Reducing Lipid Absorption in Highly Crosslinked Grafted Vitamin E Polyethylene

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Statement of Purpose: Absorption of synovial joint constituents has been suggested to participate in the de-stabilization of melt stabilized highly crosslinked UHMWPE (HXPE), most likely via a free radical initiated oxidation, as lipid materials are known to be prone to oxidative instability [1]. Crosslinking and melt stabilization processes that are used to reduce polyethylene wear are known to increase lipid absorption [2]. Polyethylene stabilizers such as vitamin E (VE), a highly efficient free radical scavenger, are now being utilized to stabilize HXPE materials against oxidation in lieu of melt stabilization. Our hypothesis was that the addition of VE may influence the absorption of lipids that may affect implant oxidative stability.

Methods: A central composite design of experiments (DOE) was utilized for this investigation. The design contained three numerical variables and one categorical variable, resulting in 40 conditions. The material and process variables included type of polyethylene (Ticona GUR 1020 and GUR 1050), % by weight of VE, irradiation dose level, and material temperature achieved during irradiation. The UHMWPE powder was blended with Vitamin E, compression molded into slabs and then sectioned into blocks for irradiation. The block thickness allowed full penetration with a 10 MeV electron beam from one side. Wear test pins (10mm diameter x 25 mm long) were fabricated to be tested on an AMTI OrthoPOD six-station pin on disc wear test machine (Watertown, MA). Prior to wear testing the pins were soaked in undiluted bovine calf serum @ 37 °C until weight gain stabilized. Control wear pins fabricated from melt stabilized electron beam 100 kGy cold irradiated polyethylene (CISM) and melt stabilized electron beam 65 kGy warm irradiated polyethylene (WISM), both being representative of first generation highly crosslinked UHMWPE (HXPE), were also soaked to equilibrium weight gain in bovine serum. The DOE blocks were also tested for % crystallinity using a TA Instruments Q1000 differential scanning calorimeter (DSC) per ASTM F2625-10, with $\Delta H_f = 293$ J/g.

Results: The bovine serum absorption was significantly higher for the highly crosslinked materials that had been melt stabilized. The wear pin bovine serum pre-soak weight gain results are shown in Figure 1, with best fitting polynomial regression lines. The weight gain results analysis of variance (ANOVA) showed that the weight gain was influenced by only two variables, resin type and VE level, with $p<0.0001$ for model significance, see Figure 2. The % crystallinity results ANOVA, with $p<0.0001$, show that crystallinity was only influenced by resin type and temperature achieved during irradiation, with higher crystallinity for GUR 1020 and lower temperatures. Both DOE models had insignificant lack of fit. The absorption level for the non-melted materials containing VE was affected by the choice of UHMWPE resin, where GUR 1020, with higher crystallinity levels in the VEHXPE material, reduces absorption when compared to GUR 1050, with lower crystallinity levels. Irrespective of resin type, the addition of VE to UHMWPE by blending which is then crosslinked by electron beam (VEHXPE) reduces the amount of bovine serum absorption in a linear fashion based on amount of VE added, up to 0.3% VE.

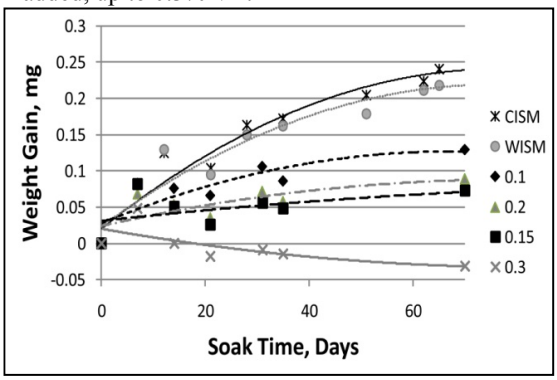

Figure 1. VE level vs. OPOD Change in Pre-Soak Weight

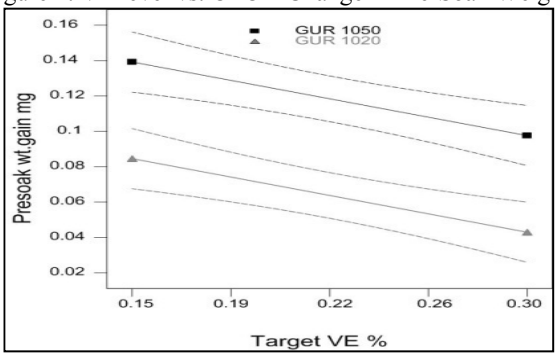

Figure 2. Serum weight gain vs.VE level-Resin Type

Conclusions: The resin effect on absorption is likely due to the difference seen in crystallinity, which was affected by resin type and temperature during irradiation. Crystallinity levels for HXPE materials are typically lower after melting, which may explain some of the difference seen when compared to absorption behavior of the non-melted VEHXPE materials in Figure 1[3]. As a general rule, higher crystallinity levels reduce the rate and amount of fluid absorption in a polymer [4]. Addition of VE by blending has the potential to prevent degradation on two fronts, in that it is an efficient antioxidant, and it also reduces absorption of potential destabilizing synovial fluid constituents. Combining the choice of UHMWPE resin utilized in conjunction with a higher level of blended vitamin E has been shown to play a significant role in reducing lipid absorption.

References: [1] (Oral E. Orthopedic Research Society 2010;paper #234) [2] Greenbaum et al, *Biomaterials* 25 (2004) 4479-4484 [3] Oral et al, Biomaterials 27 (2006) 917–925 [4] Klute, *J. Polymer. Sci.* 39 (1959) 307-317