Delamination Resistance of a Chemically Crosslinked UHMWPE/Vitamin-E Blend for Total Joint Arthroplasty Implants

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INTRODUCTION: Gamma irradiation remains the most common method for crosslinking ultra-high molecular weight polyethylene (UHMWPE) for total joint arthroplasty bearings. Presently, greater than 99% of all primary hip arthroplasty procedures and nearly 80% of primary total knee arthroplasty use either highly crosslinked or antioxidant-stabilized highly crosslinked UHMWPE as a bearing material[1]. The inability of gamma irradiation supply to meet the growing demand of total joint arthroplasty procedures underscores the need to seek out alternative methods of crosslinking UHMWPE. Chemical crosslinking with peroxides provides an attractive option for fabricating antioxidant-stabilized highly crosslinked UHMWPE as the crosslinking step occurs simultaneously with consolidation of the blended resin and has higher crosslinking efficiency than gamma irradiation in the presence of a free radical scavenger like an antioxidant[2]. In addition, peroxide crosslinking of antioxidant stabilized UHMWPE followed by inert high-temperature melting has been shown to produce material with superior toughness compared to traditional blended or diffused gamma crosslinked antioxidant UHMWPE materials[3]. The objective of this study was to compare the delamination resistance of a compression molded UHMWPE/vitamin-E/di-cumyl peroxide blend followed by high-temperature melting in an inert gas oven (Activit-E™) with conventional polyethylene (CPE) and sequentially annealed and irradiated polyethylene (SXL) under both unaged and accelerated aged conditions. We hypothesized that the Activit-E material would show the greatest resistance to delamination and would be least affected by aging.

METHODS: Polyethylene pucks approximately 50mm in diameter by 13mm thick were fabricated from Activit-E, CPE, and SXL UHMWPE materials. The Activit-E samples consisted of a compression molded UHMWPE/vitamin-E/di-cumyl peroxide blend followed by high-temperature melting in an inert gas oven and then terminally sterilized via gamma under vacuum. The CPE samples were fabricated from GUR 1050 resin and gamma sterilized under vacuum. The SXL material was fabricated from GUR 1020 blocks that underwent three sequential gamma irradiation doses for a total maximum dose of 100 kGy followed by annealing for 8 hours at 130ºC after each gamma dose exposure. A set of samples from each material group were tested in an unaged condition, as well as after aging for two weeks and four weeks in a pressure vessel (5atm of pure O_2) placed in a convection oven at 70ºC[4]. Delamination testing was carried out using unidirectional reciprocating motion and load as previously described[5]. Each puck was affixed to a linear reciprocating table programmed with a 17mm stroke at a rate of 2Hz. A constant load of 375lbf was applied to each puck using a pneumatic press on which two unicompartmental knee femoral components were attached. Testing was conducted in bovine serum stabilized with EDTA and penicillin-streptomycin. All samples were tested out to 2 million cycles (MC) or until the polyethylene sample failed due to delamination or forming large pits on the articular surface and testing could no longer continue due to the extremely rough UHMWPE surface. Testing was paused after every 0.5 MC and cleaned prior to photographing and measuring the depth of the damage scar.

RESULTS: All unaged sample groups completed 2 MC of unidirectional reciprocating motion without delamination failure. After two weeks of accelerated aging, the CPE samples failed at 0.5 MC and therefore the 4-week aged CPE samples went untested. The 2-week aged Activit-E and SXL samples completed 2 MC successfully. The 4-week aged SXL samples did not survive beyond 0.5 MC while the 4-week aged Activit-E samples completed 2 MC successfully with no sign of delamination or pitting (Figure 1). The depth of the damage scar for all materials remained approximately at 0.5mm until failure occurred where depths extended to approximately 2.5mm due to pitting and delamination of the UHMWPE surface (Table 1).

DISCUSSION: The Activit-E samples successfully completed 2 MC of reciprocation without failure even after 4 weeks of accelerated aging. While the SXL material was able to achieve 2 MC after 2 weeks of accelerated aging, these samples failed early in the experiment after 4 weeks of aging thus reinforcing the importance of antioxidant stabilization of highly crosslinked UHMWPE. The results indicate that Activit-E is more resistant to aging and delamination than conventional UHMWPE and sequentially irradiated and annealed UHMWPE under the tested conditions. The present study adds to the growing body of literature demonstrating competitive and often superior mechanical properties of peroxide crosslinked and antioxidant stabilized UHMWPE followed by inert high-temperature melting.

SIGNIFICANCE/CLINICAL RELEVANCE: Peroxide crosslinked, vitamin-E stabilized and high temperature melted UHMWPE represents an appealing material option due to its superior scalability and production efficiency compared to gamma irradiation crosslinking of UHMWPE. Resistance to delamination is an important requirement for UHMWPE materials used in total joint arthroplasty. This study demonstrated superior resistance to delamination of the peroxide crosslinked UHMWPE material compared to conventional UHMWPE and sequentially annealed and irradiated UHMWPE.

REFERENCES: 1. AJRR 2022 Annual Report. 2. Oral et al. *J. Biomed. Mater. Res. Part B Appl. Biomater.*, 2017. 3. Oral et al. *J. Biomed. Mater. Res. Part B Appl. Biomater.*, 2019. 4. ASTM F2003-02 (2022). 5. Wannomae et al. *J. Arthroplasty.*, 2010.

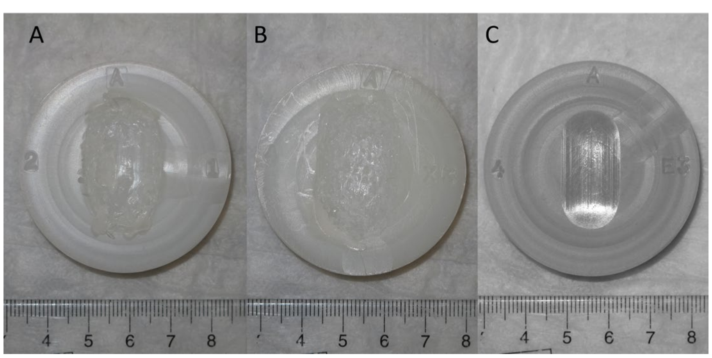

Figure 1: A: CPE (2-week aged) failed after 0.5 MC; B: SXL (4-week aged) failed after 0.5 MC; C: Activit-E (4-week aged) passed 2MC without delamination failure.

		0.5 MC	1.0 MC	1.5 MC	2.0 MC
CPE	Unaged	0.46 ± 0.01	0.46 ± 0.00	0.47 ± 0.01	0.49 ± 0.02
	2 wk Aged	2.57 ± 0.43	Untested		
	4 wk Aged	*Untested*			
SXL	Unaged	0.25 ± 0.08	0.48 ± 0.04	0.53 ± 0.02	0.56 ± 0.04
	2 wk Aged	0.49 ± 0.05	0.53 ± 0.06	0.57 ± 0.06	0.59 ± 0.06
	4 wk Aged	2.71 ± 0.53	*Untested*		
Activit-E™	Unaged	0.51 ± 0.04	0.56 ± 0.03	0.60 ± 0.01	0.61 ± 0.01
	2 wk Aged	0.49 ± 0.05	0.50 ± 0.05	0.52 ± 0.05	0.54 ± 0.04
	4 wk Aged	0.41 ±0.03	0.45 ± 0.03	0.50 ± 0.03	0.57 ± 0.03

Table 1: Damage scar depth measurements (mm) at each interval of testing. Numbers in red indicate sample Failure.