In Vitro Aging Method Yields Clinically Relevant Oxidation in Joint Bearing Materials

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Introduction

Oxidative degradation of Ultra High Molecular Weight Polyethylene (UHMWPE) precedes in vivo damage and fatigue failure such as cracking and delamination in joint replacement devices[1]. These damage modes result in significant material loss and jeopardize the longevity of the device.

Pre-implantation oxidation has been eliminated with the introduction of vacuum-foil packaging and, alternatively, material fabrication processes that stabilize radicals formed in the crosslinking process[2]. Despite the absence of free radicals in a number of materials, FTIR retrieval studies have revealed in vivo oxidation in highly-crosslinked polyethylene and gamma-barrier devices.

The current ASTM artificial aging method (F2003) states "this practice is not intended to simulate any change that may occur in UHMWPE following implantation." Thus, studying long-term stability of these materials is limited to retrieval studies with small sample sets, short in vivo times, and uncontrollable surgeon- and patient-specific variables.

The current objective is to map a more gentle (relative to ASTM F2003) in vitro artificial aging of gamma barrier devices to published in vivo oxidation trend lines, and to use the system to predict stability of an antioxidant material.

Materials and Methods

Five rectangular prisms (5 x 5 x 8 cm) were cut from GUR 1020 resin stock materials, prepared as follows:

-Virgin- non-cross-linked polyethylene (TVI= -0.001)

-**Antioxidant**- PHBP-containing, 85kGY γ-irradiation, EtO (TVI= 0.03)

-**Remelted**- 75 kGy γ-irradiation, melted in argon, gas plasma (TVI= 0.024)

-**GVF-Low**- conventional UHMWPE, gamma vacuum foil (Mean TVI = 0.014)

-**GVF-High**- conv. UHMWPE, gamma vacuum foil (TVI = 0.016).

Blocks were aged in a pressure vessel under 45 PSI (3 atm) O_2 at 63°C for 10 weeks, with sampling at intermediate time points. Oxidation at 0, 4, 6, and 10 weeks is reported as the maximum KOI measured from test coupons collected at each time point (Figure 2).

Uniaxial tensile testing was conducted with an Intron 5544 load frame with a 2-kN load cell, pneumatic sample grips, and a video extensometer on ~200 micron thick dogbone specimens stamped from thin sections microtomed from the longitudinal sides of the prisms at each time point (ASTM spec D638). The crosshead speed (25 mm/min) was selected to result in a gauge region strain rate of 100%/min.

For historical comparison, oxidation profile and trend line data for retrievals were sourced from an IRB-approved retrieval database queried for γ-barrier sterilized tibial components. 216 retrievals were analyzed, with in vivo duration from 0 to 190 months and average duration of 54 months. Literature-based retrieval maximum oxidation and mechanical data [1] are provided for comparison to the present results.

Results

The ketone oxidation index (KOI) profile of the in vitro-aged GVF materials showed a sub-surface peak after 4 weeks (Figure 1, left). The oxidation profile of a tibial bearing retrieval implanted for 6.8 years is shown for comparison to the oxidation profile at Week 6 (Figure 1, middle). After 10 weeks, the subsurface peak observed in GVF materials shifted closer to the material surface. Virgin and Remelted materials displayed deep broad oxidation peaks (Figure 1, right).

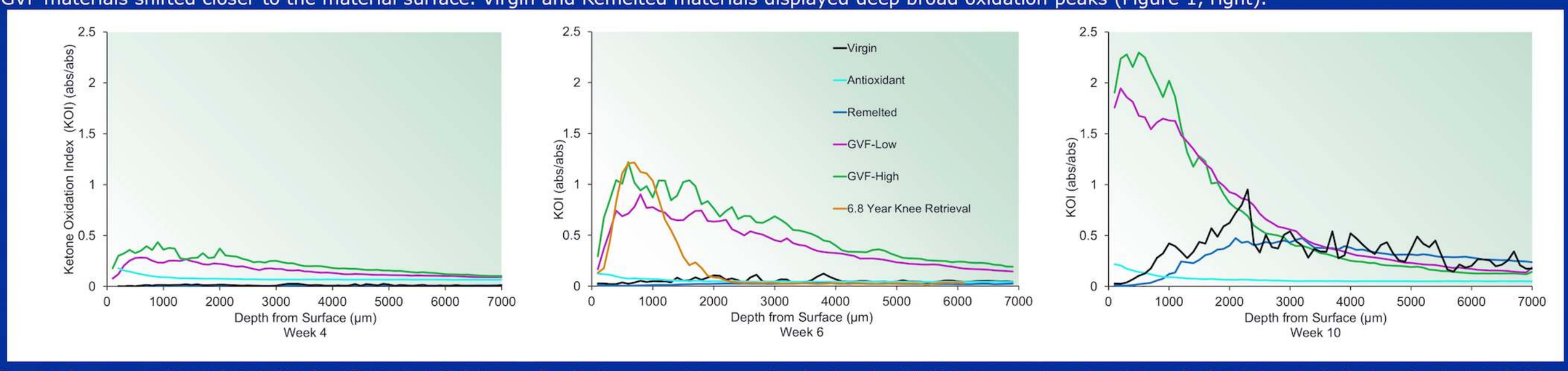

Figure 1 (Left corresponds to Week 4, Center to Week 6, and Right to Week 10). Oxidation profiles of in vitro-aged materials measured 7mm from the surface. Week 6 displays comparison to the oxidation profile of a typical γ-barrier tibial bearing retrieval implanted for 6.8 years.

KOI measured in the GVF materials increased exponentially with time over six weeks (Figure 2). Aggregate oxidation rate data from retrieved γ-barrier knee retrievals is shown for comparison (Figure 2). Remelted and Virgin are chemically stable for at least 6 weeks in vitro (Figure 1, 2). Antioxidant is stable for at least 10 weeks. Increasing KOI negatively correlated with Ultimate Tensile Strength (UTS) in a manner similar to that seen in retrievals (Figure 3). Similar results are found for elongation at break and tensile toughness (not shown).

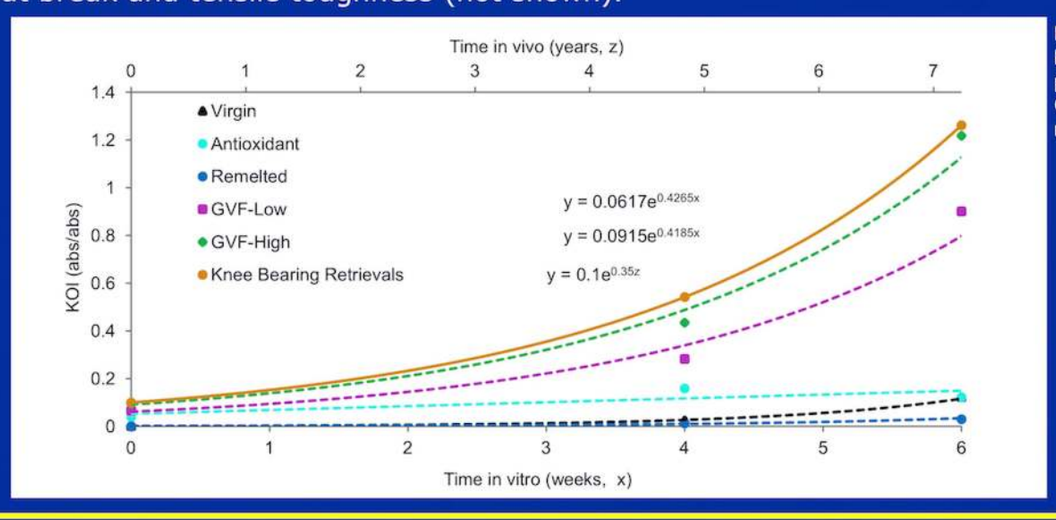

Figure 2: Maximum KOI in mobile knee bearing retrievals is compared to in vitro-aged polymers. Exponential fit lines proposed for GVF poly and retrievals suggest a conversion rate of 1 week in vitro to ~1.2 years in vivo.

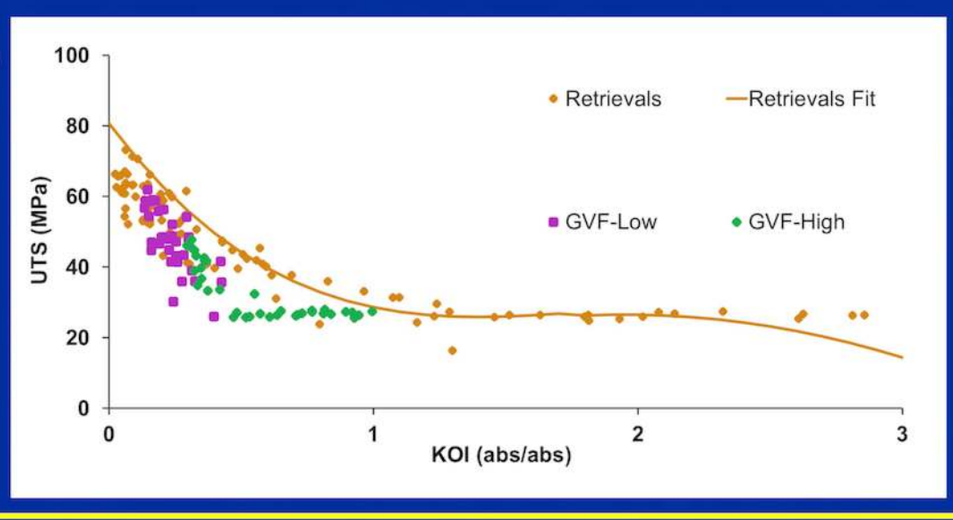

Figure 3: Ultimate Strength (UTS) decreases with increasing KOI in both in vivo- and in vitro-aged polymer. Retrieval trend line and data from Reference 1.

Discussion

In vitro oxidation of GVF materials yielded oxidation profiles similar to those observed in gamma-sterilized retrievals, as characterized by the subsurface oxidation peak and identity of chemical species. While the oxidation peaks appear at approximately the same depth, the breadth of the peak is greater in the artificially aged samples, likely owing to increased oxygen diffusivity in the high-pressure/high-temperature environment. In vivo aging can be mapped to an accelerated aging process by a conversion factor of ~1.2 years in vivo to 1 week in vitro. To achieve clinically relevant 7-year oxidation in GVF-Low and GVFA-High (KOI 1.0-1.5), the aging process presented in this study takes approximately 6 weeks (Figure 2). The effects of this oxidation on UTS and other tensile properties were analogous to those observed in retrieval studies (Figure 3). The relative chemical stability of virgin, remelted, and antioxidant materials in the absence of an initiator (e.g. stress, lipids, etc.) is consistent with a free-radical mediated oxidation mechanism but does not suggest an explanation for in vivo oxidation of remelted highly cross-linked polyethylene [3]. Antioxidant material appears stable to this aging method for 10 weeks, though we caution that this time point may lack clinical relevance.

Significance

In vivo oxidation of gamma-barrier materials is mimicked in oxidation profile and oxidation rate by a more gentle in vitro aging environment than that specified in ASTM F2003. This technique has promise in evaluation of material stability against the free-radical oxidation pathway. Future work must be done to assess other (e.g. lipid-related) pathways.

References

[1]JOA Vol. 22 No. 5 2007.
[2]JBMR-B 106.1 (2018): 353-359.
[3]JBJS-A. 2010;92:2409-18.

Acknowledgement

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