ASCENSION PYROCARBON HEMISPHERE WEAR TESTING AGAINST BONE

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The Ascension® PyroCarbon HemiSphere (PHS) is indicated for hemi-arthroplasty use in the basal thumb joint (CMC). It is manufactured by depositing a thick layer of pyrocarbon on a graphite substrate. *In situ* it articulates against bone in a cavity formed in the trapezium during implantation. Other currently available CMC implants are made from zirconia (ZrO_2), unalloyed titanium (Ti) and cobalt chromium alloy (CoCr). Wear testing of these various implants articulating against bone was conducted and results compared.

Three size 10 (smallest) and three size 50 (largest) Ascension PHS implants were tested. Control specimens included the Orthosphere Zirconia Spherical CMC Implant (two each size 8mm and 12mm) and the Swanson Titanium Basal Thumb (two each size 1and 5). Two small and two large axi-symmetric specimens fabricated from ASTM F1537 CoCr alloy with a straight stem and a spherical head diameter similar to the Ascension PHS size 10 and 50, respectively, also were tested.

Mating bone specimens were flat, cylindrical discs of cortical bone approximately 0.5 inch diameter x 0.15 inch thick. Specimens were excised from the diaphysis of fresh bovine femur and refrigerated in saline until used. Discs were machined so the test surface was parallel to and oriented outward from the long-axis of the bone. Within each disc, the long-axis of the bone was randomly oriented with respect to the test apparatus plane-of-motion.

Implants and bone specimens were mounted with epoxy in collets and subjected to cyclic articulation in a joint-motion simulator that produced ± 30 degrees of planar, angular rotation. Testing was conducted at 4 Hz in sterile bovine serum at room temperature with an axial load of 14 pounds for 5 million cycles. Specimens were characterized before, during and after the test by visual examination with a stereo-optical microscope, dimensional measurement with an optical comparator, and with a laser interferometer surface profilometer. Selected specimens were examined in a scanning electron microscope (SEM) at the completion of testing.

Before the test, pyrocarbon (PyC) surfaces were smooth and highly polished. ZrO_2 surfaces were generally smooth and highly polished, but populated with pits 1–1½ μm deep. Ti surfaces were reflective, exhibiting undulations and fine polishing scratches; some surfaces had numerous scratches ½–1 μm deep. CoCr surfaces were reflective and exhibited fine polishing scratches. On the bone specimens, its underlying layered microstructure was visible.

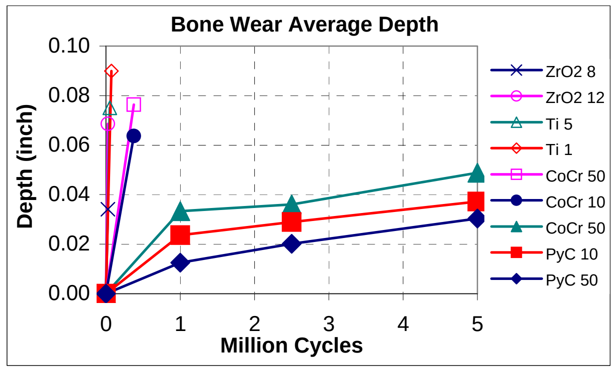
Wear testing resulted in the creation of a wear cavity in all bone specimens regardless of implant type. Due to extensive wear of the mating bone, testing was discontinued prematurely for all ZrO_2 and Ti implants, and 3 of the 4 CoCr. All PyC implants and the 4th CoCr specimen (that showed other anomalous results discussed later) were tested to 5 million cycles.

Type	Size	Total Cycles
Zirconia	8mm and 12mm	25,000
Titanium	5	50,000
	1	75,000
CoCr	(2) Small & (1) Large	375,000
	(1) Large	5,000,000
PyroCarbon	10 and 50	

After the test, the PyC surfaces were essentially unchanged; macroscopic material removal did not occur. An occasional, isolated, very shallow scratch likely created by an intrinsic 3rd-body particle was observed on some surfaces. High magnification SEM and the interferometer confirmed these scratches were less than ½ μm deep. Isolated scratches observed early in the test did not lengthen or deepen as cycles increased.

For the controls, the ZrO_2 surfaces appeared unchanged, but this is likely due in part to the very short test duration. Ti surfaces exhibited multiple wear patches within the contact zone, but wear depth was not measurable with the comparator (0.0002 inch resolution). Similar to the ZrO_2, Ti wear likely was limited due to the short test duration. CoCr surfaces with 375,000 cycles exhibited 2–4 μm deep scratches in the contact zone and 0.0005–0.0007 inch of material removal. Material removal was not measurable on the 4th CoCr surface; it had ½–1 μm deep scratches throughout the contact area at 1 million cycles, and a region at the apex that increased in size as the test progressed in which scratch depth decreased to < ½ μm. A layer of foreign material adhered to the contact area on all ZrO_2, Ti and CoCr surfaces. EDS analysis revealed this material to be calcium rich and thus likely was bone mineral; it could be removed with a cotton swab, but only with vigorous rubbing after hydration with saline.

For the bone specimens, wear cavity depth increased as a function of cycles. After 5 million cycles, bone wear depth for the PyC implants was much less than for all other implants. Bone wear was essentially independent of size for the PyC implants with the size 50's causing the least wear: 0.03 inch at 5 million cycles. In contrast, the Ti size 1's caused the most wear: 0.09 inch at 75,000 cycles.



Overall, these test results were unexpected and remarkable. PyC implants achieved 2 orders of magnitude more cycles than all other implants but one, and bone wear was much less. Thus, compared to ZrO_2, Ti and CoCr, PyC couples exhibited exceptional performance. This exceptional performance is similar to that observed for the Ascension MCP[i] and Ascension PIP[ii] two-component total joint implants. For both of these pyrocarbon-on-pyrocarbon implants, wear tests revealed: 1) an absence of macroscopic material removal and an occasional very shallow scratch less than ½ μm deep; and 2) wear behavior independent of size.

Results for the CoCr outlier are not consistent with the other CoCr specimens in this test, nor with CoCr specimens in 2 prior unreported similar tests. This unusual behavior may be related to specimen-to-specimen material properties/hardness variations of the mating bone, and requires further examination.

The wear test results observed here are also similar to animal study results wherein cartilage degeneration was much less for PyC as compared to CoCr alloy, Ti-6Al-4V, and alumina ceramic implants.[iii,iv] Differences in cartilage response were thought to be related to the lower elastic modulus of the PyC material. One effect of lower elastic modulus would be lower contact stress. In the current study, the PyC size 50 generates the lowest contact stress, which is consistent with the lowest wear depth results, and the ZrO_2 implants generate the highest contact stress, which is consistent with the shortest total cycle durations. However, overall contact stresses differ only by a factor of ~3 (5.5 to 14.4 ksi) even though there is almost an order of magnitude difference in elastic moduli. Although wear depth results are consistent with the trend in contact stress, a factor of 3 difference in stress does not seem to explain fully the order of magnitude differences in behavior observed between the control and the PyC implants. Additional research is necessary to understand the fundamental reason for the exceptional wear performance of the PyC implants observed in this work.

[i] P000057 Summary of Safety and Effectiveness Data, FDA, 11/19/01.
[ii] H010005 Summary of Safety and Probable Benefit, FDA, 3/21/02.
[iii] SD Cook *et al*, "Articular Cartilage Response To Implant Material Modulus and Method of Fixation," 11th Annual Meeting of the Society for Biomaterials, San Diego, CA, U.S.A., April 25-28, 1985.
[iv] SD Cook *et al*, "Wear Characteristics of the Canine Acetabulum Against Different Femoral Prostheses," *J Bone Joint Surg Br*, Vol 71-B, No. 2, 189-97, 1989.