The Effects Of Serum Protein Concentration On The Wear Rates In A Hip Simulator

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Statement of Purpose: This research was conducted to investigate the effects of varying the serum concentration on the results of wear testing in a hip joint simulator. Both ASTM and ISO are in the process of standardizing the testing parameters for hip wear simulation but there is still disagreement about the proper concentration of serum that should be used as the lubricant.

Methods: The experimental materials were eight 22 mm hip acetabular cups that had been removed from packaging and stored in the laboratory without being protected by an inert gas for 5 years. Four of the cups had been crosslinked by irradiation to about 60 kGy in an inert environment while being maintained at 190 °F (SCMX). The remaining four cups had been sterilized by radiation (30 kGy) but had not undergone the crosslinking procedure (SCM). The cups (four of each type) were potted in polyurethane within testing fixtures. 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 samples had already been subjected to 5,000,000 cycles of testing using a 50% dilution of bovine calf serum. For this study, the samples were subjected to an additional 3,000,000 cycles, half using 91% serum and half using 25% serum, to see what the differences in wear rates would be. Comparisons were made to published results conducted using these same concentrations of serum.

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. The cups were removed from the machine every 500,000 cycles for cleaning and weighing. Weight changes due to wear were adjusted for fluid uptake using the loaded soak control samples.

Results/Discussion: The wear rates measured are detailed in Table 1 averaged for 1,500,000 cycles for each of the three serum concentrations. Because a single sample seemed to have run-away wear, the data for the SCM samples are expressed with and without the high wear sample.

Table 1
Comparison of Wear Rates Based upon Serum Concentrations

	Wear Rate	Wear Rate	Wear Rate
	50% Serum	25% Serum	91% Serum
Sample	(mg/mc)	(mg/mc)	(mg/mc)
22mm SCM (n=3)	36.9 ± 13.2	58.7 ± 31.1	36.9 ± 22.4
22mm SCM (n=2)	29.2 ± 0.6	40.8 ± 3.5	24.0 ± 3.9
22mm SCMX (n=3)	12.2 ± 1.7	15.7 ± 5.4	8.9 ± 3.4

In the non-crosslinked samples, the difference in wear rates is significant at the p<0.05 level for comparison of the 25% to 91% serum and at the p<0.10 level for comparison of the 25% to 50% serum. Similar trends are

seen in the crosslinked samples but they were not statistically significant at this sample size. The results were compared with other results (1, 2, 3) in which other head sizes were used (28 mm, 32 mm, 36mm) and it was found that the trends were different with inconsistencies between laboratories as well as within laboratories. A synopsis of some of the results is shown in Table 2.

Table 2
Comparison of Effects of Serum Concentration
% Change In Wear Rate

Lab	Size	Crosslink	91:50	50:25	90:25
Α	28	5Mrad	-	-	+40%
Α	36	5Mrad	-	-	+142%
Α	32	0	-37%	0	-37%
Α	32	γ	+39%	-45%	-24%
Α	32	5Mrad	+420%	-45%	+187%
Α	32	10Mrad	+33%	-100%	-100%
В	32	0	+3%	+18%	+22%
В	32	γ	+59%	+51%	+140%
В	32	5Mrad	+125%	+41%	+216%
В	32	10Mrad	+550%	+40%	+910%
В	28	5Mrad?	+64%	+6%	+74%
С	32	0	+51%	-38%	-6%
С	32	γ	+92%	+25%	+141%
С	32	5Mrad	+292%	-16%	+231%
С	32	10Mrad	+49%	-46%	-19%
This	22	γ/Age5	+22%	+40%	+70%
This	22	6.4Mrad/Age5	+38%	+28%	+77%

The results presented here reflect different cups sizes, processing conditions, and at least two different wear simulators, in addition to looking at the effect of serum concentration. Even when the cup sizes and processing are the same, as in the twelve studies from three centers, the effect of changing serum concentration varies from laboratory to laboratory.

Conclusions: While there has been much discussion of the effects of serum protein concentration on the results of hip simulator wear testing, the published data reveals that a great deal is still unknown about the wear phenomena being modeled and the appropriate parameters to be used in testing. Additional research in this area and coordinated multi-center testing is necessary to better define the appropriate parameters to be used in testing.

References:

- 1. McKellop et al, SFB 2006, Abstract 224
- 2. McNulty et al, SFB 2006, Abstract 220
- 3. Chen et all, SFB 2006, Abstract 546

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