Polyethylene Wear Debris From a Knee Simulator Model: Effect of Crosslinking and Counterface Material

INTRODUCTION:
Improved wear resistance of crosslinked UHMWPE has been well demonstrated in both hip and knee [1-4]. A reduction of 70% can be shown in knee simulations from conventional crosslinked tibial inserts (CXPE) gamma-irradiated at 3.5Mrad to 7Mrad highly crosslinked inserts (HXPE). Hip simulator models indicated that 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 condyles have been used in Japan (but not approved in USA). The expectation with use of both HXPE and ceramic condyles was that the polyethylene wear rate would be exceedingly low. Hence, even with small volumes of wear an adequate quantity of particles can be easily obtained for analysis. Therefore, an “un-measurable” weight change in the gravimetric wear estimation does not signify zero wear or an insufficient sample size of particles. This prompted some to develop advanced techniques in wear-rate estimation employing wear debris [8]. However, little is known about these combined effects on wear debris production. It seemed likely that analysis of wear debris would be a useful adjunct for examining the combined wear effects of HXPE and zirconia condyles. Therefore, the objective of this study was to determine how 1) increased crosslinking from 3.5 to 7Mrad and 2) counterface material (zirconia ceramic versus CoCr 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). 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 then annealed. A commercial knee simulator was used with 20° of flexion, 6mm of A-P translation, and ±5° of internal-external rotation. The load profile was 2.6kN peak at a frequency of 1.8 cycles/sec [4]. The lubricant was Alpha calf serum diluted to 50%. Wear was determined gravimetrically and wear rates estimated by linear regression.

Lubricant samples were analyzed at 2 and 4 million cycles (Mc) using a reported method [5]. The sample was then filtered through a 0.1µm pore filter and mounted on an SEM stub. The specimens were imaged with SEM (Philips, XL30-FEG), images measured (Image J, NIH), and data analyzed for morphology. The equivalent circular diameter (ECD), aspect ratio (AR), and circular shape factor (CSF) or form factor were calculated. Descriptive statistics were generated and one-way ANOVA with test for multiple comparisons performed on the data.

RESULTS:
Approximately 300 to 750 particles were analyzed for each group (Table 1). With CoCr condyles, the size (ECD) of the polyethylene debris showed little difference with crosslinking (Figure 1). The particle size appeared to increase with increased crosslinking for Zr at 2Mc (Figure 1). For the median data, CSF for all groups varied by less than 10% (Table 1). With regards to size and shape, only the Zr-HXPE at 2Mc demonstrated a change of more than 20%. At 4Mc the Zr-CXPE and Zr-HXPE particles were generally 7 to 14% smaller than with CoCr-CXPE and CoCr-HXPE (Figure 1). At 4Mc the Zr-HXPE and CoCr-HXPE debris were smaller by 39% and 13% respectively. With respect to CoCr-CXPE and Zr-CXPE a change was also evident, but less than 10%. Except for Zr-HXPE at 2Mc there were no significant differences between any of the groups.

DISCUSSION:
The important question was how well could the gravimetric wear method discriminate low crosslinked PE wear rates. Combining variations in microbalance techniques and fluid absorption, our experience indicated PE wear rates were measurable above 0.5mm/Mc, equivalent to 0.25mm³ for one-half million cycles duration. For an average particle of 0.3 microns, this would produce in the order of 18 billion particles. Thus, the estimated lubricant concentration would be 36 million particles in each milliliter of fluid.

As we predicted, there was no difficulty in collecting and imaging sufficient wear debris in any of these wear models. With CoCr condyles, the higher crosslinking did not show any measurable effects from 2 to 4Mc. In contrast there was an increased size effect with Zr-HXPE at 2Mc, but it was not clear why. While not statistically significant (p>0.5), there did appear to be a size decrease for all groups as the test progressed.

Our data suggested that the femoral condyle material used against the crosslinked PE might be as important as the amount of crosslinking. Also, the crosslinked PE and counter-face material work in a synergistic effect related to the decreased particle size with increased duration from 2Mc to 4Mc.

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