Wear Properties of a Pyrolytic Carbon Intervertebral Disc Replacement

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Statement of Purpose: The purpose of this study was to determine if pyrolytic carbon particles were generated during wear simulation of the Regain™ lumbar nuclear disc replacement against bovine cortical bone.

Pyrocarbon has been established as a highly biocompatible material for prosthetic use following several decades of implantation history in finger joint and heart valve prostheses. Its mechanical strength is three to four times that of cortical bone and has an elastic modulus similar to bone. These factors allow for exceptional mechanical compatibility and stress transfer. Additionally, pyrocarbon does not exhibit fatigue failure as observed with metallic materials and is highly resistant to wear. *In vivo* studies in dogs and primates have demonstrated excellent wear properties when articulating on cartilage in which cartilage was maintained rather than lost over time.

For this study, a unique process was developed in which a custom wear simulator articulates the Regain™ against bovine cortical bone in a physiological lubricating solution, simulating the worst-case clinical scenario of complete endplate cartilage loss. The lubricating solution is then subjected to a novel digestion process to eliminate serum salts and proteins. This allows the number and size of pyrocarbon debris particles to be counted using a laser particle counter. Thus, the traditional method of analyzing wear rates of hip and knee prostheses which relies on the quantification of weight change of the device over the course of a simulation is not necessary.

Methods: Six Regain™ devices were mounted in a custom wear simulator which subjected them to 10 million cycles of articulation against mating bovine cortical bone pieces within a chamber of 30% bovine serum solution**.** A load of 850 N was applied while articulating the device through a 10 degree range of motion. Serum was collected at 0, 2.5 million, 5 million, 7.5 million, and 10 million cycles for particle counting. Device surfaces were photographed at each interval.

In order to remove serum aggregates from any particulate pyrocarbon wear debris, serum was subjected to a primary digestion using 37% HCl in a 5:1 acid to solution volume ratio. It was then centrifuged to separate supernatant from pellet. The supernatant was saved while the pellet was rinsed with filtered distilled water and re-centrifuged. Digestion was repeated with 37% HCl in the same volume ratio after which it was again rinsed and centrifuged. The original supernatant was rinsed/centrifuged, digested with the same acid/solution ratio as the pellet, and finally rinsed/centrifuged once more. Care was taken throughout the process to ensure a particle free environment.

After digestion of all bone debris and salts, particle counts were performed on the final pellet and supernatant solutions using the Spectrex PC-2000 Laser Particle Counter (Spectrex Corp., Redwood City, CA). Five counts of particle concentration per cc of solution were used to calculate mean counts per cc and mean absolute count of particles in solution. Results were analyzed using analysis of variance test (ANOVA) across number of cycles. A doping experiment was conducted to validate the experimental digestion process in which a baseline (0 cycles) lubricating solution was doped with a known pyrocarbon count and then subjected to the digestion procedure. Results were compared to the known particle count.

In order to further quantify wear, 3D point scans of device articular surface were taken at 0 and 10 million cycles using the Legend IMC™ CMM (coordinate measuring machine, EMD Inc., Budd Lake, NJ) and compared to three calibration scans performed on two un-tested devices. An implant geometry repeatability study was conducted on the CMM using two untested Regain™ devices, comparing three consecutive scans on each part. Mean deviations for these un-tested parts defined the repeatability of the CMM to within a 0.34 μm range around zero.

Results/Discussion: After the digestion procedures all samples were clear to the eye with no visible pellet. There was no significant difference between the mean number of particles per cc at baseline (0 cycles) and all other intervals ($p = 0.47071$).

Mean particle counts per cc for all devices (p/cc)		
Cycles	**Final Pellet**	**Supernatant**
0	1205 ± 330	725 ± 113
0-2.5M	1167 ± 356	703 + 73
2.5M-5M	1197 ± 326	640 ± 132
5M-7.5M	1178 ± 346	641 ± 118
7.5M-10M	1211 ± 340	669 ± 116

Additionally, there was no difference in the mean particle counts between the six devices ($p = 0.1499$).

In contrast to these six samples, the doped sample clearly exhibited carbon particles in solution. There was no significant difference between the known carbon particle count and the carbon particle counts of the doped sample ($p = 0.4039$).

Following 10 million cycles, CMM surface morphology comparisons reflected no detectable changes in geometry with a 99.999% degree of confidence. There was no significant difference between the CMM scans at 0 and 10 million cycles (ANOVA, $p = 0.1513$).

Conclusions: No significant differences or visible pyrocarbon particles were found in evaluations of all six samples from 0 cycles to 10 million cycles of wear simulation. CMM scans confirmed no significant changes in surface morphology following 10 millions cycles. Thus, there is no detectable wear of the Regain™ lumbar nuclear disc replacement after 10 million cycles of articulation in a worst-case clinical scenario. Furthermore, this study establishes a unique process for the wear testing, isolation, and evaluation of pyrolytic carbon implants on bone.