A Comparison of Small Punch Results on Aged Highly Crosslinked UHMWPE

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Statement of Purpose: Since its introduction in the late 1990s, highly crosslinked ultrahigh molecular weight polyethylene (UHMWPE) has been used effectively in total hip and knee arthroplasties as a bearing surface. These first generation materials were thermally treated by melting or annealing after irradiation in an attempt to reduce oxidative degradation. Starting in 2005, a new generation of materials has been introduced in an attempt to provide the desired wear resistance of the first generation materials while maintaining the mechanical properties of the unirradiated materials. Two methods for dealing with free radicals, which can lead to oxidation, were used. Stryker introduced X3™ in 2005, a GUR 1020 resin irradiated to 30 kGy, annealed at 130ºC, and then re-irradiated and re-annealed twice more to reduce free radical content [1]. Zimmer introduced Vivacit-E® in 2012, a Vitamin E blended GUR 1020 that is then radiation crosslinked. The Vitamin E is used to sequester free radicals. ASTM F2759 "Assessment of the UHMWPE used in orthopedic and spinal devices" requires mechanical testing by small punch according to ASTM F2183, along with accelerated aging by ASTM F2003 for determining oxidative stability. This protocol was performed on these two materials to determine the change in mechanical properties with aging and to see their resistance to oxidation.

Methods: Never-implanted acetabular cups (2) made from X3 were obtained, along with cups made from Vivacit-E. Both sets of cups were placed in an oxygen bomb, pressurized to 5 atmospheres with oxygen, and aged in an oven at 70ºC according to ASTM F2003.Samples were removed from the oven at 2 weeks, 4 weeks. Vivacit-E was aged an additional 29 weeks for a total of 33 weeks. Cores were cut from each cup, and 5 specimens were obtained for each time point, including no aging. Small punch testing was conducted and analyzed according to ASTM F2183-02.

Results: The raw load-displacement curves for the X3 sample shows a substantial change in form when accelerated aging time is increased (Fig. 1), with shorter displacement and lower ultimate load. In contrast, the Vivacit-E sample shows no measurable difference up to 4 weeks; even at 33 weeks of accelerated aging, the curve is similar (Fig 2). Student's T-test evaluation of the data shows a statistically significant difference between the Ultimate load and Work to Failure between 0 and 4 weeks for the X3 sample (α=0.05, $p<0.04$), but no statistically-significant difference for the Vivacit-E, even up to 33 weeks (α=0.05, $p>0.1$) (Fig. 3).

Conclusions: The incorporation of Vitamin E into UHMWPE to provide long term oxidative stabilization is well-known [2]. The X3 sample, lacking an antioxidant, shows a 54 to 68% loss in mechanical properties when accelerated aged up to 4 weeks, and had a work to failure that was 2.4 times less than Vivacit-E at 4 weeks of aging.

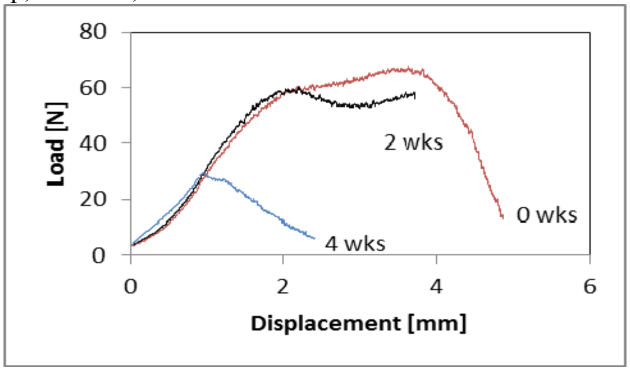

Figure 1: Representative small punch curves for aged X3™. Aging weeks are shown on the figure (0-4 weeks).

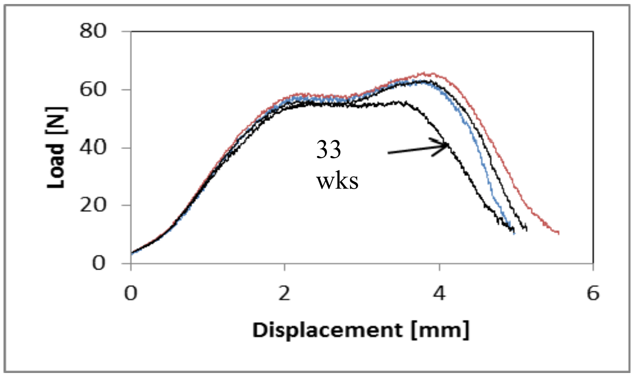

Figure 2: Representative small punch curves for aged Vivacit-E®. Aging weeks are shown on the figure (0-4 weeks) are tightly grouped. The 33 week aged component is indicated.

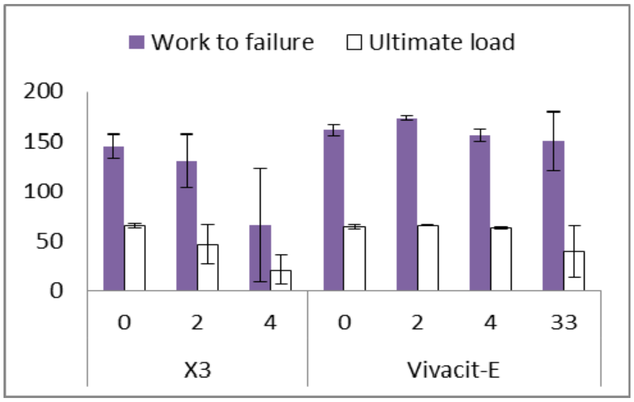

Figure 3: Summary of small punch results as a function of aging time. Results show average +/- 1 std dev.

Vivacit-E sample shows no statistical change in properties over 33 weeks of bomb-aging, corresponding to well over 20 years of real-time aging based on a Q10 relationship. Typical accelerated aging tests stop at 4 weeks. The results indicate that Vivacit-E is more oxidation resistant than X3 under these conditions.

References: [1] Kurtz, "UHMWPE Biomaterials Handbook", 2009. [2] Oral et al. JOA 21(4): 580-91 (2006).

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