

The Effect of Oxidation on the Impact Toughness of Clinically Relevant UHMWPEs

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Statement of Purpose: Radiation cross-linked ultrahigh molecular weight polyethylene (UHMWPE) is preferred in total joint arthroplasty [1] because it decreased wear and the incidence of peri-prosthetic osteolysis [2]. In addition to wear resistance, oxidation resistance is important as oxidation decreases the mechanical and fatigue strength of UHMWPEs [3].

In this study, we determined the effect of oxidation on the IZOD impact strength of three clinically relevant highly cross-linked UHMWPEs: (1) irradiated and melted UHMWPE without additives (CISM); (2) sequentially irradiated and annealed UHMWPE without additives (SXL); and (3) irradiated, vitamin E-diffused UHMWPE (E1).

Methods: Sample Preparation (1) GUR 1050 UHMWPE was irradiated to 100 kGy and then melted (CISM); (2) GUR 1050 UHMWPE was irradiated with 3 sequential doses of 30 kGy for a cumulative total of 90 kGy-with annealing at 130°C after each irradiation (SXL); (3) 100-kGy gamma irradiated, vitamin E-diffused and gamma sterilized (E1) tibial preforms were obtained from Biomet.

All of these samples were then machined to 6.35 x 12.7 x 63.50 mm impact testing coupons according to ASTM F648-07. **Accelerated aging:** (a) Machined samples of each kind (n=4) were accelerated aged 'as is' at 70°C and 5 atm. of oxygen for 0, 2, 3 or 4 weeks. (b) Some samples (n=4 each) were accelerated aged after doping in a lipid emulsion comprising 0.0625 % wt each of cholesteryl linoleate, cholesterol, cholesteryl stearate, and squalene emulsified in 22.5 wt% Tween 20 or 5 wt% Tween 80. Lipid doping was performed at 40°C for 3 weeks and accelerated aging at 5 atm of oxygen at 70°C for 0, 2, 3, or 4 weeks. **Characterization** IZOD impact testing was conducted according to ASTM Standard F648-07 using Instron CEAST 9050. Determination of carbonyl index was conducted using FTIR on 150 um thin slices that were extracted using boiling hexane for 16 hours. A carbonyl index was determined by taking ratio of the area of peak at 1740 cm⁻¹(1680-1780 cm⁻¹) to 1370 cm⁻¹(1330-1390 cm⁻¹). An average oxidation index was calculated. Crosslink density of the surface (0-1 mm) and bulk (4-6 mm) of the material was determined gravimetrically according to ASTM F2214-02.

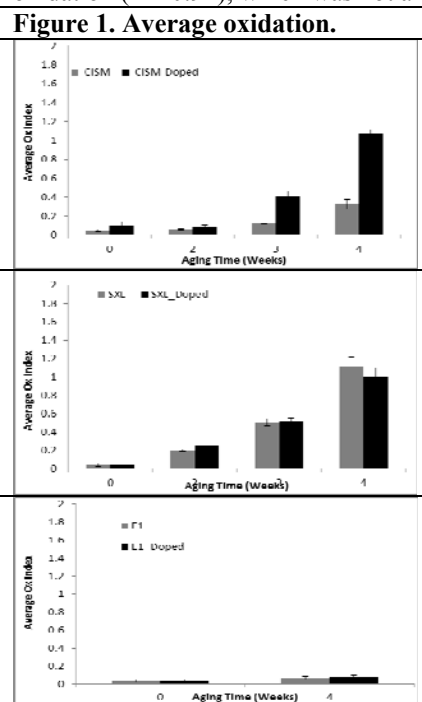
Results: The impact strength of CISM aged as is or in the presence of absorbed lipids was increased after 2 weeks of aging (p =0.03 for doped samples and p=0.05 for undoped) but then significantly decreased after 3 weeks (p=0.0007 for doped samples and p = 0.045 for undoped samples). After aging for 3 and 4 weeks, the impact strength of the lipid-doped samples were 18% (95 % CI = 11-25) and 82% less than their undoped counterparts (95 % CI = 79-84). In contrast, lipid doped and undoped SXL showed a significant decrease in impact strength after aging for 2, 3 or 4 weeks (p<0.01). There was no

significant difference in impact strength between the lipid-doped and undoped samples after aging at all durations. Impact strength of E1 samples were not significantly changed throughout aging for 4 weeks.

The oxidation of all samples except E1 increased with aging time (p<0.05; Fig 1). At all aging durations, the order of oxidation from lowest to highest was: CISM <SXL (p<0.05). Lipids alone did not significantly change the oxidation for all samples except CISM, where lipid doping significantly increased oxidation (3.3 times higher at 4 weeks (95 % CI = 2.8-4.1).

After aging for 4 weeks without lipid doping, the oxidation index of SXL was roughly 3 times higher than CISM (95 % CI = 2.8-4.3). After lipid doping and aging for 4 weeks, the average oxidation index of SXL was similar to CISM (95 % CI = 0.8-1.1).

Cross-link density of both CISM and SXL decreased as aging length increased (not shown). There was no significant change in crosslink density for E1 with aging. Impact strength decreased linearly with increasing oxidation (R²>0.94), which was not affected by lipids.



Conclusions:

This study suggests that oxidation, even at low levels, has detrimental effects on impact toughness, which correlates with fatigue resistance [4].

Accelerated aging as is or in the presence of synovial fluid lipids resulted in increased oxidation (Fig 1), decreased cross-link density and the deterioration of

impact strength (not shown) for the two virgin highly cross-linked UHMWPEs without antioxidant stabilization. Vitamin E effectively inhibited the cascade of oxidative reactions of irradiated UHMWPE in the absence and in the presence of lipids.

References: [1] Canadian Joint Registry 2007 Annual Report.; [2] Kurtz et al. Clin Orthop Rel Res 2011; 469: 2262-2277; [3] Baker et al. Polymer 2000; 41: 795-808; [4] Doshi et al. ORS 2013; 1820.