Effect of Crosslinking and Femoral Material on Polyethylene Wear Debris in a Knee Simulator Model

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Statement of Purpose: Improved wear resistance of crosslinked UHMWPE (XLPE) in both hip and knee has been well demonstrated [1-4]. Investigations of XLPE in the hip indicated that the debris size decreased with increased crosslinking [5]. In the knee it has been suggested that ceramic femoral condyles also reduced UHMWPE wear compared to CoCr [4,6]. Both alumina and zirconia femoral condyles have been used in Japan (but not approved in USA). However, little is known about these combined effects on production of wear debris from tibial inserts. Therefore, the objective of this study was to determine how 3.5 to 7Mrad crosslinking and zirconia femoral condyles influenced the wear debris morphology in a knee simulator model.

Methods: Four knee combinations (Table 1) were studied using the K-Max™ total knee (Japan Medical Materials; JMM Inc., Osaka, Japan). Alumina doping of the zirconia femoral condyles was reported as <1%.

Table 1: Descriptions of groups studied.

Group	Designation	Femoral Condyle	Tibial Insert
1	M-PE	CoCr	3.5 Mrad XLPE
2	M-XLPE	CoCr	7 Mrad XLPE
3	Zr-PE	Zirconia	3.5 Mrad XLPE
4	Zr-XLPE	Zirconia	7 Mrad XLPE

The tibial inserts were from one lot of ram-extruded UHMWPE sterilized with either 3.5 or 7 Mrad of gamma radiation under vacuum and annealed. A commercial knee simulator was used with 20º of flexion, 6mm of A-P translation, and ±5º of internal-external rotation. The load profile was 2.6kN peak at a frequency of 1.8 cycles/sec [1,4]. The lubricant samples at 2 and 4 million cycles (Mc) were analyzed for debris using a method previously reported [5].

Results/Discussion: For the M-PE the size (ECD) of the debris showed little difference with crosslinking (Figure 1). The particle size did increase with increased crosslinking for Zr-PE and Zr-XLPE at 2Mc (Figure 1). At 4Mc the Zr-PE and Zr-XLPE particles were generally 7 to 14% smaller than with M-PE and M-XLPE (Figure 1). The Zr-XLPE debris at 4Mc was 39% smaller than at 2Mc and the M-XLPE was 13% smaller. This change in particle size with increased duration was not observed with M-PE or Zr-PE. The Zr-XLPE at 2Mc had a 32% higher median aspect ratio than the other groups (Figure 2). For size and shape, only the Zr-XLPE at 2Mc demonstrated a change of more than 20%.

Conclusions: In this study, increased crosslinking (from 3.5Mrad to 7.0Mrad) did not appear to have a measurable effect on debris size with a CoCr femoral condyle. Increased crosslinking appeared to have an effect with the zirconia femoral condyle only at 2Mc. It was not clear why there was such a size difference only with Zr-XLPE at 2Mc. Our data suggested that the femoral condyle material used against the XLPE may be as important as the amount of crosslinking.

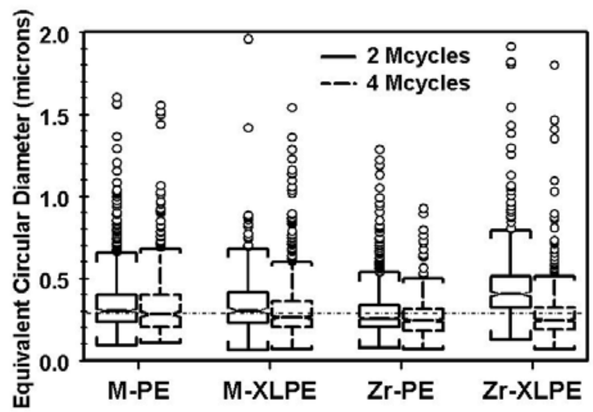

Figure 1: Box plot of ECD for the four material combinations at 2 and 4Mc.

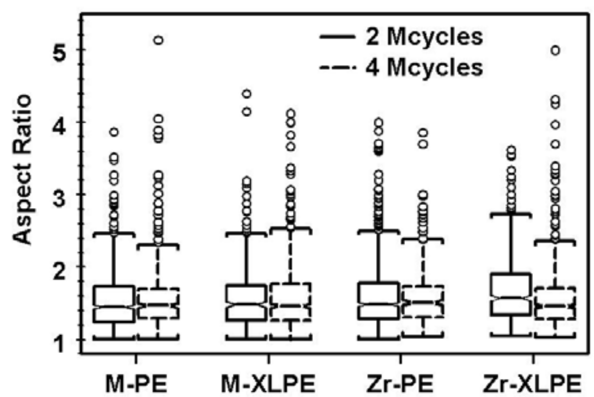

Figure 2: Box plot of Aspect Ratio for the four material combinations at 2 and 4Mc.

References: [1] M. Akagi, et al., J Orthop Res, in publication, 2006. [2] A. Wang, et al., *Tribology International* **31**, 17-33, 1998. [3] H. McKellop, et al., *J Orthop Res* **17**, 157-67, 1999. [4] R. Tsukamoto *et al.*, *Acta Orthop* **77**, 505-11, 2006. [5] K. Yamamoto *et al.*, *J Biomed Mater Res* **56**, 65-73, 2001. [6] H. Oonishi *et al.*, in *Bioceramics 15*, vol. 240-2, pp. 735-754, 2003. [7] Y. Minoda *et al.*, *Biomaterials* **26**, 6034-40, 2005.

Acknowledgements: The authors thank Japan Medical Materials (Osaka, Japan) and Krassimir Bozhilov, Central Facility for Advanced Microscopy and Microanalysis, University of California, Riverside.

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