 74.0]	68.0 [61.0, 75.0]
[Min, Max]	[31.0, 98.0]	[45.0, 95.0]	[31.0, 98.0]
Missing	1 (0.5%)	0 (0%)	1 (0.3%)
Weight			
Mean (SD)	83.8 (18.4)	98.4 (20.5)	90.9 (20.8)
Median [Q1, Q3]	81.5 [70.3, 95.0]	96.0 [83.0, 108]	90.0 [77.8, 102]
[Min, Max]	[33.0, 146]	[65.0, 165]	[33.0, 165]
Missing	78 (38.2%)	71 (37.0%)	149 (37.6%)
Height			
Mean (SD)	162 (8.99)	178 (6.68)	170 (11.3)
Median [Q1, Q3]	163 [157, 167]	178 [175, 183]	170 [162, 178]
[Min, Max]	[113, 184]	[162, 197]	[113, 197]
Missing	95 (46.6%)	84 (43.8%)	179 (45.2%)
BMI			
Mean (SD)	31.5 (6.68)	31.4 (6.19)	31.5 (6.43)
Median [Q1, Q3]	30.7 [26.2, 35.4]	31.0 [27.1, 34.6]	30.9 [26.4, 35.3]
[Min, Max]	[19.2, 57.0]	[20.1, 51.3]	[19.2, 57.0]
Missing	94 (46.1%)	83 (43.2%)	177 (44.7%)
BMI_category			
Normal	15 (7.4%)	15 (7.8%)	30 (7.6%)
Overweight	34 (16.7%)	34 (17.7%)	68 (17.2%)
Obese I	31 (15.2%)	33 (17.2%)	64 (16.2%)
Obese II	18 (8.8%)	18 (9.4%)	36 (9.1%)
Obese III	12 (5.9%)	9 (4.7%)	21 (5.3%)
Missing	94 (46.1%)	83 (43.2%)	177 (44.7%)
Activity			
Low	45 (22.1%)	24 (12.5%)	69 (17.4%)
Moderate	81 (39.7%)	79 (41.1%)	160 (40.4%)
High	61 (29.9%)	69 (35.9%)	130 (32.8%)
Missing	17 (8.3%)	20 (10.4%)	37 (9.3%)

[BMI=body mass index; W=women; M=men; N=total number; Q=quartile; SD=standard deviation]

Table 2: Summary of implant characteristics

	Overall (N=439)
Insitu	
Mean (SD)	4.38 (3.53)
Median [Q1, Q3]	3.30 [1.40, 7.00]
[Min, Max]	[0, 17.0]
Missing	2 (0.5%)
Implant Classification	
Cruciate Retaining	217 (49.4%)
Cruciate Substitution	106 (24.1%)
Posterior Stabilised	111 (25.3%)
Missing	5 (1.1%)
Manufacturer	
OSTEONICS	28 (6.4%)
STRYKER	410 (93.4%)
STRYKER; ORTHOMED	1 (0.2%)
Fixation	
Cemented	157 (35.8%)
Uncemented	79 (18.0%)
Hybrid	60 (13.7%)
Missing	143 (32.6%)
Side	
Left	207 (47.2%)
Right	230 (52.4%)
Unknown	2 (0.5%)

[N=total number; Q=quartile; SD=standard deviation]

Table 3: Brittle Fracture: Summary of the patient characteristics by fracture status.

	Fractured (N=39)	Not Fractured (N=400)	Overall (N=439)
Age at implantation			
Mean (SD)	63.1 (9.25)	63.7 (9.81)	63.6 (9.76)
Median [Min, Max]	64.9 [40.3, 82.1]	63.0 [30.4, 92.0]	63.1 [30.4, 92.0]
Missing	0 (0%)	3 (0.8%)	3 (0.7%)
In situ			
Mean (SD)	7.77 (3.09)	4.05 (3.40)	4.38 (3.53)
Median [Min, Max]	8.00 [1.80, 14.0]	3.00 [0, 17.0]	3.30 [0, 17.0]
Missing	0 (0%)	2 (0.5%)	2 (0.5%)
Sex			
W	31 (79.5%)	191 (47.8%)	222 (50.6%)
M	8 (20.5%)	209 (52.3%)	217 (49.4%)
Weight			
Mean (SD)	86.3 (15.2)	91.5 (20.9)	90.9 (20.5)
Median [Min, Max]	84.5 [65.0, 127]	90.0 [33.0, 165]	90.0 [33.0, 165]
Missing	11 (28.2%)	149 (37.3%)	160 (36.4%)
Height			
Mean (SD)	166 (5.77)	171 (11.7)	170 (11.3)
Median [Min, Max]	166 [157, 185]	171 [113, 197]	170 [113, 197]
Missing	14 (35.9%)	181 (45.3%)	195 (44.4%)
BMI			
Mean (SD)	31.5 (5.25)	31.4 (6.41)	31.4 (6.29)
Median [Min, Max]	32.9 [23.2, 41.5]	30.7 [19.2, 57.0]	30.8 [19.2, 57.0]
Missing	14 (35.9%)	179 (44.8%)	193 (44.0%)
BMI categories			
Normal	2 (5.1%)	31 (7.8%)	33 (7.5%)
Overweight	10 (25.6%)	68 (17.0%)	78 (17.8%)
Obese I	8 (20.5%)	64 (16.0%)	72 (16.4%)
Obese II	3 (7.7%)	39 (9.8%)	42 (9.6%)
Obese III	2 (5.1%)	19 (4.8%)	21 (4.8%)
Missing	14 (35.9%)	179 (44.8%)	193 (44.0%)
Activity			
Low	11 (28.2%)	66 (16.5%)	77 (17.5%)
Moderate	14 (35.9%)	158 (39.5%)	172 (39.2%)
High	11 (28.2%)	138 (34.5%)	149 (33.9%)
Missing	3 (7.7%)	38 (9.5%)	41 (9.3%)

[BMI=body mass index; W=women; M=male; N=total number; SD=standard deviation]

Table 4: Multivariable model for fractures

Parameter	Estimate	Std. Error	z value	2.5%	97.5%	p-value
(Intercept)	-5.0052	0.5982	-8.3668	-6.1777	-3.8327	0.0000
Sex female	1.5980	0.4822	3.3142	0.6530	2.5430	0.0009
In situ	0.2788	0.0499	5.5815	0.1809	0.3766	0.0000

Table 5: Univariable association with visual oxidation

Variable	Estimate	Std. Error	z value	2.5%	97.5%	p-value
Time in situ	0.5115	0.0564	9.0767	0.4010	0.6219	<0.001
Sex male	-0.3206	0.2498	-1.2833	-0.8101	0.1690	0.199
Weight	-0.0004	0.0066	-0.0643	-0.0134	0.0126	0.949
BMI	0.0225	0.0242	0.9266	-0.0250	0.0700	0.354
Activity moderate	0.0899	0.3591	0.2505	-0.6139	0.7938	0.802
Activity high	0.1226	0.3724	0.3293	-0.6073	0.8526	0.742

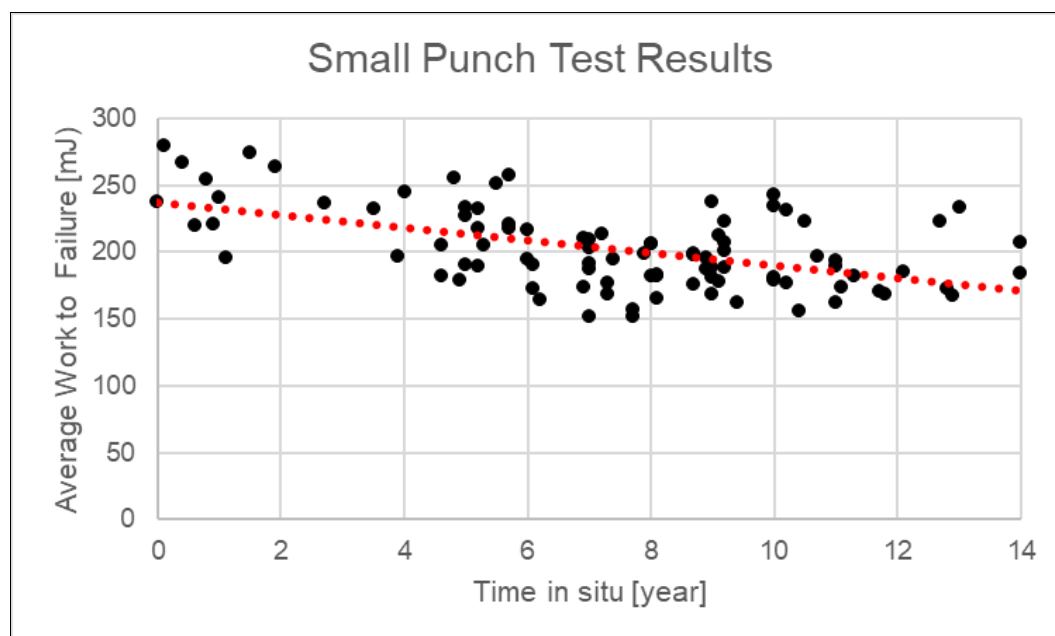


Fig 1: A decrease of work to failure in relation with time in situ was detected. The turning point in mechanical properties occurred at approximately year 7, indicating oxidative degradation.

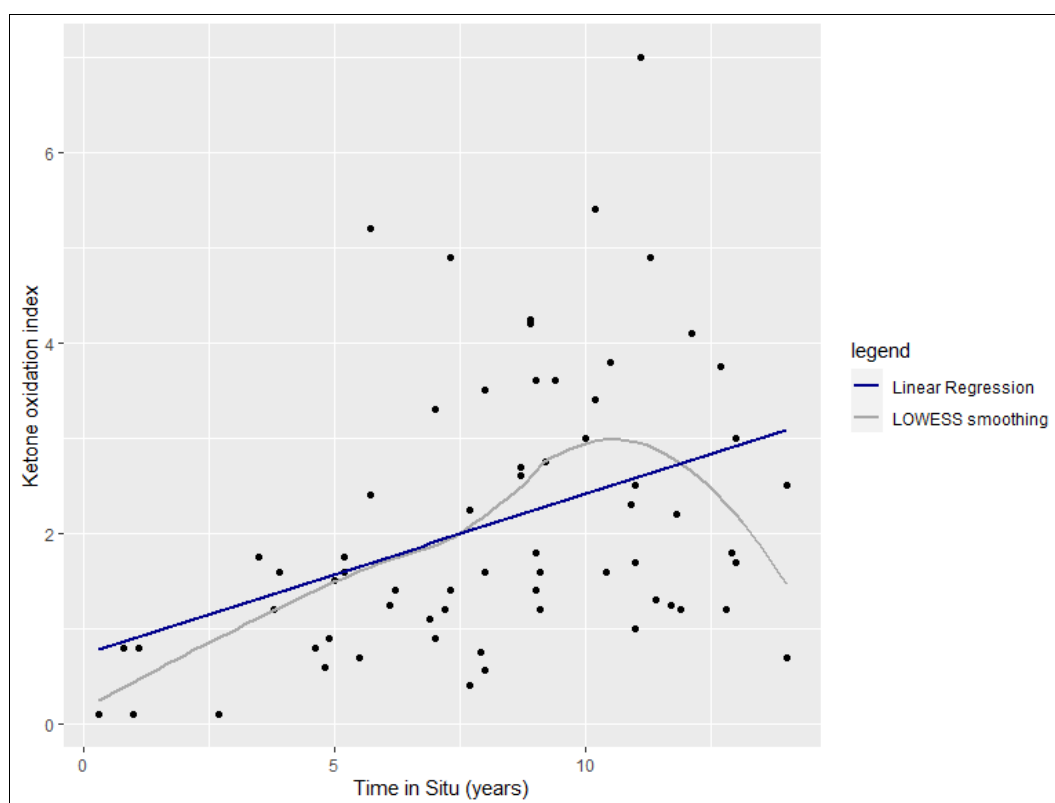


Fig 2: There is a positive relationship between time in situ (TIS) and ketone index (KI) over the first 10 years. KI > 1.2 indicates oxidation.

Conclusion

In this 14-year retrieval analysis of 439 sequentially irradiated and annealed (X3) tibial bearings, we observed a strong association between TIS and visual oxidation, with the odds of visible oxidation increasing by 66.8% per implant-year ($p < 0.001$). FTIR revealed that KI increased with TIS, and SP testing demonstrated that mechanical toughness fell below 200 mJ beyond 7 years. Fracture occurred in 39 inserts; the risk increased by 32.1% per year ($p < 0.001$) and was markedly higher in heavier women (4.94-fold; 95% CI, 1.9-12.7). These findings confirm the presence of oxidation in non-remelted UHMWPE, most likely due to retained free radicals. Instability-related posterior contact stresses may further

predispose the material to fatigue and fracture. Despite registry data showing excellent overall performance of the Triathlon CR system, our results identify at-risk subgroups and support targeted follow-up and consideration of patient-specific risk in implant selection. Prospective, controlled studies are warranted to confirm causality and define thresholds for clinical intervention.

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removal and observations at the time of removal.

Conflict of Interest

Not available.

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Not available.

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