Sequentially Enhanced Polyethylene In 10 Million Cycle And Knee Simulation Study

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Statement of Purpose: Polyethylene wear debris generated from articulating surfaces can cause osteolysis and late aseptic loosening of components even in total knee replacements [1]. Wear of ultra high molecular weight polyethylene (UHMWPE) is a major factor that affects the longevity of total joint replacements. In total replacements (THR, TKR), crosslinked polyethylene (XLPE) has been shown to be effective in reducing wear in experimentally [2, 3, 4]. Highly crosslinked polyethylenes have recently demonstrated less volumetric wear than non-crosslinked polyethylenes in laboratory knee studies [4]. However, XLPE has not found widespread in clinical use in TKR, primarily because the crosslinking processes inevitably leads to reductions in critical mechanical properties such as toughness and fatigue strength [5]. Thus improvements have been suggested with improved wear resistance XLPE for tibial inserts and improved mechanical properties.
Therefore the aim of this study was to compare the wear of conventional versus a new sequentially enhanced UHMWPE run against CoCr femoral implants. Our hypothesis was that the sequentially enhanced tibial inserts would offer superior wear performance.

Methods: Compression molded GUR1020 UHMWPE was processed by irradiating to 30 kGy followed by annealing at 130°C for 8 hours. This cycle was repeated twice more resulting in a cumulative dose of 90 kGy (SXPE). The CR tibial inserts (9mm thick) were machined from either SXPE (Triathlon™ Stryker Inc, NJ, USA) or 3-Mrad Duration™ stock (controls). SXPE inserts were finally gas-plasma sterilized. Additional tibial inserts were used for soak control and stored unloaded in deionised water for 60 days prior to testing. Knee simulation was conducted on a 6 station simulator (Shore Western Manufacturing, Monrovia, CA). Motion included 20 degrees of flexion/extension, ±5 degrees of internal/external rotation, 6mm of anterior/posterior translation. All knee components were subjected to 10 million cycles of normal walking (2.9 kN max, freq 1.4 Hz). Lubricant was 50 % Alfa calf serums (20mg/ml protein) with additive EDTA. Serum was changed every 0.5million cycles until 5 Mc and every 1 million cycles until 10 Mc. Wear was measured gravimetrically. Microscopic characterization was carried out on the polyethylene tibial inserts using confocal Raman microprobe spectroscopy (irradiation with a blue laser with wavelength 488 nm).

Results: Initial technical challenges were encountered with the weight-loss measurements from 0 to 1 Mc duration and so the wear data were presented from 1 to 7 Mc duration (Fig1, 2). The weight-loss patterns showed uniform linear trending (regression coefficients > 0.95). Wear of the control implants (CoCr / UHMWPE) averaged 4 mm^3/Mc with good control of experimental variance (Fig 1). Wear of the SXPE implants (CoCr / SXPE) averaged 0.64 mm^3/Mc, also with good control of experimental variance (Fig 2). This difference was statistical significant ($p<0.01$).

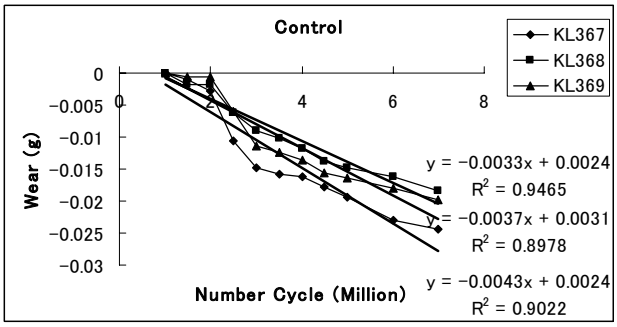

Figure1. Gravimetric wear rates of control UHMWPE (3-Mrad) tibial inserts against Co-Cr femoral implants.

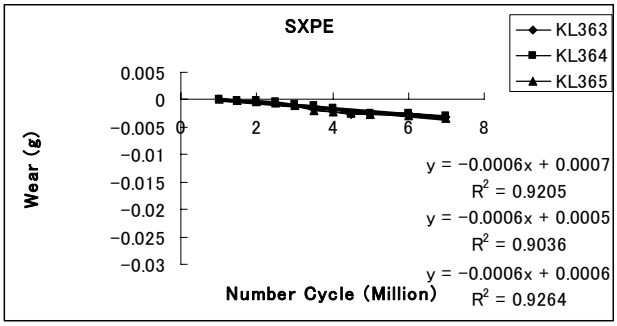

Figure2. Gravimetric wear rates of SXPE (9-Mrad) tibial inserts against Co-Cr femoral implants.

Discussion: The most significant finding was that the SXPE tibial inserts reduced wear by 7-fold compared to control. There was a clearly a beneficial effect of sequentially enhanced UHMWPE for knees. Our long term study now to 10 Mc duration was comparable to a prior study that showed a 5-fold wear reduction for SXPE with a 5 Mc duration of study [6]. Thus SXPE implants may prove excellent for active patients who may otherwise risk high wear rates over many years of use.

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