

OXIDATION OF VITAMIN-E STABILIZED CROSSLINKED UHMWPE AFTER 7 YEARS AGEING

Y. Dirix¹, A. Becker¹, L. Brunner¹, H. Schmotzer¹

¹Smith & Nephew Orthopaedics AG, Schachenallee 29, 5001 Aarau, Switzerland.

INTRODUCTION: Oxidation and wear of UHMWPE are two major factors that might affect the long term clinical survivorship of total joint replacements [1]. In the past, Vitamin E (Vit-E) has been suggested as an additive for UHMWPE to tackle the problem of oxidation [2]. The oxidative stability was tested using accelerated ageing protocols to simulate real time ageing. From these ageing studies, the Vit-E stabilized polyethylene can have a superior oxidative stability. However, no real-time ageing data are available. Therefore, the goal is to compare the oxidation after 7 years of real-time ageing of a gamma-sterilized highly crosslinked UHMWPE with- and without Vit-E addition.

METHODS: The UHMWPE (GUR 1020) blocks containing 0 and 0.2% w/w Vitamin E were prepared at PolyHiSolidur. Crosslinking was done by E-beam irradiation in air (10 MeV) to a total dose of 100 KGy followed by remelting. Pins according to DIN31680 were machined and used for a pin-on disc test at a speed of 0.5 m/s under dry conditions (TRM 200/Wazau Berlin; 9 MPa pressure). A polished stainless steel ring was used as a counterpart (INA, $R_z = 3.57 \mu\text{m}$). The linear wear of the pins ($n=3/\text{mat}$) was measured after 40 km sliding distance [3]. For the ageing experiment, the crosslinked pins were packaged in a single peel pouch consisting of a first generation barrier film. The packaging was flushed with nitrogen before gamma sterilization with a dose of 30.5 KGy. The packaged pins were stored in the dark at room temperature and were removed from their peel pouch after 86 months. The oxidation index was measured after ASTM F2102-06. Thin ($150 \mu\text{m}$) cross sections were cut from the pins and used for FTIR measurements to measure the oxidation index.

RESULTS: The wear rate for the crosslinked materials is significantly lower compared to the non-crosslinked reference polyethylene ($p=0.020$). The wear rate for the stabilized and crosslinked material is higher compared to the non-stabilized counterpart and almost at the level of the non-crosslinked reference ($p=0.570$). Ageing: The xlinked and gamma-sterilized material without a stabilizer shows a typical subsurface oxidation maximum and a high (>3) bulk oxidation (Fig 2) suggesting that the material has degraded. The stabilized polyethylene has only a relatively low surface oxidation (0.38).

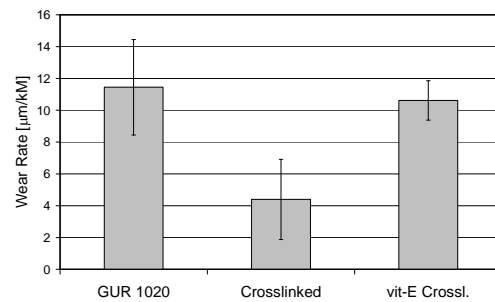


Figure 1: Wear rates for the UHMWPE pins before ageing (non-sterile).

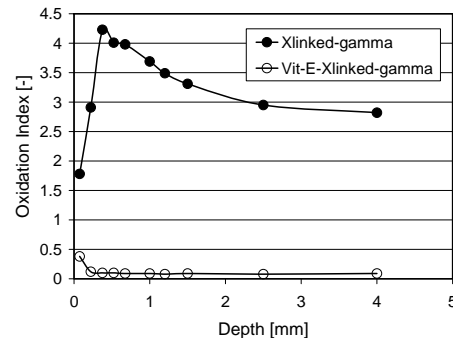


Figure 2: Oxidation index vs. depth for the gamma sterilized materials after 7 years of real time shelf ageing.

CONCLUSIONS: The crosslinking efficiency for UHMWPE was shown to be reduced by the presence of Vitamin E [4]; these results are confirmed by our tests. Although both materials received identical irradiation doses, the stabilized material had only marginal improved wear resistance. Therefore, the optimum balance between crosslinking and stabilization might be found at lower additive amounts [5]. The maximum oxidation for the crosslinked and sterilized pins was high ($\text{OI}=4$). Although packaged under nitrogen, the packaging used is of a first generation with moderate barrier performance, still enabling air penetration and therewith oxidation. However, the Vitamin E stabilized and crosslinked material, packaged and stored under identical conditions has virtually no oxidation, showing the protective power of this additive in a real-time ageing experiment.

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ACKNOWLEDGEMENTS: We acknowledge KATZ Aarau for experimental help and KTI (Grant 3211) for financial support.