Highly Impact Resistant Surface Crosslinked UHMWPE for Total Joint Implants

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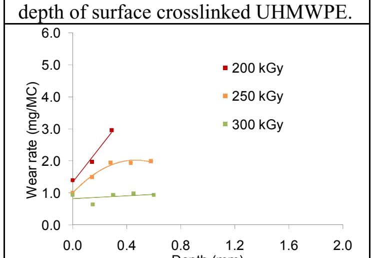
Statement of Purpose: Wear particle-induced periprosthetic osteolysis led to the development of radiation crosslinked wear resistant ultrahigh molecular weight polyethylenes (UHMWPE). However, increased crosslinking decreases the fatigue strength, increasing concerns about the failure of crosslinked UHMWPEs under adverse conditions[1]. A novel, surface cross-linked UHMWPE was achieved by creating a gradient in the concentration profile of the antioxidant vitamin E, which is used to also stabilize radiation crosslinked UHMWPE against oxidation. Because vitamin E hinders cross-linking with increasing concentration[2], a highly cross-linked surface could be achieved by having low vitamin E concentration on the surface and vice versa in the bulk[3]. The goal of this study was to determine the wear and fatigue resistance of surface crosslinked UHMWPEs.

Methods: Surface crosslinked UHMWPE was prepared by (1) extracting the surface vitamin E from uniformly vitamin E-blended UHMWPE or (2) layered blending of UHMWPE with two different vitamin E concentrations; each followed by radiation crosslinking. Using the first method, samples were prepared by blending 1, 1.5 or 2 wt% vitamin E in GUR1050 medical grade UHMWPE powder, consolidation of the blend, extraction in boiling Tween 20 solution (20 v/v% in water) for 40 hours. Using the second method, blended UHMWPE with 0.1 wt% vitamin E and 1 wt% vitamin E were layered and consolidated into 6.4 mm-thick pucks. Subsequently, the extracted materials were irradiated using e-beam irradiation to 150, 200, 250 or 300 kGy and the layered molded were irradiated to 150 kGy.

Wear testing was performed on a bidirectional pin-on-disc tester at 2 Hz for 1.2 million cycles (MC) as previously described[2]. Double notched IZOD impact testing was performed at Orthoplastics (UK) per ASTM F648.

Results:

Figure 1. The wear rate as a function of depth of surface crosslinked UHMWPE.



It was previously demonstrated that by using surface cross-linking, one could obtain a low wear rate (1-2 mg/MC), comparable to radiation crosslinked UHMWPEs[4] in current clinical use showing low penetration rates[5]. It is shown here that the wear rate profile as a function of depth from the surface could be manipulated by increasing the radiation dose (Fig 1). It is estimated that a highly crosslinked region with a thickness of 1 mm will be enough to last 40 years at a penetration rate of 0.025 mm/year. The impact strength of surface crosslinked UHMWPE was significantly improved compared to uniformly crosslinked UHMWPE at the same surface vitamin E concentration and radiation dose and to clinically available highly crosslinked UHMWPEs (Table 1).

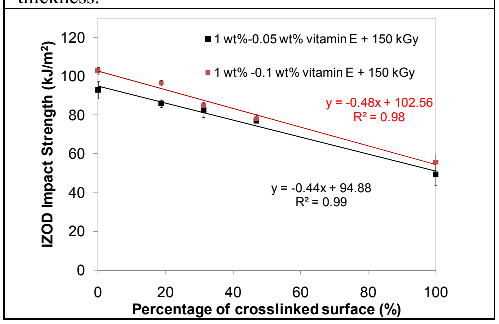
Table 1. The impact resistance of irradiated vitamin E blends.

Vitamin E concentration (wt%)	Radiation dose (kGy)	IZOD (kJ/m^2)
Uniform blends		
0.1	150	56±4
Surface cross-linked blend		
1 - 0.1 (1 mm surface)	150	97±2
Control/clinically available		
-	100	66±1
-	100/melt	60±2

The dependence of the impact strength on surface thickness showed a linear profile (Fig 2). Increasing the surface concentration increased the overall strength slightly. The impact strength of surface crosslinked UHMWPE was improved by 68-72% compared to uniformly crosslinked, vitamin E-stabilized UHMWPE for samples whose surface thickness was 20% of the entire component thickness.

Vitamin E-stabilized, irradiated UHMWPE showed much improved oxidation resistance when compared to clinically available irradiated and melted UHMWPE with similar wear resistance[7], even in the presence of a pro-oxidant. Thus, surface cross-linked UHMWPEs made by this method are expected to be highly oxidation-resistant.

Figure 2. The dependence of impact strength on surface thickness.



Conclusions: Surface crosslinked UHMWPE provides an alternative to current UHMWPE joint implant materials with equivalent wear resistance and much improved mechanical properties and oxidation resistance.

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