Morphology and size distribution of polyethylene debris generated during multiple activity knee wear testing

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Statement of purpose: Several studies have implicated polyethylene wear debris as a potential cause of osteolysis. Particulate debris, with sizes ranging from submicron to several hundreds of microns have been identified on tissues surrounding retrieved knee implants [1]. Younger patients impose more frequent severe activities of daily living (ADL) such as stair climbing, chair rise and descent, and deep squatting on knee implants. These conditions may significantly change the size distribution and morphology of the wear debris with potential osteolysis consequences. The purpose of this study was to characterize the wear debris produced by conventional and crosslinked UHMWPE tibial inserts subjected to various ADL

Materials and methods: Twelve, high flexion, NexGen® CR-Flex femoral components (Zimmer, Inc., Warsaw, IN) were articulated against aged conventional (CPE) and crosslinked (HXPE) GUR 1050 ultra high molecular weight polyethylene (UHMWPE) tibial inserts for 5.5 million cycles. The CPE inserts were gamma sterilized at a dose of 37 KGy while the HXPE ones were electron beam irradiated with a dose of 65 kGy, melt annealed and gas plasma sterilized. They were tested on a six station knee simulator (AMTI, Boston, MA, USA) 100% bovine calf serum lubricant. The test protocol [1], divided in three phases, was designed to reproduce the ADL as quantified by Morlock et al [2]. Phase I consisted of 3 million cycles (Mc) of walking. Phase II, consisted of trigait (chair rise, stair climb and walking) motions. Phase III lasted for 0.5Mc and consisted of 67% walk and 33% deep squat (152^o flexion). The loads and motions conditions are shown in Table1 Serum lubricants were salvaged every 0.5Mc in Phases I & II and every 0.1Mc in Phase III. Wear debris particles were isolated from the salvaged serum using the method of Scott et al. [3]. The debris particles were imaged using scanning electron microscopy (SEM) and analyzed with ImagePro software. Equivalent circular diameter (ECD), elongation (E), roundness (R) and aspect ratio (AR) were calculated and used to identify particle morphologies. Particles were categorized as spheroidal ($AR \leq 2$, $R \geq 0.6$, $E \leq 2$), fibrillar, ($AR \geq 3$, $R \leq 0.4$, $E \geq 4$), granular ($2 < AR < 4$, $0.4 < R < 0.6$, $2 < E < 4$) and others (rods, platelets,).

Table 1. Simulator Input Load and Motion Values

Activity	Peak Load (N)	F/E Range (degrees)	I/E Range (degrees)	A/P Range (mm)
Walking	3188	58.0	7.6	5.2
Chair	3463	94.3	13.8	4.4
Stair	3500	90.0	11.7	13.0
Squat	4448	152.1	28.0	26.3

Results and Discussion: Table 2 summarizes the measured wear rates. Trigait motions had no significant effect on the wear of both CPE and HXPE. During high flexion activity, wear of HXPE doubled while that of CPE increased by more than an order of magnitude. Figure 1 shows SEM micrographs of the debris generated during phases I and III. The morphology distribution of the debris is shown in Figure 2. The proportion of spheroidal particles in HXPE increased from walking to high flexion (34% to 47%) while that of fibrillar particles decreased (10% to 5%). The opposite is true for the CPE debris. HXPE debris have similar size distribution with their CPE counterparts.

Table 2: Wear rates (mg/Mc) of CPE and HXPE

	Walking	Trigait	High Flexion
CPE	12.6 ± 2.6	16.1 ± 3.6	273 ± 23
HXPE	3.7 ± 0.6	3.1 ± 0.5	8.6 ± 2.2

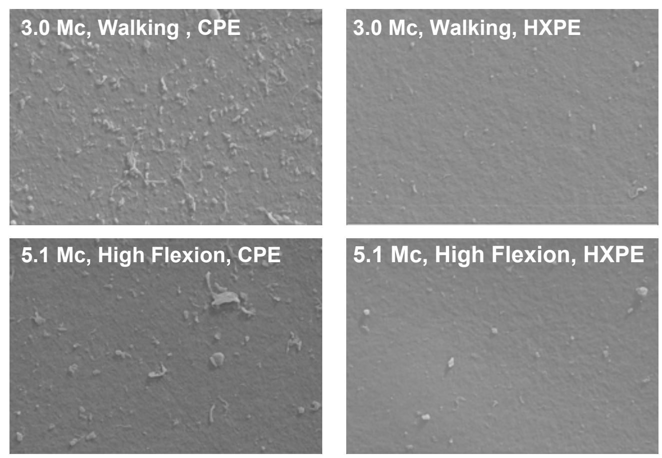

Fig**. 1: SEM micrographs of wear debris (10, 000X).**

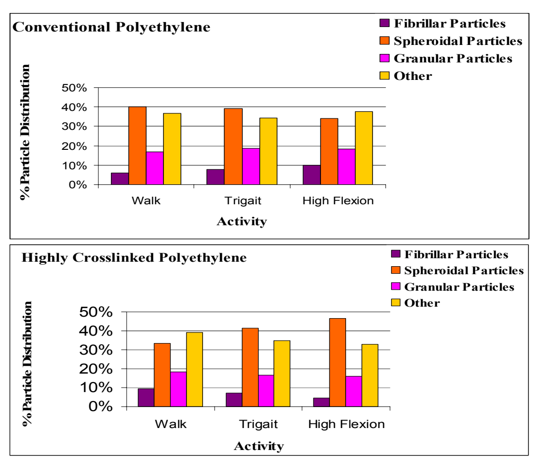

Fig. 2: Morphology distribution of debris

Conclusion: Different ADL motion and load profiles affect the debris morphology in HXPE and CPE inserts. High flexion activities favor the production of more spheroidal particles and less fibrillar ones in HXPE than in CPE. Both materials debris have similar size distributions.

References: **[1]** Schmalzried et al., J. Appl. Biomat, 1997, 21, 203-209. **[2]** Morlock et al, J. Biomech., 2001, 34, 873-881; **[3]** Scott et al., SFB 2000, 177; 7