

EVALUATION OF ATOMIC OXYGEN TEXTURED PYROLYTIC CARBON IMPLANTS

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Introduction

Pyrolytic carbon has many properties that make it suitable for use in the replacement of small joints [1]. The material has a modulus of elasticity similar to that of bone, good wear and fatigue properties, and excellent biocompatibility. Its biggest disadvantage is inadequate biological fixation. The as-deposited surface of pyrolytic carbon has a pore size of 5-10 μm and a depth of 20 μm . This is much smaller than the ideal pore size for tissue ingrowth [2]. Methods to enhance the fixation of pyrolytic carbon implants have included grit blasting and other surface modifications that did not result in improved fixation [3]. Other methods such as hydroxyapatite coating and porous titanium sleeves demonstrated improved bone attachment but are complicated and expensive procedures. The purpose of this study was to examine the feasibility of texturing the surface of pyrolytic carbon by exposure to direct atomic oxygen in order to enhance biological fixation.

Experimental

The implants used in this study were unalloyed pyrolytic carbon rods with a diameter of 2 mm. One-half the length of the rod was textured by exposure to atomic oxygen, while the remaining half retained the as-deposited surface. (Figure 1.)

The carbon rods were textured by NASA Glenn Research Center (Cleveland, OH). Half of each sample was covered with aluminum foil to act as a barrier to atomic oxygen exposure. The other half of the rod was spiral wound with a single layer of fine gold mesh to define the texture. The samples were then exposed to Radio Frequency atomic oxygen plasma for 25 days.

The adult male New Zealand White rabbit (N=6) was used as the animal model for this study. During the implantation surgery, a transcortical hole, 2 mm in diameter, was drilled through the metaphyseal region of the distal femur. The implant was then fit into the hole, such that the textured half of the rod was located in one cortex and the as-deposited half in the other cortex. All implantations were bilateral, resulting in a total of 12 implants. The textured portion of the rod was observed to

be undersized, as a result of the texturing process. This resulted in a loose fit compared with the as-deposited half. After 8 weeks, the animals were sacrificed and gross examination of the implantation site was conducted. The distal portion of the femurs was then removed. The specimens were sectioned transversely to isolate the implant, and then cut longitudinally into textured and as-deposited halves.

Push-out testing was conducted on each specimen to determine the bone/implant interface strength. The specimens were loaded at a rate of 1 mm/min and the load versus time was recorded until movement was detected at the interface. The interface strength was then calculated as: $S = F/(\pi*d*t)$, where F was the force at failure, d was the diameter of the implant, and t was the thickness of the specimen.

After push-out testing, the specimens were placed in formalin for histological processing. The samples were embedded in methyl methacrylate, sectioned, ground and polished to a thickness of approximately 100 μm . The sections were stained with Sanderson's Rapid Bone Stain, counterstained with Acid Fuchsin, and evaluated under light microscopy.

Results and Discussion

Gross examination of the implantation sites indicated no adverse response to the textured and as-deposited pyrolytic carbon implants. There was no evidence of debris attributable to either implant surface. All implants, with the exception of two, were located in the metaphyseal region of the femur and thus, were implanted primarily in cancellous bone. Two implants were found to be located closer to the diaphyseal region of the femur, and as a result, were placed partially in cortical bone. These implants are excluded from the study data presented.

The results from the push-out tests are shown in Table 1. The data indicated that, for specimens implanted into metaphyseal bone, the interface strength for the textured specimens was greater than that for the as-deposited implants.

Table 1: Interface Strength (N/mm²)

<u>as-deposited</u>	<u>textured</u>	<u>p-value</u>
1.80 ± 0.71 (N=10)	3.25 ± 1.38 (N=9)	0.012

The results from the push-out tests suggest that texturing the surface of pyrolytic carbon with atomic oxygen increases the interface strength nearly two-fold when the implants are placed in metaphyseal bone.

Percent bone apposition is greater for the textured implants than for as-deposited implants, but not significantly. (Table 2)

Table 2 Percent Bone Apposition

<u>as-deposited</u>	<u>textured</u>	<u>p-value</u>
47.59±12.49 (N=8)	50.82±10.78 (N=9)	0.579

The Bone Apposition Efficiency Factor, calculated by dividing the interface strength by the fraction of bone apposition, for the textured implants is greater than that for the as-deposited implants and determined to be significant. (Table 3)

Table 3 Bone Apposition Efficiency Factor (N/mm²)

<u>as-deposited</u>	<u>textured</u>	<u>p-value</u>
3.77±1.15 (N=8)	7.27±3.68 (N=9)	0.023

This indicates that the fixation obtained by the bone was much more effective for the textured implants. Thus, the findings of this study suggest that biological fixation of pyrolytic carbon can be enhanced by direct exposure to atomic oxygen, without compromising its biocompatibility.

Results from histological analysis of the samples indicated no abnormal adverse inflammatory reaction to either the textured or as-deposited portions of the implant. Good bone apposition was observed for both implant surfaces. New bone growth appeared to conform to the surface of the textured pyrolytic carbon implants at points of contact.

Conclusion

This initial investigation indicates that texturing the surface of unalloyed pyrolytic carbon by direct exposure to atomic oxygen significantly enhances the biological fixation of the implant. Furthermore, the texturing process does not appear to adversely affect the biocompatibility of the carbon. Compared to other methods to enhance fixation of pyrolytic carbon implants, atomic oxygen texturing may provide for a less complex and more cost effective procedure. Future projects are directed toward optimizing

the configuration of the microtexture in both unloaded and loaded models.

References

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Figure 1 Photograph of implant showing textured and as-deposited surfaces.