Mechanical Properties and Wear Resistance of an Anti-oxidant Stabilized Crosslinked Polyethylene

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Introduction: Since 1998, crosslinked-remelted polyethylenes have shown high resistance to wear (1,2) and negligible osteolysis (3,4). Remelting provides high resistance to oxidation, but can reduce fatigue resistance. (5) This report describes the mechanical and wear properties of a radiation-crosslinked polyethylene stabilized with an anti-oxidant, rather than by remelting.

Materials & Methods: The control poly was extruded GUR 1020 (MediTECH, Ft. Wayne, IN) gamma-crosslinked at 75 kGy, melted at 155 ºC, and machined into liners (AltrX™, DePuy Orthopaedics, Inc., Warsaw, IN). The anti-oxidant poly (115AO-Poly) was GUR 1020 powder (MediTECH, Fort Wayne, IN) mixed with pentaerythritol tetrakis [3-(3,5-di-tert-butyl-4-hydroxyphenyl) propionate] at 0.075 w/w, compression molded, machined into liners, vacuum packed and gamma sterilized/crosslinked at 115 kGy. Six samples of each poly were tensile tested (ASTM D638, Type V samples.) Five samples were double-notched Izod impact (DNI) tested (ASTM F648.) Crystallinity was measured per ASTM F 2102. A single value of $\Delta K_{inception}$ for each poly was calculated from three fatigue crack propagation tests of each material (Case Western Reserve University), using compact tension test specimens (ASTM E647.)

Four 36mm ID liners of each poly were wear tested (Orthopaedic Hospital) on an OBM hip simulator (Shore Western, Monrovia, CA) under a Paul-type load with a 2000-N maximum, at 1 Hz, in bovine serum (63 mg/ml protein, 0.2% sodium azide, 20mM EDTA.) At intervals of 0.5 Mc, the liners were cleaned, dried and weighed, using loaded soak-controls. Six Mc were run against CoCrMo heads (ASTM F-1537), then 3 Mc against ceramic heads (Biolox® Delta, DePuy Orthopaedics). Additional DNI tests were performed after artificial aging for 40 days at 63 °C and 3 atm O_2 (6), and three of the four AO-Poly liners were similarly aged after 9 Mc wear cycles and tested to 12 Mc.

Results: Crystallinity of the 115AO-Poly was about 20% higher than AltrX™ (Table 1). The tensile properties of 115AO-Poly were uniformly higher, except impact strength, which was 6% and 11% higher for AltrX™ before and after aging, respectively. The steady state (i.e., > 1 Mc) wear rates (Fig. 1; Table 2) wear rate of the 115AO-Poly liners was 11% less than AltrX™ (p=0.1) against CoCr heads (1 to 6 Mc) and 11% less (p=0.3) against ceramic heads (6 to 9 Mc). The mean wear rates of the AltrX™ liners and the 115AO-Poly liners against ceramic heads were 34% less (p=0.002) and 34% less (p=0.0001), respectively, than with CoCr heads. Artificial aging of the 115AO-Poly had little effect on its mean wear rate.

Discussion: The wear resistance and mechanical properties the AO-poly compared favorably to the 75 kGy-remelted polyethylene that has been in extensive clinical use for four years. The AO-Poly also exhibited excellent resistance to oxidative degradation.

Property	Crosslinked UHMWPE		
	AltrX™	115AO-Poly	p-value
Tensile Strength at Yield (MPa)	20.0 ± 0.1	22.3 ± 0.1	2xE-06
Tensile Strength at Break (MPa)	49 ± 0	55 ± 3	0.01
Elongation at Break (%)	291 ± 33	312 ± 20	0.3
Impact Strength (kJ/m²)	68 ± 1 (unaged)	64 ± 3 (unaged)	0.008
	72 ± 1 (aged)	65 ± 2 (aged)	0.0002
$\Delta K_{inception}$	1.06	1.4	N/A
%Crystallinity	49 ± 1	59 ± 1	0.0005

Table 1: Mechanical properties of AltrX and AO-Poly

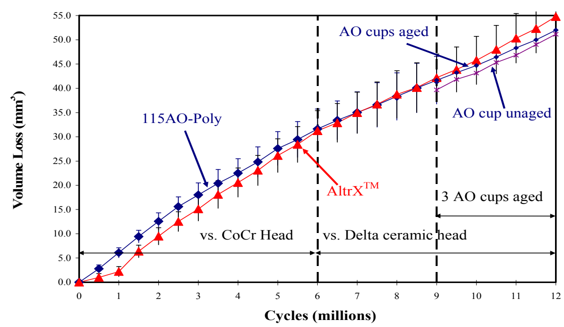

Figure 1: Volumetric wear of AltrX™ and 115AO-Poly

Test Interval	115AO Poly		AltrX™
	Mean wear rates ± S.D. (mm³/Mc)		
1–6 Mc vs. CoCr	5.0 ± 0.3		5.6 ± 0.6
6–9 Mc vs. Ceramic	3.3 ± 0.1		3.7 ± 0.5
	3 liners aged	1 liner unaged	unaged
9-12 Mc vs. Ceramic	3.3 ± 0.3	3.8 ± 0.5	4.2 ± 0.1

Table 2: Mean wear rates for indicated intervals

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