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A COMPARISON OF EX VIVO, IN VITRO TESTED, AND UNUSED PYROLYTIC CARBON PROSTHESES

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Introduction Clinical results of pyrolytic carbon arthroplasty in the small joints of the hand are mixed. To provide better understanding of the reasons for this, three related studies were undertaken: **explant analysis** of 10 pyrolytic carbon components; **in vitro testing** of 4 pyrolytic carbon proximal interphalangeal (PIP) components (2 prostheses) to 5 million cycles of flexion-extension; and a **roughness study** of the articulating surfaces of 8 unused pyrolytic carbon PIP components (4 prostheses) of different sizes.

Methods In all studies topographical surface measurements of the articulating surfaces of the pyrolytic carbon components were taken using a white light interferometer with a sensitivity of 1nm. Roughness measurements included average (Sa) and root mean square (Sq) roughness. Ten **explanted** pyrolytic carbon components were obtained: four distal and two proximal components from PIP joints; one distal and one proximal from a metacarpophalangeal joint; and two components from carpometacarpal joints. Time in vivo was from 3 weeks to 3 years. For the **in vitro testing** a proven finger simulator was used to test two sizes (one size 30, one size 40) of pyrolytic carbon PIP prosthesis. Flexion-extension (90°-0°-90°) was applied with dynamic forces of 10-15N. At intervals of 3,000 cycles, a static load of approximately 100N was applied for 45 seconds. Dilute bovine serum at 37°C was used as the lubricant. An additional two control prostheses (same sizes as test prostheses) were used to account for any lubricant uptake. Wear measurements were taken at regular intervals until the test was ended after 5,000,000 cycles. In the **roughness study** of the unused pyrolytic carbon components (one pair each of size 10, size 20, size 30 and size 40), a coordinate-measuring machine was additionally used to measure the radii of all components.

Results For the **explanted** components, results showed that the majority of the articulating surfaces were unworn with near pristine surface finishes, even following use in vivo. Some surfaces showed signs of minor pitting and scratching. From the **in vitro testing**, minimal wear for all of the components was measured with a negligible increase in Ra for most of the components. Like the test components, the control components showed no change in weight. One condyle of one (size 30) implant showed an increase in roughness. In the **roughness study** of the unused pyrolytic carbon components, radii were 2.5; 3.3; 4.2; and 4.7 mm for proximal, and 4.0; 5.1; 5.6; and 6.3 mm for medial components. The average, non-stratified values for the measured parameters were: Sa, 20 nm (95% CI 17 nm to 23 nm); and Sq, 35 nm (95% CI 30 nm to 41 nm). Sa and Sq correlated negatively with radius ($p=0.001$; 0.001).

Discussion This is the first independent analysis of retrieved pyrolytic carbon implants. The lack of damage on the articulating surfaces of the 10 explanted components suggests that they were unworn and therefore that the reason for removal was not wear related. Low wear and minimal changes in surface roughness for most components was confirmed by the 5,000,000 cycles of in vitro testing. When studied in detail it was found that unused components with the smallest radii exhibited the highest roughness. Smaller components may be more difficult to polish.