INTRODUCTION:

Highly crosslinked and thermally stabilized ultra high molecular weight polyethylene (UHMWPE) have been used to reduce wear and oxidation in joint replacement devices during the last decade. In 2007, an irradiation-crosslinking and vitamin E stabilized UHMWPE (E-Poly™ HXLPE, Biomet, Warsaw, IN) received US FDA clearance for THA devices. The manufacturing process involved diffusion of vitamin E into crosslinked UHMWPE and a homogenization step to ensure uniform distribution of this antioxidant additive at a heat stabilization temperature of 120 °C (below melting temperature of UHMWPE). Alternatively, pre-blending 500 ppm of vitamin E into UHMWPE resin before consolidation process had been identified to provide enhancement in oxidation resistance after material is crosslinked by irradiation.

We prepared two types of vitamin E-doped crosslinked UHMWPE by: (1) pre-blending 500 ppm, and (2) diffusing 30,000 ppm; both materials received identical irradiation and heat treatment. Our primary hypothesis was that crosslinking UHMWPE by 100 kGy irradiation, stabilizing it at 120 °C for 69 hours and sterilizing it by 33 kGy irradiation in argon will deteriorate material’s ultimate tensile strength; a vitamin E diffusion and homogenization process performed at 120 °C will further degrade tensile yield strength. Our secondary hypothesis was that fast consumption of vitamin E will occur in crosslinked UHMWPE during storage when it is doped by the 120 °C diffusion and homogenization method.

MATERIALS AND METHODS:

GUR1020 UHMWPE resin was used as starting material. Two sheets (2 m long, 0.7 m wide, 80 mm thick) of materials were simultaneously consolidated using the same resin lot and process parameters by a single compression molding cycle in 2 separate mold cavities at a commercial vendor. The consolidated material without vitamin E was designated as REFERENCE (Table 1). The other sheet of material contains 500 ppm vitamin E (designated as 500 ppm); it was blended into UHMWPE resin before consolidation process. A post compression molding annealing step was executed to ensure dimensional stability of machined specimens.

Rectangular blocks (63.5 mm x 12.7 mm x 6.35 mm) were machined from these materials for further treatment. The subsequent process steps included: (1) 100 kGy irradiation-crosslinking, (2) 5 hours post-irradiation annealing at 120 °C in argon, (3) additional 64 hours homogenization annealing at 120 °C in argon, and (4) 33 kGy γ sterilization in argon. Crosslinked UHMWPE produced were designated as BLENDED and CONTROL using 500 ppm and REFERENCE as precursors, respectively.

Diffusion and homogenization of vitamin E process used REFERENCE rectangular blocks as precursor. All of the above-mentioned steps (1) through (4) were performed; vitamin E diffusion and homogenization process was carried out in conjunction with steps (2) and (3) following protocol described in reference 1. The measured weight gain (3 wt%) and vitamin E index of these specimens were similar to published data. This material was designated as DIFFUSED.

RESULTS:

Test results for crystallinity (N=5) and tensile strength (YS and UTS, N=8) are listed in Table 2 while vitamin E index (N=3) measured before and after accelerated aging are presented in Table 3.

DISCUSSION:

This is the first study to report an analysis of crosslinked UHMWPEs stabilized by two different processes: blending and diffusing vitamin E. They received identical irradiation dose and heat stabilization treatment.

Results support our primary hypothesis that crosslinking UHMWPE by 100 kGy irradiation, stabilizing it at 120 °C for 69 hours and sterilizing it by 33 kGy irradiation in argon will deteriorate material’s UTS; a vitamin E diffusion and homogenization process performed at 120 °C will further degrade tensile yield strength. UTS of CONTROL and DIFFUSED (vs. REFERENCE) was significantly (p=0.001) decreased by 22 and 26%, respectively, after all process steps. The 30,000 ppm vitamin E diffusion and homogenization process executed during steps (2) and (3) significantly (p=0.001) reduced YS of DIFFUSED (vs. CONTROL) by 19%. Process effect on YS was also confirmed by a significant (p=0.001) decrease of crystallinity in DIFFUSED (vs. CONTROL) by 4%; general correlation exists between yield strength and crystallinity in UHMWPE materials. Long duration of heat treatment at 120 °C and excessive vitamin E at grain boundaries of materials were responsible for strength deterioration. No major strength deterioration occurred in BLENDED.

Results also support our secondary hypothesis that fast consumption of vitamin E will occur in crosslinked UHMWPE during storage when it is doped by the 120 °C diffusion and homogenization method. The vitamin E index measurements indicated more than 63% of vitamin E (in dex decreased from 0.41 to 0.15) was consumed during the 2-week aging experiment. Consequently, long-term in-vivo stability of diffused vitamin E in devices shall be a primary concern since the aging protocol is designed to simulate just 3 to 5 years shelf storage. The logical explanation for fast vitamin E consumption was that it reacted with residual free radicals generated during irradiation-crosslinking of UHMWPE and free radicals re-generated during aging.

The result of aging experiments also indicated BLENDED and DIFFUSED provide equivalent protection against oxidative challenge.

REFERENCES: