

INTRODUCTION:

Ultra-high molecular weight polyethylene (UHMWPE) articulating surfaces continue to be the most common choice for hip and knee arthroplasties. Much progress has been made to tailor the UHMWPE materials to optimize clinical longevity. Recent studies have used Vitamin E as an alternative method to stabilize highly crosslinked UHMWPE without melt annealing.¹ Vitamin E is a well known oxidation stabilizer for commercial polyolefin materials. It is also attractive for use in implant materials due to its biocompatibility. This study describes a Design of Experiments (DOE) approach to investigate the oxidative resistance of commercial compression molded GUR-1050 and GUR-1020 UHMWPE blended with 0.2%, 0.5%, and 1.0% vitamin E.

MATERIALS AND METHODS:

For this study, GUR 1050 and GUR 1020 UHMWPE resins were mixed with 0.2 wt%, 0.5 wt% and 1 wt% Vitamin E (d/l- α -tocopherol) prior to consolidation. Compression molded bars were preconditioned and e-beam irradiated according to a five factor DOE. The factors are as follows: 1. material (GUR 1050 and GUR 1020), 2. Vitamin E concentration (0.2%, 0.5% and 1%), 3. preheat (warm and cold), 4. dose (90 kGy, 150 kGy and 200 kGy) and 5. dose rate (75, 155 and 240 kGy-m/min). The responses analyzed here are the Oxidation Index (OI) per ASTM standard F-2102 and Vitamin E Index (VEI). VEI was calculated using the FTIR Vitamin E absorption near 1265 cm^{-1} and normalizing the area of the peak using the 1370 cm^{-1} polyethylene peak area. VEI was calculated from FTIR on microtomed film specimens before and after accelerated aging per ASTM F-2003. OI measurements were collected after aging and after the test films were extracted with hot hexane to remove vitamin E interference peaks in the IR spectra. The DOE was analyzed using Design Expert 6.0.

RESULTS AND DISCUSSION:

In general, the vitamin E material exhibited good oxidative stability, with OI values for samples ranging from approximately 0 to 0.1. The most significant effect, although a relatively small effect, on oxidation after accelerated aging was the temperature of the material during irradiation, with $p < 0.0001$. Material that is irradiated cold trends slightly higher in OI levels after aging (see Figure 1, red data series). Vitamin E content and the interaction of dose rate with Vitamin E content also had small but significant effects on oxidation, both with $p < 0.05$. Interestingly, at a high dose rate, the level of vitamin E did not have a large effect on the oxidation level; whereas at a low dose rate, lower levels of vitamin E result in slightly higher oxidation (see Figure 1, blue data series). It should be noted that the highest OI observed in the DOE was still only on the order of 0.1.

VEI was most affected by Vitamin E content and resin, as well as the interaction between vitamin E and resin. In general, these trends held true for both the unaged and aged films.

CONCLUSION:

Results show that Vitamin E imparts oxidative stability at 0.2% levels even after high dose level irradiation. However, several interesting trends were observed in the chemical properties of the Vitamin E material. These results indicate that Vitamin E doping prior to irradiation may be a viable route to highly crosslinked UHMWPE with no subsequent thermal annealing. Future studies include the examination of the dose rate and vitamin E level interaction that appears to affect the oxidative stability of the material.

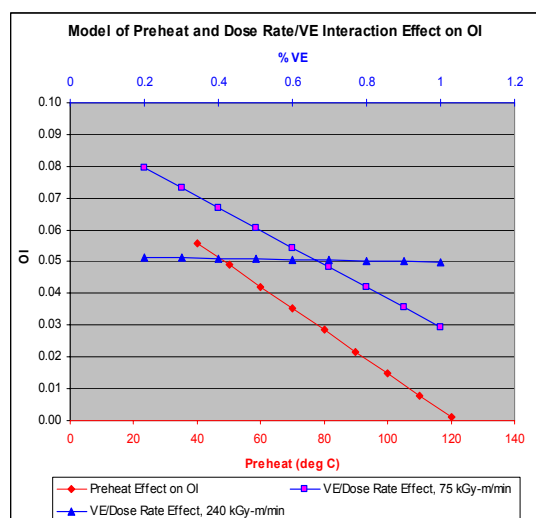


Figure 1: Effect of Preheat and Dose Rate/Vitamin E Level Interaction on OI

¹Oral, E., et. al. J Arthroplasty, 2006. 21(4): p. 580-591.