VITAMIN E HXLPE FOR LOW WEAR AND OXIDATION RESISTANCE OF HIP BEARINGS

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INTRODUCTION
Cobalt chrome on ultra high molecular weight polyethylene (UHMWPE) remains a widely used bearing surface combination in total joint replacement. Wear induced osteolysis remains a concern with such bearings and first generation highly cross-linked polyethylene (HXLPE) materials were introduced to address this issue [1]. However, there are concerns regarding bulk material property degradation of HXLPE [2] and oxidation after implantation which has been hypothesised to be as a result of lipid absorption or cyclic loading [3].

ECIMA is a cold-irradiated, mechanically annealed α-tocopherol (vitamin E) blended UHMWPE and is a next generation HXLPE developed to maintain mechanical properties, minimise wear and to improve the oxidation resistance in the long-term.

The aim of this study was to compare the in-vitro wear rate and mechanical properties of three different UHMWPE acetabular liners; conventional UHMWPE, HXLPE and ECIMA (before and after ageing). In addition, the oxidative stability of ECIMA was assessed.

METHODS
A total of fifteen acetabular liners (Corin, UK) underwent a hip simulation (servo-hydraulic, type C6/2-07). Three conventional UHMWPE liners (GUR 1050, Ø32 mm, gamma sterilised in nitrogen to 30kGy) were tested to 3 million cycles (mc). Six HXLPE liners (GUR 1020, Ø40 mm, cross-linked to an irradiation dose of 75kGy and EtO sterilised) and six ECIMA liners (GUR 1020 blended with 0.1wt% vitamin E, Ø40 mm, cross-linked to an irradiation dose of 120kGy, mechanically deformed and annealed, and EtO sterilised) were tested to 5 mc. All liners articulated against CoCrMo alloy femoral heads to ASTM F75 (hot isostatically pressed and solution annealed) (Corin, UK).

The wear testing was performed in accordance with ISO 14242 parts 1 and 2. The wear simulator used a double-peak force curve according to Paul [4], with a maximum force of 3.0 kN. The test lubricant used was calf serum with a protein content of 30 g/l supplemented with 1% (v/v) patricin as an antibacterial agent. The simulators operated at a frequency of 1 Hz and were stopped after the first 0.5 mc and every 1.0 mc thereafter, so that the volumetric wear rate could be determined gravimetrically. The location of the specimens within the simulator was periodically changed to reduce the affects of inter-station variability. Moisture uptake was monitored using loaded soak controls; one for UHMWPE, and two for HXLPE and ECIMA.

Following completion of the ECIMA wear testing, three of the tested liners were cut in half. One half of each was subject to accelerated ageing in accordance with ASTM F2003-02 (5atm of pure oxygen at 70ºC for 14 days), while the other half was tested as received. Each liner half was cross-sectioned and a microtome was used to section 200μm thick slices from each cross-section. Hexane extraction was performed under reflux for three days on both the aged and unaged samples prior to oxidation analysis to remove any lipid contaminants from the wear testing. Oxidation analysis was performed using a Fourier Transform Infra-red technique in accordance with ASTM F2102-01 throughout the thickness of each liner half. Average oxidation indices for each sample were determined.

To provide comparative data, samples of untested ECIMA material (n=3) were aged in accordance with ASTM F2003-02. Post-ageing, 200 μm thick slices of material were micromtomed from the centre of each specimen. Oxidation analysis was performed in accordance with ASTM F2102-01. Surface (SOI) and bulk (BOI) oxidation indices for each of the samples were determined.

Dog bone specimens, 3.2 mm thick (ASTM D638 type V) were machined from ECIMA material. Half of the samples were aged in accordance with ASTM F2003-02. Uniaxial tension testing was carried out as per ASTM D638 to characterise the mechanical properties of the aged and unaged material. Specimens were machined in three different directions; parallel to the direction of consolidation, parallel to the direction of deformation and orthogonal to both of these directions. Ultimate tensile strength (UTS), yield strength and percent elongation values were measured. These values were compared to mechanical data available for the other material types.
RESULTS AND DISCUSSION

Figure 1 shows the wear rates for the three different materials tested. There was a 95% and a 83% reduction in the wear rate for the ECIMA liners compared to the conventional UHMWPE and HXLPE liners respectively (Figure 1). The wear results reported in this study indicate that ECIMA is a very low wearing material which has the potential to reduce wear related osteolysis in-vivo.

All of the oxidation values for the wear tested ECIMA liners, before and after ageing, and the aged, untested ECIMA samples were negative, which shows oxidation levels below the level of detection throughout the thickness of the samples. This indicates a high level of through-thickness oxidation resistance for the ECIMA specimens even after being subject to an aggressive ageing protocol and cyclic loading. This data supports previous studies of a similar HXLPE material which contained 0.1wt% vitamin E and demonstrated good oxidation resistance throughout the thickness of the material [5].

The average of the UTS, yield strength and percent elongation for the three directions for aged and unaged ECIMA are presented in Table 1 alongside previously published data for a conventional UHMWPE and a HXLPE material. There was an increase in UTS, yield strength and percent elongation of 45%, 16% and 32% respectively, for unaged ECIMA compared to HXLPE. Following ageing of the ECIMA samples, there was minimal change in all three mechanical properties. Importantly, the mechanical properties were not substantially degraded and were more comparable to conventional UHMWPE than HXLPE. Further to this, following an aggressive ageing protocol, the ECIMA material maintains the mechanical properties of the unaged condition.

CONCLUSION

The reduced wear rate during in-vitro hip simulation of ECIMA compared to conventional UHMWPE, coupled with improved mechanical properties and long-term oxidation resistance in comparison to HXLPE, makes ECIMA a promising next generation UHMWPE bearing material.

Additional mechanical testing and aggressive wear testing of the ECIMA material presented in this paper are being performed in order to further validate this material for use in-vivo.

REFERENCES


<table>
<thead>
<tr>
<th>UHMWPE GUR 1020 (γ-barrier) [6]</th>
<th>HXLPE 100kGy, melted, GUR 1050 [7]</th>
<th>ECIMA</th>
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<tr>
<td>UTS (MPa)</td>
<td>57±3.7</td>
<td>38±3</td>
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<td>Yield strength (MPa)</td>
<td>22.1±0.5</td>
<td>19±0</td>
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<td>Elongation (%)</td>
<td>418±19</td>
<td>262±9</td>
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Table 1: Comparison of Mechanical Properties
Note: ECIMA data presented is the average of the directions tested