

# Vitamin E Does Not Elute Out of Vitamin E-Grafted Ultra High Molecular Weight Polyethylene

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## INTRODUCTION

The use of vitamin E (VE) to improve the oxidation resistance and mechanical properties of highly crosslinked ultra high molecular weight polyethylene (HXPE) is well established [1-2]. Progressive loss of VE due to elution can render the material prone to *in-vivo* oxidation and reduce device efficacy over time. It is postulated that VE is sequestered within the polymer and does not elute out of VE blended HXPE (VE-HXPE). The aim of this study was to quantify the elution (if any) of VE from VE-HXPE during immersion in aqueous solution and upon compressive loading.

## MATERIALS & METHODS

**Material Preparation:** The test material (VE-HXPE) was made from GUR 1020 resin, blended with > 0.1% VE and e-beam irradiated at >100kGy. Negative control HXPE material was made from compression molded GUR 1050, e-beam crosslinked at > 100 kGy and remelted.

**Water Elution:** Sixteen 32 mm-diameter acetabular cups (14 VE-HXPE and 2 HXPE) were individually immersed in 800 mL of de-ionized (DI) water at 40°C in sixteen sealed containers. On four of the sealed containers (2 VE-HXPE, 2 HXPE), 40 mL aliquots of water were drawn (and replenished with fresh DI water) after 0, 1, 2, 4, 8, 12 and 24 weeks of immersion. The aliquots were analyzed using UV-Vis spectroscopy to detect and quantify VE concentration [3]. The UV-Vis absorbance was scanned through from 320 nm to 280 nm wavelength. Two of the remaining VE-HXPE liners were taken out of water at the above time intervals and dried. 150µm thick slices were microtomed from the liners, extracted in hexane for 16 hours, and vacuum dried. The slices were analyzed using FTIR to determine vitamin E index (VEI) before hexane extraction as well as surface oxidation index (SOI) after hexane extraction. VEI is defined as the intensity ratio of IR bands at 1262 cm<sup>-1</sup> and 1895 cm<sup>-1</sup>. OI is defined as the ratio of the areas under 1740 cm<sup>-1</sup> and 1370 cm<sup>-1</sup> peaks.

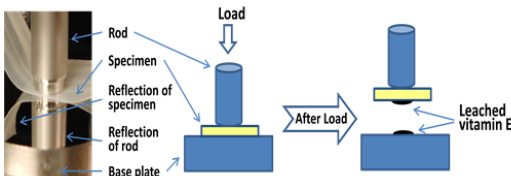


Figure 1: Picture and schematic of testing apparatus and procedure for the pressure induced VE leaching

**Pressure Induced Elution:** The pressure-induced elution method was used to determine the amount of elution of VE that might occur under normal and extreme compressive loading that might occur *in vivo*. Thin sections (~150 µm thick) were microtomed from VE-HXPE pucks, cleaned in isopropyl alcohol solution and subjected to static pressures of 3 MPa and 30 MPa (Fig. 1) for 1 minute at room temperature. The VE that leached

out was collected in ethanol and quantified using standard fluorescence spectroscopy [4]. A series of VE in ethanol solutions were made to generate a calibration curve.

## RESULTS

VE was not detected in any of the water aliquots analyzed. This indicates that the quantity of extracted VE was either zero or below the 0.1ppm detection limit of UV-Vis spectroscopy. Fig. 2 compares the VEI of microtomed slices after various times of extraction to the VEI of unsoaked control acetabular liners. There is no statistically significant difference between the VEI of unsoaked and extracted liners ( $p > 0.05$  in all cases). There was no change of VE concentration observed in specimens immersed in DI water for 24 weeks. The SOI of all slices analyzed were < 0.1, indicating negligible oxidation. Fluorescence spectra of ethanol solutions after pressure induced elution tests are shown in Fig. 3. There was no difference between non-VE controls and VE-HXPE after loading under 3 MPa and 30MPa. No elution was observed on any of test specimens.

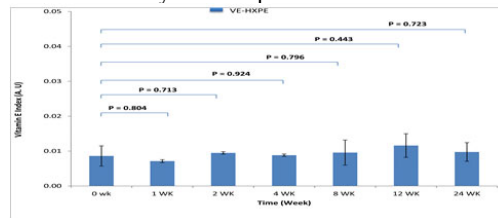


Fig. 2: VEI of VE-HXPE specimens after immersion in water for up to 24 weeks (Student's t-Test  $p$ -value is presented above the bar which demonstrates no difference between samples).

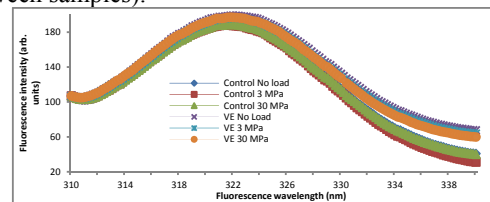


Fig. 3: Fluorescence spectra of ethanol solutions after pressure induced elution test. Control represents HXPE. VE represents VE-HXPE

## DISCUSSION

Detailed analyses of potential VE elution were studied by UV-Vis, FTIR and Fluorescence spectroscopy. No VE elution was detected from the VE-HXPE material after 24 weeks immersion in DI water and under low (3MPa) and high compressive pressures (30MPa). Therefore, it can be concluded that VE does not elute from the VE-HXPE material under physiological conditions.

## REFERENCES

- [1] Wolf C, *J Mat. Sci Mater Med* 2002
- [2] Oral E, *Biomaterials* 2004
- [3] Puertolas JA, *Journal of Applied Polymer Science*, 120 (2011) p2282-2291.
- [4] Okubo Y, *J. Biomech. Sci. and Eng.*, 5, 154 (2010).