MULTI-LAB EVALUATION OF HIP SIMULATOR TEST CONDITIONS ON RELATIVE WEAR RATES OF CROSSLINKED POLYETHYLENES

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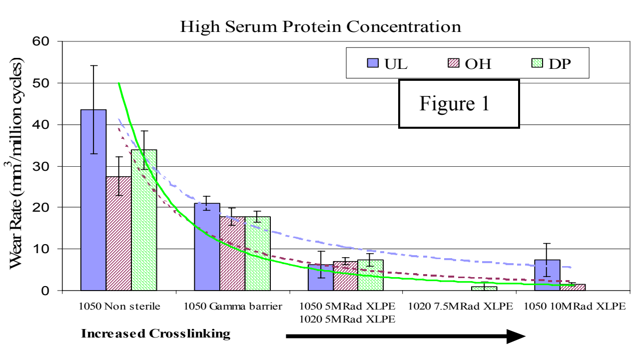
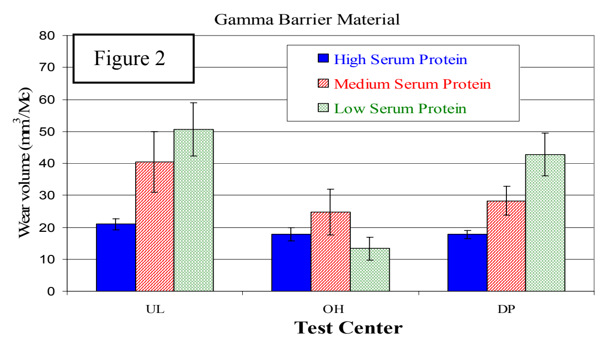
Introduction: Hip wear simulations are an effective method to assess the clinical potential of crosslinked relative to conventional UHMWPE materials.[1-4] In general, recently published short and mid term clinical studies for crosslinked and conventional UHMWPE indicate good agreement with simulation results.[5-7] However, there remain substantial differences in the preferred test conditions among laboratories internationally. This study investigated the effect of test conditions from 3 test centers on the wear of conventional and crosslinked polyethylenes. To permit comparisons, each center included common UHMWPE materials, and multiple serum protein concentrations. Conditions unique to each test center, including load magnitude and profile, simulator kinematics and serum chamber volume were unaltered from their earlier studies.

Materials and Methods: CoCrMo femoral heads (32mm) were tested against Duraloc acetabular components. Liner groups included non-crosslinked, gamma barrier (2.8-3.2 Mrad), moderately crosslinked (5Mrad/Remelted) and two with high crosslinking (7.5 and 10Mrad/Remelted). Details on materials/resins, sample size and machine setup for the three test centers, University of Leeds (UL), Orthopaedic Hospital (OH) and DePuy Orthopaedics (DP), are given below. All liners were placed in titanium alloy shells after a minimum 4 week soak in RO water. Bovine serum consisting of 3 protein concentrations: high (61 to 63mg/ml), medium (33 to 35mg/ml) and low (13 to 16mg/ml) was used as the test lubricant. Materials were tested for 2 million cycles in each serum protein concentration at 1Hz using the Paul-type loading curve. UL mounted the components with the cup above the ball in a 10 station hip simulator (Prosim, UK). Serum was changed at 0.33M intervals and cups were measured at 0.66M intervals, omitting the first million cycles to reduce creep effects. A coordinate measuring machine was used to map the surface and calculate wear volume. OH and DP mounted components in OBM-type 12 station hip simulators (Shore Western, Monrovia, CA) in the inverted position. Cups were weighed at 0.5M intervals, corresponding to serum change, and volumetric wear was calculated using a density of 0.935 g/cm^3. Load soak controls were used to correct for fluid absorption. Wear rates were calculated using linear regression and compared statistically using a two-tailed student t-test

	UL	OH	DP
Non sterile (1050)	N=2	N=3	N=3
Gamma Barrier (1050)	N=2	N=3	N=3
5Mrad (1050) XLPE	N=3	N=3	
10Mrad (1050) XLPE	N=3	N=3	
5Mrad (1020) XLPE			N=3
7.5Mrad (1020) XLPE			N=3
Load (N)	3000	2000	2000
Flexion/Extension (Deg)	+30º / -10º	23	23
I/E Rot: AD/AB (Deg)	±10º	23	23
Serum Volume (ml's)	500	60	160

Results and Discussion:
In high protein concentration,wear decreased monotonically with increasing gamma dose (Fig. 1). The overall trend was similar with medium and low concentrations, but with two notable exceptions where gamma barrier wore more than non-crosslinked poly. The effect of protein concentration on wear rate was much stronger in the UL and DP simulators than the OH simulator (e.g., Fig. 2 for gamma barrier poly) These differences may be attributable to the volume of lubricant used, i.e., greater percentage of precipitates resulting from a smaller chamber volume (OH) may have reduced the effect of protein concentration on wear.[8-9]





High Serum Protein Concentration Wear Rates (mm^3/million cycles)

Test Center	Non X-linked	Gamma Barrier	Moderately Crosslinked	Highly Crosslinked
UL	43.6 ± 10.7	21.0 ± 1.7	6.2 ± 3.2	7.3 ± 4.0
OH	27.5 ± 4.6	17.8 ± 2.1	1.8 ± 7.0	2.3 ± 1.5
DP	33.8 ± 4.6	17.8 ± 1.3	7.3 ± 1.5	1.0 ± 0.1
UL:OH	p=0.25	p=0.17	p=0.70	p=0.12
UL:DP	p=0.40	p=0.17	p=0.62	p=0.10
OH:DP	p=0.17	p=0.98	p=0.80	p=0.51

Med Serum Protein Concentration Wear Rates (mm^3/million cycles)

Test Center	Non Sterile	Gamma Barrier	Moderately Crosslinked	High Crosslinked
UL	65.7 ± 1.0	40.4 ± 9.5	24.3 ± 10.0	10.9 ± 1.8
OH	17.4 ± 2.9	24.8 ± 7.2	7.8 ± 0.4	2.0 ± 0.8
DP	34.8 ± 2.7	28.3 ± 4.6	16.4 ± 0.7	6.5 ± 1.3
UL:OH	p=0.00	p=0.20	p=0.10	p=0.01
UL:DP	p=0.00	p=0.29	p=0.31	p=0.03
OH:DP	p=0.00	p=0.52	p=0.00	p=0.01

Low Serum Protein Concentration Wear Rates (mm^3/million cycles)

Test Center	Non Sterile	Gamma Barrier	Moderately Crosslinked	Highly Crosslinked
UL	40.8 ± 3.4	50.7 ± 8.3	20.5 ± 5.3	5.9 ± 5.5
OH	17.3 ± 2.5	13.4 ± 3.6	4.3 ± 1.2	-0.1 ± 0.9
DP	41.1 ± 2.2	42.8 ± 6.8	23.1 ± 0.9	9.1 ± 0.5
UL:OH	p=0.02	p=0.07	p=0.03	p=0.00
UL:DP	p=0.93	p=0.39	p=0.49	p=0.41
OH:DP	p=0.00	p=0.01	p=0.00	p=0.00

The differences in wear rates among centers was greater in medium and low concentrations of serum (Table.) It was noteworthy that, in most cases, UL had comparable or higher wear rates than OH and DP, even though the UL machine generates less cross-shear per cycle than the OBM's. This could be attributed to a number of interacting factors including, but not limited to: the higher UL load, the upright cup position, which would minimize precipitated protein settling to the wear interface, and the larger chamber volume, which results in a lower percentage of precipitate at the interface. This study is continuing to evaluate the interactive effects of load and chamber volume, including the use of scratched femoral balls.

References: 1. McKellop et al., CORR 369, 1999 2. Galvin et al., SFB 2005 # 78 3. Liao, et al. SFB 2004 #2829 4. Muratoglu et al., JOA 16 2001 p. 149 5..Hopper et al., JBJS 85-A(3) 464, 2003; 6.Heisel et al., JBJS(4),48,2005: 7.. Door et al, JBJS 87-A, 1816, 2005., 8. Liao Bioceramics 17, 2004 p.991 9. Wang et al., SFB 1998 #218.

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