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Biocompatibility and in vitro tests

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Investigating the effect of crosslinking on the wear resistance of Vitamin-E diffused UHMWPE, when articulating against cortical bovine bone

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Introduction: The wear resistance of crosslinked vitamin-E diffused UHMWPE (E-HXLPE) is known to be much greater than historic UHMWPE, when used in metal-on-polyethylene and ceramic-on-polyethylene joint replacements. It is proposed that E-HXLPE could therefore be sufficiently wear resistant when articulating against cortical bone for use *in-vivo* in short-term surgical intervention applications. The current study investigates this through a preliminary pin-on-plate (PoP) wear test, comparing E-HXLPE and standard vitamin-E enhanced UHMWPE (E-UHMWPE).

Experimental methods: A PoP tribometer was used to test the wear rates of E-HXLPE and E-UHMWPE articulating against cortical bovine bone plates. There were n=2 test pins of each polymer, n=4 bone test plates and n=3 soak controls of each material. As the usable lifespan of the bone plates was unknown, the tribometer was operated for incrementally longer time periods with measurements taken at each break, maximising data gathered towards the experiment start. Once an operating time of 6 hours was reached this measurement point was maintained until termination at 200,000 cycles. Downtime was minimised to 1 hour per break, during which wear of the components was measured gravimetrically.

The lubricant used to replicate synovial fluid was bovine calf serum (BCS) diluted to a protein concentration of 21 g/l. Lubricant was changed at each break. BCS temperature and pH were measured pre- and post- each test. Topographical analysis of the pins was carried out pre- and post-test using white-light interferometry surface analysis. Silicone moulds of the bone plates were taken pre- and post- test, which were then cast and analysed for characteristic surface features.

Image:

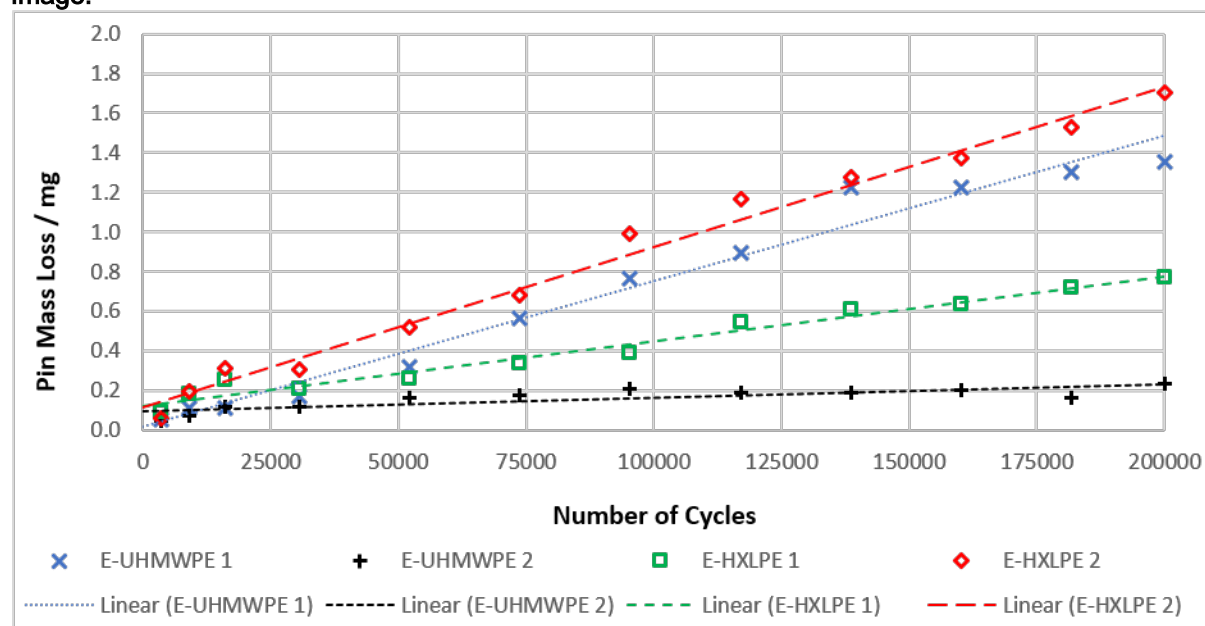


Figure 1: The mass loss of the four polyethylene test pins during the wear test. Each data point represents the mean mass of a pin after multiple repeat readings, corrected for the mean mass change of the relevant soak control pins.

Results and discussions: The E-HXLPE pins gave wear factors of 2.57 and 5.67 $\times 10^{-6}$ mm³/Nm. One of the E-UHMWPE pins (pin E-UHMWPE 2, Figure 1) underwent plastic deformation near the start of the test, causing a subsequent

absence of mass loss. Consequently, this pin was removed from the wear and topography analysis. The remaining E-UHMWPE pin had a wear factor of $4.53 \times 10^{-6} \text{ mm}^3/\text{Nm}$, indicating that crosslinking had little impact on wear resistance. Wear of the bone plates was investigated gravimetrically, but the minimised downtime meant it was not possible to achieve mass stabilisation.

Monitoring of BCS pH indicated a mean test sample increase from 7.24 ± 0.10 to 8.31 ± 0.02 , across both polymers. There was negligible change in control BCS pH, indicating that the pH increase occurred due to the effects of the wear process on the BCS, not bone plate degradation. The temperature of all BCS samples remained aligned with the ambient temperature. The topographical study found a similar reduction in surface roughness (S_a) across both polymers; the final S_a values for E-UHMWPE and E-HXLPE were $0.28 \pm 0.12 \text{ } \mu\text{m}$ and $0.26 \pm 0.10 \text{ } \mu\text{m}$, respectively. The surface skewness (S_{sk}) decreased more for E-UHMWPE than E-HXLPE, likely due to the relative softness of E-UHMWPE compared to E-HXLPE.

Conclusions: This preliminary study has formed a new methodology for testing the wear of materials against cortical bone without the limiting effects of degradation. The wear results indicate that E-HXLPE performs similarly to E-UHMWPE, however further work is required to substantiate this. Topographical analysis found that the E-HXLPE surface topography was less impacted than the E-UHMWPE, warranting further research.

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