In Vivo Oxidation in Remelted Highly Cross-linked Bearings: A Clinical Concern?


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Introduction: Oxidation in remelted highly cross-linked (HXL) materials has been reported to occur in the absence of measurable free radicals. Concerns about the clinical implications of oxidation are based on experience with the free radical oxidation mechanism in radiation sterilized materials. If oxidation in remelted materials occurs by an alternative mechanism, it is possible that oxidation will not lead to chain scission and material property degradation.

The present work aims to determine whether in vivo oxidation in remelted HXL acetabular and tibial bearing materials represents a clinical concern by determining whether in vivo oxidation causes material property changes, and whether those changes occur on a clinically relevant timescale.

Methods: Seventy-eight retrieved remelted HXL bearings from an IRB-approved retrieval center were evaluated. This set included thirty-nine acetabular liners (50 kGy: n = 12; 75 kGy: n = 14; 100 kGy: n = 13) and thirty-nine tibial bearings (50 kGy: n = 25; 65 kGy: n = 14). Two acetabular components were removed for disassociation of the polyethylene component, and all other reasons for retrieval were unrelated to the polyethylene bearing. Mean in vivo duration for all devices was 28 months (0-124.5 months).

Oxidation was measured by FTIR using the ketone peak height ratio. Cross-link density was measured by gravimetric gel swell.

Results: All materials had a significant correlation between peak oxidation and in vivo duration (Figure 1). Regression analysis suggested a strong linear relationship between oxidation and in vivo duration for the range of data available for all three acetabular materials, while the relationships for both tibial materials were not linear and were better described by an exponential curve.

There was a significant relationship between articular cross-link density and oxidation for both tibial bearing materials, with cross-link density decreasing with increasing oxidation, while there was no significant relationship for any of the acetabular materials (Figure 2).

Discussion: In the last five years the phenomenon of in vivo oxidation in HXL acetabular and tibial bearings has been well established. The strong correlations between peak oxidation and in vivo duration observed in this study suggest that higher oxidation levels can be anticipated as longer duration retrieved devices become available for analysis.

In vivo oxidation in HXL tibial bearings is correlated to cross-link density changes indicative of material degradation, yet none of the acetabular materials exhibited this trend. However, ketone values observed in acetabular components in this study were lower than in the tibial components, potentially limiting the statistical power.

Historically, clinical failures associated with oxidation did not occur until ketone levels exceeding 1.2. If the current oxidation rates persist, oxidation in HXL acetabular materials will not reach this critical level.
until more than thirty years in vivo. Thus, even if oxidation does lead to material degradation, it appears that in vivo oxidation in remelted HXL acetabular bearings does not represent an immediate clinical concern. In contrast, oxidation in HXL tibial materials will reach this critical level after 15-20 years in vivo. These results suggest that if oxidative degradation continues on its current course, then oxidation has the potential to become a clinically relevant concern in remelted HXL tibial bearings.

Significance: In vivo oxidation is occurring in remelted HXL bearing materials. If degradation continues at its current rate, it may represent a clinical concern in tibial bearings after 15-20 years in vivo.

![Graph](image)

**Figure 1:** Maximum ketone oxidation versus *in vivo* duration for five different remelted HXL bearing materials. All five materials have significant (*p < 0.05*) trends of increasing oxidation with duration.
Figure 2: Articular cross-link density versus average articular ketone oxidation for five remelted HXL bearing materials. Both tibial materials showed significant (p < 0.05) linear relationships of decreasing cross-link density with increasing oxidation, while none of the acetabular materials had a significant trend.