A SECOND GENERATION HIGHLY CROSSLINKED UHMWPE: VITAMIN E STABILIZATION DOES NOT ADVERSELY AFFECT THE WEAR RATE OF IRRADIATED ACETABULAR LINERS

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ABSTRACT

We developed a second generation highly cross-linked UHMWPE by doping and stabilizing irradiated UHMWPE with the antioxidant vitamin E. With this stabilization method, the crystallinity of the irradiated polyethylene is not decreased as with melting, and hence mechanical properties and fatigue strength can be preserved. Vitamin E-doped, irradiated second generation highly cross-linked UHMWPE showed wear comparable to and higher strength and fatigue resistance than that of 100-kGy irradiated and melted first generation highly cross-linked UHMWPE.

INTRODUCTION

Cross-linking by ionizing radiation increases the wear resistance of ultra-high molecular weight polyethylene (UHMWPE) but also generates residual free radicals, precursors of long-term oxidative embrittlement. To eliminate these residual free radicals, in the first-generation highly cross-linked UHMWPEs, oxidative stability was achieved by post-irradiation melting. While effective in increasing oxidative stability, melting reduced the crystallinity of UHMWPE; resulting in a decrease in fatigue strength [1].

Vitamin E, a potent antioxidant, has been suggested as a stabilizer to gamma-sterilized (25-40 kGy) UHMWPE by blending with UHMWPE powder prior to irradiation [2-4]. However, due to a decrease in cross-linking efficiency in the presence of Vitamin E [5], we proposed an alternative method of Vitamin-E (α-tocopherol) doping by diffusion into already highly cross-linked UHMWPEs, oxidative stability was achieved by post-irradiation melting. While effective in increasing oxidative stability, melting reduced the crystallinity of UHMWPE; resulting in a decrease in fatigue strength [1].

Vitamin E stabilizing replaces melting, the crystallinity of the irradiated polyethylene is not decreased and hence mechanical properties and fatigue strength are preserved. To use this technique in the fabrication of acetabular liners, we propose the following steps: (1) machine the liners, (2) irradiate to 85-kGy, (3) dope the liners with Vitamin-E at an elevated temperature, (4) anneal the liners at an elevated temperature to homogenize Vitamin E throughout the liners, (5) package and γ-sterilize the liners.

The elevated temperature doping and homogenization is to ensure that Vitamin-E is present throughout the thickness of the liners. However, this may result in dimensional changes beyond the machining tolerances of the liners. γ- Sterilization is proposed to ensure that the Vitamin-E in the polyethylene is sterile. Finally, it is not known if the acetabular liners thus fabricated will be as wear resistant as a 100-kGy irradiated and melted polyethylene.

We hypothesized that the dimensional stability will not be compromised by doping and homogenization, and that the 85-kGy irradiation combined with γ-sterilization will effectively result in the wear resistance of 100-kGy irradiated and melted polyethylene. In addition, we hypothesize that the fatigue strength and mechanical properties of irradiated, Vitamin-E doped, and γ-sterilized UHMWPE will be better than those of irradiated and melted UHMWPEs.

MATERIALS AND METHODS

Hot isostatically pressed GUR1050 UHMWPE stock was used in all experiments. Conventional UHMWPE and irradiated and Vitamin-E doped UHMWPE were prepared. All test samples of the cross-linked/Vitamin-E group were machined out of annealed UHMWPE stock to minimize potential dimensional changes during high temperature doping. The Vitamin-E group samples were then γ-irradiated to 85-kGy in inert gas packaging. These samples were then doped with Vitamin-E at 120°C for 2 hours followed by annealing at 120°C in argon for 24 hours. Samples of the conventional group were machined from the consolidated stock. All samples from both groups were packaged in inert gas and γ-sterilized.

In the Vitamin-E group, all samples were analyzed by IR to determine the diffusion profile of Vitamin-E in UHMWPE. The samples were cut in half and sectioned (150 µm) using a
Microtome. Infrared spectra were collected by a BioRad UMA 500 microscope with an aperture size of 50x50μm as a function of depth away from the free surface. A Vitamin-E index was calculated as the ratio of the areas under the 1265cm⁻¹ α-tocopherol and 1895cm⁻¹ polyethylene skeletal absorbannces.

The articualr and backside surfaces of the acetabular liners of the Vitamin-E group were digitizated by a Brown&Sharpe coordinate measuring machine (CMM) before and after doping/homogenization/sterilization to determine the extent of dimensional changes.

Vitamin-E acetabular liners with 28 and 36 mm inner diameter (ID) and conventional acetabular liners (gamma-sterilized) with 28 mm ID (n=4) were tested on a twelvestation, Boston Hip Simulator at 2 Hz under normal gait conditions for 5 million cycles (MC) in clean serum and at 1 Hz for 3 MC in serum with third-body particulate. Gravimetric measurements were made every 0.5 MC.

Fatigue crack propagation testing was done following ASTM E-647 on both groups (n=3). Compact tension specimens (A1) were pre-cracked at the notch, and a stress ratio of 0.1 in tension was applied at 40°C in water. Stress intensity factor ranges at crack inception (AK) were reported with a threshold crack growth rate of 10⁻⁶ mm/cycle.

To determine crystallinity, samples (n=3) and reference were heated at a rate of 10°C/min from -20 to 180°C in a differential scanning calorimeter (DSC). Crystallinity was determined by integrating heat flow from 20°C to 160°C, and normalizing it with the enthalpy of melting of 100% crystalline polyethylene, 291J/g.

Sample Type       | UTS (MPa) | YS (MPa) | (AK_i) (MPa m 1/2) | Crystallinity (%) |
-------------------|-----------|---------|---------------------|-------------------|
Conventional       | 52±5      | 24±1    | 1.32 (n=2)          | 68±2              |
Vitamin-E          | 47±2      | 23±1    | 0.78±0.02           | 72±0              |
100-kGy 1st gen.   | 35±5      | 17±0    | 0.56±0.02           | 48±1              |
UHMWPE             |           |         |                     |                   |

CONCLUSION

Hip simulator wear of second generation Vitamin E stabilized cross-linked UHMWPE is comparable to that of irradiated and melted UHMWPE. The mechanical properties of this second generation cross-linked UHMWPE are better than that of irradiated and melted UHMWPE. Based on earlier data on oxidative stability of irradiated, Vitamin-E stabilized, sterilized and accelerated aged UHMWPE [1], mechanical and wear properties are not expected to change upon aging. Vitamin E stabilization of irradiated UHMWPE can be used for the fabrication of acetabular liners for wear and oxidation resistance. More importantly, with the improved mechanical and fatigue properties, this technology might allow the use of highly crosslinked, low wear UHMWPE in high stress applications such as posterior stabilized total knees.

ACKNOWLEDGMENTS

This study was funded by BIOMET Inc.

REFERENCES