A Low Wear, High Fatigue Strength UHMWPE with a Gradient Vitamin E Concentration

1Ghali, B; 2Rowell, S; 3Micheli, B; 4+Oral, E; 5Muratoglu, O

+ Harris Orthopaedic Biomechanics and Biomaterials Laboratory, Massachusetts General Hospital, Boston, MA

3 Harvard Medical School, Boston, MA

Ghali@partners.org

INTRODUCTION:

Radiation cross-linking is used to decrease wear in ultra high molecular weight polyethylene (UHMWPE) as a total joint arthroplasty bearing surface [1,2] but it also reduces its fatigue strength [1]. Current research focus is to improve the fatigue strength of wear and oxidation resistant cross-linked UHMWPEs in order to improve their use in high stress applications and young and active patients. It has been shown that the residual free radicals in radiation cross-linked UHMWPE can be stabilized by vitamin E [1]. In addition, vitamin E hinders radiation cross-linking in UHMWPE with high cross-link density on the surface for wear resistance and low cross link density in the bulk for fatigue resistance while maintaining oxidative stability. For this purpose, we radiated cross-linked Vitamin E blended UHMWPE with 0.05 wt% Vitamin E on the surface and 0.5 wt% Vitamin E in the bulk. We performed pin-on-disc (POD) wear testing to determine wear resistance, and fatigue crack propagation testing to determine fatigue strength. We also determined the delamination resistance of the gradient cross-linking interface by tensile testing and articulation under unidirectional motion.

METHODS:

Vitamin E blended UHMWPE (62 mm dia., 39 mm length) with 0.05 wt% Vitamin E in one half (region 1, Fig. 1) and 0.5 wt% Vitamin E in the other half (region 3, Fig. 1) were gamma irradiated to 150 kGy. Blocks with uniform 0.5 wt% and 0.05 wt% Vitamin E were used as controls. Cubes (3 mm) were cut from the low and high vitamin E regions (n=3) and the gradient region (n=6). Specimens were swollen in 25 ml of hot xylene (130°C) for 2 hours, then blot-dried and weighed. The gravimetric swelling ratio was converted to cross link density per reference [2].

Pins were machined for POD wear testing such that the articulating surfaces were at either region 1, 2 or 3 (Fig 1). We tested the pins against CoCr, under 163N load per pin, in bovine serum at 2 Hz for up to 2 million cycles (MC) [4]. Wear was determined gravimetrically every 0.5 MC. Wear rate was calculated as the linear regression of weight loss versus number of cycles from 0.5 MC to the end of the test.

Tensile tests were performed on ASTM D-638 type V dog-bone specimens (n=5) punched from 3.2 mm sections machined from the blocks at 10 mm/min on an electromechanical testing system using a laser extensometer.

Fatigue crack propagation tests were on A1 C(T) specimens per ASTM E 497 at 40°C in distilled water with a stress ratio of 0.1 at 5Hz. Cracks were measured optically every 20000 cycles. The stress intensity factor range at crack inception (ΔK) at 10⁶ mm/cycle was calculated.

Cylindrical pucks (50 mm dia., 12.7 mm thickness, n=2) were machined from irradiated blocks with gradient vitamin E concentration such that the articulating surface was located 2 mm into the highly cross-linked region. The pucks were accelerated aged at 80°C in air for 5 weeks, then were artificiated by CoCr right-lateral uni-compartmental femoral components (Zimmer Inc., Warsaw, IN) in undiluted preserved bovine serum under a constant load of 375 lbf per puck at 2Hz for 5 MC. Photographs of the top surface were taken every 1 MC. After the test, oxidation profiles were measured by Fourier Transform Infrared Spectroscopy (FTIR). The oxidation index was the ratio of the area under the carbonyl absorbance at 1740 cm⁻¹ to the area under the methylene absorbance at 1370 cm⁻¹ after boiling in hexane for 16 hours. One puck was melted in vacuum at 170°C.

RESULTS AND DISCUSSION:

By varying Vitamin E concentration we tailored a gradient of cross-linking in vitamin E-blended, cross-linked UHMWPE. Crosslink density had an inverse relationship with vitamin E concentration (Table 1). The improved wear resistance due to high cross-link density at the surface provided the benefits of 1st and 2nd generation highly cross-linked UHMWPEs (Table 1). Fatigue strength had an inverse relationship with vitamin E concentration (Table 1) with high bulk fatigue strength compared to irradiated, melted UHMWPE and to irradiated, vitamin E doped UHMWPE (Table 2).

<table>
<thead>
<tr>
<th>Region-Vitamin E</th>
<th>dV [mol/m³]</th>
<th>Wear [mg/MC]</th>
<th>UTS [MPa]</th>
<th>EAB [%]</th>
<th>ΔK [MPa·m¹/₂]</th>
</tr>
</thead>
<tbody>
<tr>
<td>(1)-Low</td>
<td>190 ±7</td>
<td>1.7±0.1</td>
<td>408±1</td>
<td>207±6</td>
<td>(0.71±0.01)</td>
</tr>
<tr>
<td>(2)-Gradient</td>
<td>139±15</td>
<td>3.9±0.8</td>
<td>44±6</td>
<td>288±11</td>
<td>-</td>
</tr>
<tr>
<td>(3)-High</td>
<td>108±5</td>
<td>4.9±0.41</td>
<td>52±8</td>
<td>374±24</td>
<td>(0.93±0.03)</td>
</tr>
</tbody>
</table>

Table 1: Cross-link density, tensile mechanical properties and fatigue strength where sample (1) and sample (3) specimens were from respective irradiated controls with uniform concentration Vitamin E. A1; crosslink density.

One concern was the weakness of the gradient interface. We observed that the irradiated gradient material had a uniform tensile strength (UTS) and elongation at break (EAB) that maintained or improved upon that of the 0.05% vitamin E and irradiated UHMWPE (Table 1), suggesting that the interface was not the weakest part of the material.

It has been shown that conventional UHMWPE pucks, after aging for 5 weeks in air at 80°C, delaminate under unidirectional loading at less than 2 MC due to sub-surface oxidative embrittlement [5]. We observed no such delamination for the aged irradiated gradient pucks even after 5 MC. This demonstrated (1) the presence of a cross-link gradient 2 mm below the surface did not cause subsurface weakness and (2) the vitamin E prevented oxidation. This was supported by the surface oxidation index of aged and delamination tested samples, which was 0.10. After melting, we observed no delamination and the creep/wear scar recovered to its original height, except for a shallow striated depression (Fig 2).

In UHMWPE blended with a gradient of vitamin E concentration and subsequent radiation cross-linking, high cross-link density in the surface region resulted in high wear resistance and low cross-link density in the bulk region resulted in high fatigue strength. The gradient interface was well integrated with high delamination resistance. This novel UHMWPE has great potential for use in demanding high stress application such as in posterior stabilized total knees as a wear and oxidation resistant cross-linked UHMWPE with improved fatigue strength.

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REFERENCES:

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