PERFORMANCE OF 38 mm MECHANICALLY ENHANCED POLYETHYLENE LINERS UNDER STANDARD AND SEVERE SIMULATOR WEAR MODES

Bowsher J G; Williams P A; Clarke I C; Green, D D; Donaldson T K
Orthopaedic Research Center, Dept of Orthopaedic Surgery, Loma Linda University Medical Center, California, 92354.
FAX: (909) 558-6018 *Email: johnbowsher@hotmail.com Website: www.lluorc.com.

Statement of Purpose: Sequential irradiation/annealing processes have been shown to improve the wear and oxidation resistance of modern polyethylene's [1]. However, we still know little about synergistic effects of surface roughness and alternative modes of wear for these new materials [2]. As there is an increasing demand for large ball sizes for active patients, this also raises long-term clinical concerns as stated by Charnley [3].

Analysis of retrieved Co-Cr balls has revealed roughness up to 500 nm (Ra) [4]. A recent XLPE study combining fast-jogging activities and rough Co-Cr balls reported almost 40-fold wear increase, generating higher numbers of submicron-sized particles [5]. Hence, combined wear modes may have synergistic effects.

Although studies have reported less PE wear with micro-separation [6], its role in combined wear modes is unknown, particularly for large balls. Therefore, we developed a 'severe' wear protocol combining femoral roughening in 36 mm balls with micro-separation. Our hypotheses was that mechanically enhanced PE (MEP) would show 1) superior wear performance under severe wear modes, and 2) fewer wear particles compared to conventional UHMWPE.

Methods: Twelve PE-on-Co-Cr hip bearings (36mm) were investigated (Biomet, Inc, Warsaw, IN). The control liners (Group 1) were γ sterilized UHMWPE at 3 Mrads in argon. MEP liners (Group 2) were: 5 Mrad irradiated, pre-heated and solid-state deformed, stress relieved and gas plasma sterilized. The Co-Cr balls were provided in both pristine and rough conditions (Table 1).

Table 1	Ra (nm)		Rp Max (nm)
	Mean	Range	
New Balls (n=6)	7	4 – 12	50
Rough Balls (n=6)	566	475 - 643	3800

All liners were positioned anatomically in an orbital hip-joint simulator and run with a Paul load curve (3kN peak, 1Hz) with a 1.5mm swing-phase micro-separation. Alpha-calf serum (HyClone) was diluted to 20 mg/ml of protein as the lubricant. Test duration was 5 million cycles (Mc). Wear was measured gravimetrically. Fluid samples at 1 and 4 Mc were analyzed for debris. The number of particles generated (N_G) was estimated using particle volumes (from ECD) and volumetric wear rate [7].

Results / Discussion: With new balls, UHMWPE and MEP wear rates were 65 and 36 mm^3/Mc. This represented a 44 % reduction in favor of MEP liners ($p<0.05$) (Fig 1). With rough balls, the wear rates were 279 and 263 mm^3/Mc for the UHMWPE and MEP, respectively ($p=0.7$). Overall, the MEP liners showed a greater sensitivity to rough balls compared to UHMWPE. This suggested no major advantage for MEP under our severe protocol, and negated our 1st hypothesis.

The most pronounced change in wear debris was the size distribution (ECD) with rough balls. The median ECD increased by 30% and 60% for UHMWPE and MEP, respectively, compared to smooth balls (Table 2). Also, the percentage of elongated fibrils was more than doubled with rough balls. In terms of numbers of particles, MEP generated 50% to 60% less than UHMWPE with smooth and rough balls. Therefore, our 2nd hypothesis was proved.

Conclusions: 1) Under both pristine and severe conditions, MEP liners generated less wear particles compared to conventional UHMWPE. 2) When viewed against prior work for 28 mm liners, these results suggested some risk of using large ball sizes with polyethylene liners in young and active patients. 3) The use of ceramic femoral balls against modern PE would obviate roughness concerns of Co-Cr.

References: [1] Essner A, et al, 51ST Trans ORS, 830, 2005. [2] McKellop H, et al, Clin Orthop, 311, 3-20, 1995. [3] Charnley et al, Med Biol Eng, 7(1), 1969. [4] Bauer *et al*, JBJS, 78(2), 1244-7, 1996. [5] Bowsher JG, et al, 51ST Trans ORS, 12, 2005. [6] Williams S, et al, Proc Instn Mech Engrs, 217, 147-153, 2003. [7] Scott et al, JBMR, 73, 325-37, 2005.

Acknowledgements: The authors thank Biomet Inc, Warsaw, IN, for support, and K Bozhilov at UC Riverside, CA, for SEM assistance.

Table 2: Wear particle morphological parameters at 4 million cycles (median values).

Parameter	New Balls		Rough Balls	
	UHMWPE	MEP	UHMWPE	MEP
Debris Counted	434	425	580	702
ECD (μm)	0.25	0.27	0.34	0.43
Aspect Ratio	1.513	1.54	1.62	1.78
CSF	0.84	0.83	0.79	0.74
% Submicron	92.9	86.5	83.6	76.5
% Fibrils	1.77	1.52	3.83	7.86
N_G (10^{12}/Mc)	23.8	10.3	39.7	18.4

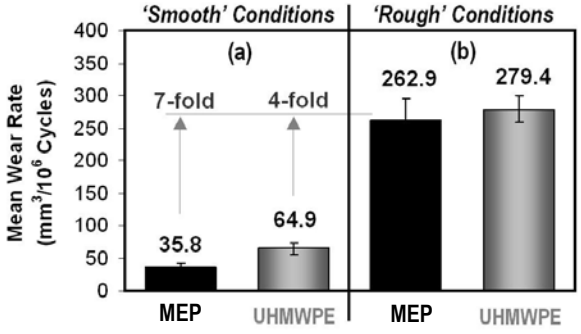

Figure 1. Mean volumetric wear rates for 36 mm MEP and UHMWPE liners under (a) smooth, and (b) rough conditions. [Error bars = standard error]