Comparative stability of irradiated, vitamin E-stabilized and irradiated, melted UHMWPE joint implants

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Statement of Purpose:

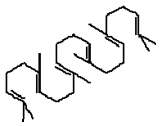
Our current understanding of oxidation resistance in UHMWPE is focused on the presence of radiation-induced residual free radicals, which are known to cause oxidation *in vivo*[1]. Recently, oxidation has been reported in irradiated and melted UHMWPEs without residual free radicals after the first decade of service *in vivo*[2], which was unexpected. We hypothesized some phenomena occurring *in vivo* could make irradiated UHMWPEs susceptible to oxidation; namely lipid exposure from the synovial fluid and cyclic loading/deformation.

Highly crosslinked UHMWPE stabilized by the antioxidant vitamin E was developed to improve the mechanical properties of irradiated/melted crosslinked UHMWPEs while maintaining oxidative resistance. Therefore, in this study, we compared the oxidative behavior of irradiated/melted and irradiated, vitamin E-stabilized UHMWPEs against oxidation initiated by exposure to squalene, an unsaturated lipid known to absorb in UHMWPE *in vivo*[3] and cyclic deformation.

Methods:

Medical grade GUR1050 UHMWPE was e-beam irradiated to 100-kGy. Irradiated UHMWPE was either (1) doped with vitamin E at 120°C followed by homogenization at elevated temperature and terminal gamma sterilization or (2) melted at 170°C in air. Cubes ($1 \times 1 \times 1$ cm^3) were machined.

Figure 1. Structure of squalene.

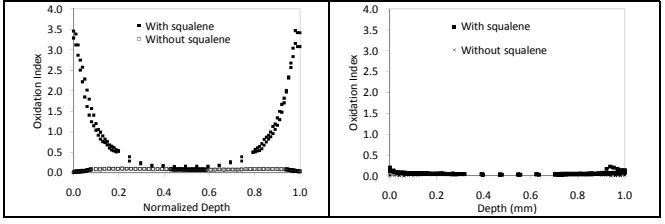


The oxidation and crosslink density of irradiated (100 kGy)/melted UHMWPE and irradiated (100 kGy)/vitamin E diffused/gamma sterilized UHMWPE were measured before and after accelerated aging (n≥3): (1) Standard ASTM testing: 70°C, in 5 atm. oxygen, 14 days (ASTM); (2) Lipid absorption: Doping with squalene (Fig 1) for 2 hours at 120°C followed by accelerated aging at 70°C, in 5 atm. oxygen for 14 days; (3) cyclic deformation as described previously[4].

Oxidation was determined by infrared spectroscopic measurements of the carbonyl groups normalized to a polyethylene crystalline peak as previously described[4].

Results:

Figure 2. Oxidation index profiles of accelerated aged irradiated/melted (a) and irradiated/vitamin E-stabilized UHMWPEs with and without squalene (b).



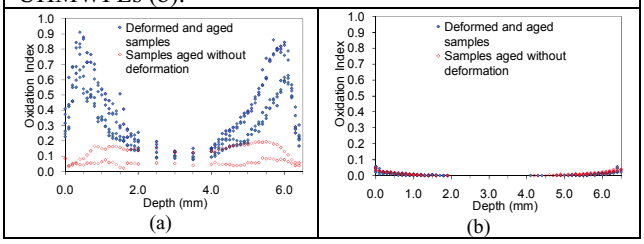
Squalene, an unsaturated lipid, which is a major component of our skin lipids, was found in explant components *in vivo*[3], but its effect on the oxidation of UHMWPE was recently discovered[5]. Irradiated, vitamin E-stabilized, terminally sterilized UHMWPE showed higher resistance to squalene-initiated oxidation (Fig 2) despite containing radiation-induced free radicals[6]. This is presumably due to the activity of the antioxidant vitamin E against free-radical initiated oxidation mechanisms.

Table 1. Crosslink density of lipid, doped accelerated aged samples.

	Before aging	After aging
Irradiated/melted UHMWPE		
Irrad./melted	178±3	53±6
Irrad./vitamin E	173±5	181±1

The extent of oxidative degradation was measured as a decrease in crosslink density in irradiated/melted UHMWPE (Table 1), whereas the crosslink density of irradiated, vitamin E diffused UHMWPE was maintained. Since wear resistance is a strong function of crosslink density[7], the effects of this decrease on wear will be investigated.

Figure 3. Oxidation index profiles of accelerated aged irradiated/melted (a) and irradiated/vitamin E-stabilized UHMWPEs (b).



Cyclic loading, which has also been absent from standard accelerated aging techniques, also accelerated the oxidation of irradiated/melted UHMWPE (Fig 3a) and did not cause oxidation in irradiated, vitamin E-stabilized UHMWPE when tested for 5 million cycles (Fig 3b).

These results suggest the importance of some new oxidation mechanisms of UHMWPE and warrant further investigation.

Conclusions:

In the absence of residual free radicals, UHMWPE is expected to be stable against oxidation. However, the unsaturated lipid squalene-initiated oxidation in irradiated/melted UHMWPE by a yet unknown mechanism. The presence of the antioxidant was effectively protected against these new mechanisms as well as radiation induced free radicals.

References: 1) Premnath V Biomaterials 1996;17:1741-53. 2) Muratoglu OK JBJS 2010; Dec; in press. 3) Costa L Biomaterials 2001;22:307-15. 4) Nabar S ORS 2008:1684. 5) Oral E ORS 2010;2283. 6) Oral E Biomaterials 2006;27:5580-7. 7)Muratoglu OK Biomaterials 1999;20:1463-70.