Vitamin E Diffusion Process Elevates Remelting of Irradiation Crosslinked UHMWPE

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Introduction: Highly crosslinked ultra high molecular weight polyethylene (UHMWPE) has become the preferred material for bearing surfaces due to its low wear. Recently, a vitamin E diffusion method [1] carried out at 120 °C has been proposed to quench free radicals generated during irradiation crosslinking avoiding the strength degradation that occurs with remelting (>135 °C) [2]. E-Poly™ HXLPE (Biomet Orthopedics, Warsaw, IN) is a product based on this diffusion process [3]. However, vitamin E may act as a plasticizer reducing the melting temperature. We test a hypothesis that a vitamin E diffusion and homogenization process carried out at 120 °C for an interval of 69 hours promotes remelting in a 100 kGy irradiation crosslinked UHMWPE.

Materials and Methods: Rectangular blocks (63.5 mm x 12.7 mm x 6.35 mm) are machined from compression molded GUR1020 stock. Some rectangular blocks receive further treatments (4-step treatment) including: (1) 100 kGy irradiation crosslinking in vacuum package, (2) 5 hours post-irradiation annealing at 120 °C, (3) additional 64 hours homogenization annealing at 120 °C, and (4) 33 kGy gamma sterilization in vacuum package.

Diffusion and subsequent homogenization of vitamin E processes are carried out in conjunction with steps (2) and (3), respectively, following the described protocol [1]. The measured weight gain (3 wt%) and vitamin E index of these specimens are similar to published data. Description of program materials is listed in Table 1.

Table 1 Description of materials under evaluation

Treatment	Process Condition
VIRGIN	Compression molded GUR1020
XLINK	VIRGIN receives 4-step treatment
XLINK + DIFFUSION	VIRGIN receives 4-step treatment; 30,000 ppm vitamin E diffusion and homogenization process is also executed during steps (2) and (3)

Sheets with 1 mm thickness are machined from rectangular blocks for crystallinity and tensile property evaluations. Crystallinity measurements are performed according to ASTM F2625 using a differential scanning calorimeter (DSC). Reference materials include compression molded GUR1050 and a sequentially irradiated and annealed UHMWPE (X3®, Stryker Orthopaedics, Mahwah, NJ). Tensile yield strength (YS) and ultimate strength (UTS) are measured according to ASTM F638 using type V specimens; reference material is X3®.

Results: Typical DSC thermal scans are presented in Figure 1. Test results for crystallinity (N= 5) and tensile strength (YS and UTS, N= 8) are listed in Table 2.

Table 2 Crystallinity and tensile strength

Treatment	Crystallinity (%)	YS (MPa)	UTS (MPa)
VIRGIN	59.3 ± 1.2	25.0 ± 0.2	71.3 ± 1.8
XLINK	61.7 ± 0.8	26.3 ± 0.5	55.3 ± 1.9
XLINK + DIFFUSION	59.3 ± 0.8	21.2 ± 0.4	53.0 ± 4.2
X3	61.0 ± 0.6	25.5 ± 0.4	67.5 ± 3.0

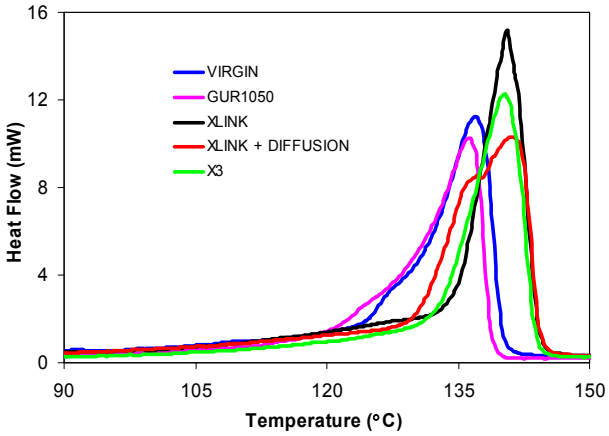

Figure 1 Typical DSC thermal scan curves

DSC thermal scan shows a shoulder in material with the XLINK + DIFUSSION treatment. The shoulder in the DSC scan is associated with remelting; the low Izod impact strength, 38 kJ/m^2 reported [4] confirms this observation. No shoulder is observed in XLINK. The reduction of UTS in XLINK + DIFFUSION shows similar behavior to that of typical crosslinked and remelted UHMWPEs; a 26% (p=0.001) lower UTS is observed as compared to VIRGIN material. There is also a significant (p=0.001) decrease, 19%, in YS (vs. XLINK). The long interval of heat treatment at 120 °C and accumulation of vitamin E at grain boundaries may be responsible for both remelting and associated strength deterioration. It should be pointed out that melting temperature of VIRGIN is higher than that of GUR1050. There are no signs of remelting with X3®.

Conclusions: Results support our hypothesis that remelting occurs in crosslinked UHMWPE when a vitamin E diffusion process is carried out following the published 120 °C stabilization and homogenization protocol. However, no indication of remelting is observed in the crosslinked material without vitamin E diffusion process that received identical 120 °C treatments.

References: 1. Wannomae KK, 53rd ORS 2007:1783. 2. Oral E, Biomat 27 2006:917-925. 3. Biomet literature #71260. 4. Biomet E-Poly™ HXLPE white paper, 2007.