Oxidative Stability of Antioxidant Containing Ultra High Molecular Weight Polyethylene at 80 kGy Sterilization Dose

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Purpose: The long term oxidative stability of Ultra High Molecular Weight Polyethylene (UHMWPE) is a very desirable for orthopedic bearing applications. Free radicals are generated during gamma processing of UHMWPE implants. A post irradiation treatment (remelting) has been implemented to quench free radicals yielding the implant much less susceptible to oxidative degradation. An alternative to this approach would be the addition of an antioxidant (AO) into the UHMWPE prior to gamma processing. An AO, pentaerythritol tetrakis [3-(3,5-di-tert-butyl-4-hydroxyphenyl) propionate], stabilized UHMWPE (AO-Poly) was prepared and gamma processed at an 80 kGy gamma dose. The oxidative stability of AO-Poly was assessed by subjecting it to an accelerated aging treatment and comparing it to non-gamma irradiated UHMWPE.

Methods: UHMWPE powder (GUR 1020 resin, MediTECH, Fort Wayne, IN) was mixed with the AO at a 0.075 w/w ratio and compression molded to produce AO-Poly. Compression molded UHMWPE (non-irradiated) (GUR 1020, MediTECH Fort Wayne IN) was used as positive control group. AO-Poly and GUR 1020 parts were gamma irradiated at a nominal dose of 80 kGy in vacuum package. The gamma irradiated GUR 1020 was used as negative control. Double notch Izod impact (DNI) testing was performed on five samples in accordance with ASTM F648. DNI samples were subjected to accelerated aging treatment prescribed in ASTM F-2003 for periods of 6, 10 and 15 weeks. FTIR analysis is conducted in absorbance mode according to ASTM F-2102.

Results: The ketone and ester bonds that are formed during oxidative degradation of UHMWPE contribute the carbonyl peak intensity. OI profiles of test samples were measured through the specimen thickness and are summarized in Figure 1. The presence of subsurface oxidation peaks (deeper than 1 mm) in the FTIR profile is clear evidence of oxidation of UHMWPE¹. Following the 6 week aging treatment non-irradiated control samples exhibited subsurface oxidation peaks. The AO-Poly samples did not exhibit subsurface oxidation peaks at any of the aging time periods.

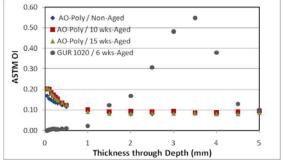


Figure 1. FTIR OI profiles; AO-Poly (80 kGy) Non-Aged, 10, and 15 weeks of aging, GUR 1020 (UHMWPE-non irradiated) after 6 wks of aging.

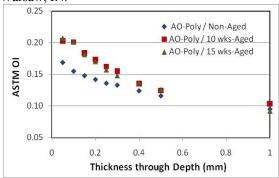


Figure 2. ASTM OI profile of AO-Poly (80 kGy) up to 1 mm (from Figure 1)

The FTIR spectra of AO-Poly samples include an initial carbonyl absorption peak due to the ester bonds present in AO molecules. After gamma irradiation, the AO molecules that react with polyethylene free radicals and/or any free radicals that may exist in the system are converted into quinone methide molecules². These molecules contribute to the ketone absorption peak which results in the slightly elevated surface OI values of the AO-Poly samples (Figure 2, AO-Poly/Non-Aged). The accelerated aging treatments of the AO-Poly samples resulted in no significant changes in the OI. The slight increase in OI up to 1 mm of depth is due to the sacrificial consumption of AO molecules to protect UHMWPE from oxidative degradation. (Figure 2)

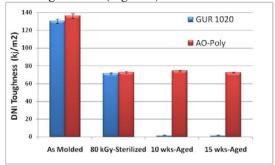


Figure 3. DNI toughness of AO-Poly in compared to GUR 1020.

Typically, gamma irradiated UHMWPE samples subjected to accelerated aging in an oxygen environment exhibit a significant decrease in DNI toughness due to oxidative degradation. This can be seen in Figure 3 for the GUR 1020-80 kGy irradiated control sample. AO-Poly (80 kGy) maintains its DNI toughness even after 15 weeks of aggressive accelerated aging.

Conclusions: This study shows the superior oxidative stability of gamma irradiated AO-Poly (80 kGy) in comparison to non free radical containing control UHMWPE samples. Additionally, AO-Poly maintains its impact strength even after an accelerated oxidative aging challenge of 15 wks.

Reference: 1) Kurtz SM. The Handbook of UHMWPE. New York, Academic Press, 2004.

2) Pospisil, J. Adv in Poly Sci. 36, 69-133, 1980.