Effects of Crosslinking on the Wear of Polyethylene after 5 Years Real Time Aging in Oxygen

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Statement of Purpose: This study was intended to evaluate the effect of crosslinking on the simulator wear of hip prosthesis cups after five years storage exposed to the laboratory environment.

Methods: The experimental materials were ten 22 mm hip acetabular cups that had been removed from packaging and stored in the laboratory without being protected by an inert gas. Five of the cups had been crosslinked by irradiation to about 60 kGy in an inert environment while being maintained at 190 ºF. The remaining five cups had been sterilized by radiation (30 kGy) but had not undergone the crosslinking procedure. Eight of the cups (four of each type) were potted in polyurethane within testing fixtures while the last two were not fixtured. Three of each type of cup were tested for wear, the other fixtured cup of each type being used as a loaded soak control. The two non-fixtured cups were soaked in serum at the same temperature as the tested cups as unloaded soak controls.

All testing was conducted on an MTS 8-station wear simulator using a Paul curve with maximum load of 3000N and at one cycle per second. Bovine calf serum, diluted 50% with deionized water and supplemented with EDTA was used as the lubricant. The cups were removed from the machine every 500,000 cycles for cleaning and weighing and testing is being carried out to 5,000,000 cycles. The weight losses of the experimental cups were corrected for fluid uptake based upon the weight changes of the loaded soak control cups. The non-loaded soak controls were also cleaned and weighed to determine whether non-loaded controls could be used for future experiments.

Results / Discussion: After 1,500,000 cycles, it was seen that the weight gains of the non-loaded soak control cups had reached a plateau after 500,000 cycles and no further weight gain was occurring. Since the loaded soak controls were continuing to experience weight gains, the non-loaded soak controls were removed from the study. Average weight loss data for the first 2,000,000 cycles are plotted in Figure 1.

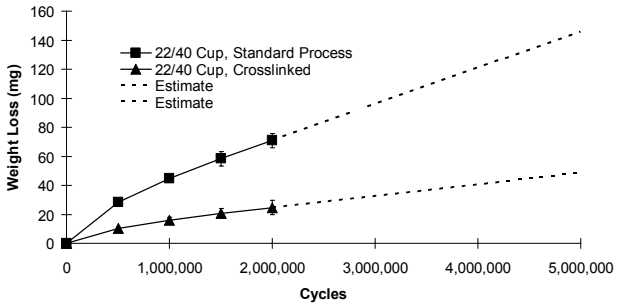

Figure 1 – Average Weight Loss of Cups

The crosslinked cups were seen to be experiencing significantly less wear than those that had not been crosslinked with total weight losses at 2,000,000 cycles being 70.8 ± 5.0 mg for the standard cups and 24.7 ± 4.8 for the crosslinked cups. From 1,500,000 cycles to 2,000,000 cycles, the wear rates for the two groups of samples were 25.0 ± 1.8 mg/mc for the standard process polyethylene and 8.0 ± 2.7 mg/mc for the crosslinked material. The wear rates appeared to be reaching a steady state and the estimated wear data for the remaining 3,000,000 cycles are extrapolated in Figure 1 based upon these wear rates, as the data is not yet available. Previous experience with this type of testing has shown that it is possible to predict further wear rates once data has been collected to 2,000,000 cycles. The remaining data is in the process of being collected.

While no accelerated aging was performed on these samples, the embedding in polyurethane for fixturing involved heating to 80 ºC for four hours. This occurred immediately after receipt of the samples and five years before testing commenced.

Conclusions: The results of this testing show clearly that the beneficial effects of the crosslinking of polyethylene on the wear properties of the material are maintained after extended exposure to oxygen at room temperature. While an attempt was made to validate the use of unloaded soak controls for fluid uptake, it became clear early in the study that the loading experienced by the loaded controls does contribute to the fluid uptake of the cups and than the unloaded controls only approximated the results for the loaded controls for the first 500,000 cycles, when the weight change appears to primarily initial diffusion of fluids into the cups. Later weight changes can be attributed to the effects of continuing to load the controls.