Performance of an Antioxidant-Stabilized XL-UHMWPE in Wear, Fatigue, and Acetabular Lock Detail Strength

Nathan Webb†, Mark Szymanski†, Doug Linton†, Jon Moseley, PhD†
†Wright Medical Technology, Arlington, TN

Disclosure: *The data presented in this abstract contains information pertaining to a medical device that has not received approval by the FDA or any other regulatory agency. Data presented is strictly for scientific understanding and is not intended to suggest future device performance.*

Statement of Purpose: The remelting of crosslinked UHMWPE is known to reduce oxidation potential after gamma irradiation, at the cost of reducing certain mechanical properties. The addition of stabilizers, in the form of antioxidants, may reduce oxidation potential without requiring remelting, retaining some material properties that would be reduced during remelting.

This experiment compared the wear performance, lock detail strength, and fatigue crack propagation (FCP) behavior of remelted UHMWPE versus material blended with a hindered amine light stabilizer.

Methods: Specimens were machined from compression-molded GUR1020. Control groups were irradiated with either 75 kGy or 100 kGy gamma and remelted. Experimental groups were machined from GUR1020 blended with a hindered amine light stabilizer (HALS), Chimassorb 944, at 1000ppm, molded, and irradiated to either 75 or 100 kGy, without subsequent remelting. All specimens were EtO sterilized prior to testing.

***Wear*:** Hip wear testing was conducted using a combination of methods outlined in ASTM F1714, ISO 14242-1, and ISO 14242-2. Testing was conducted in an orbital bearing hip wear test machine (Shore Western) in the anatomically oriented position and a 23° biaxial rocking motion. A simulated gait profile (200 N/ 2000 N), at 1 Hz, was used. The lubricant was 25% bovine serum with 0.2% sodium azide, 25 mM EDTA and distilled water. Each group was tested in conjunction with control load soak specimens. Sample numbers are noted in the results.

Lock Detail: Lock detail testing was conducted on 75kGy control and 100 kGy experimental liners according to ASTM F1820-13 except as noted. Liners were assembled according to surgical technique via impaction. Push-out samples were placed on a fixture that supported the outer lip of the shell. A ram applied a constant displacement ramp at 5.1 cm/min through a hole in the center of the shell until dislocation had occurred. For torque-out, the shell was affixed to a torsional load cell, while a CoCr head was affixed to the load frame actuator and fast-set epoxy cemented to the liner. A 100N compressive load was maintained throughout the test. A constant rotation rate of 360^o/min was applied, and the maximum torque was recorded. Lever-out testing was performed using a simple-lever, with a 1:1 moment arm. A displacement ramp was applied to the lever arm at 5.1 cm/min. Six samples were tested for each group in each test mode.

FCP: Samples were machined according to ASTM E647-08, Appendix A1, Compact Specimen, with W=25mm and B=11mm. Side grooves with a root radius of 0.25mm were cut into the side to a depth of 1.5mm. Samples were pre-notched with a razor and tested in load control. Load ratio ($R = P_{min}/P_{max}$) was set to 0.1 at 1Hz. To estimate ΔK_{incep}, Paris regime coefficients were used to determine a ΔK that would result in a da/dN of 10^{-5} mm/cycle.

Results: ***Wear*:** All groups of UHMWPE liners exhibited steady-state wear over 5M cycles as shown in Figure 1. There was no significant difference in wear between control and experimental groups irradiated to 75kGy. As expected the 100 kGy irradiated stabilized group wore at a significantly lower rate (2.15 vs. 7.0 mg/Mc). There was no significant difference between 46 mm and 28 mm liners irradiated to 100 kGy.

Lock Detail: Results were not statistically significant between materials in push-out, lever-out, or torque-out (2 sample t-test, alpha = .05). See Table 1 below.

FCP: The regressed Paris regime coefficients (of the form $da/dN = C\Delta K^m$) are listed in Table 1, along with estimated ΔK_{incep}. The difference in ΔK_{incep} values were statistically significant with p=0.011 between HALS vs both remelted materials (Fisher's pairwise test). Paris regime coefficient "C" was also significantly different (p=0.001) between HALS and both remelted materials, but Paris coefficient "m" was not statistically significant with p=0.210.

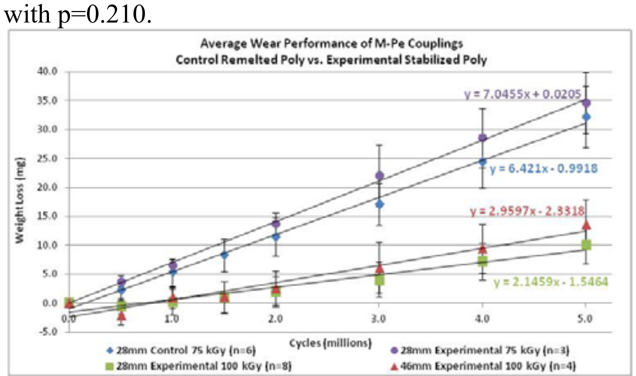

Figure 1. Gravimetric Wear of 28mm Hip Bearings

Table 1. Tabulated results (σ in parentheses)

	Control (remelted)		Exp. (HALS)
	75 kGy	**100 kGy**	**100 kGy**
Push-out (N)	721 (93)	n/a	748 (82)
Torque-out (Nm)	3.48 (0.48)	n/a	3.98 (0.36)
Lever-out (Nm)	1423 (90)	n/a	1291 (187)
Paris – C	2.78E-05 (8.1E-06)	3.5E-05 (2.4E-07)	4.3E-06 (4.0E-06)
Paris – m	6.25 (0.76)	6.41 (.29)	8.61 (2.6)
ΔK_{incep} MPa√m	0.76 (0.06)	0.74 (0.011)	1.06 (0.15)

Conclusions: The addition of HALS to the UHMWPE removes the need to remelt, increasing certain mechanical properties. By crosslinking to a higher dose and eliminating remelting following irradiation, the stabilized polyethylene exhibited superior wear properties, and superior fatigue crack propagation and initiation resistance, while retaining lock detail performance.