INVESTIGATIONS OF VITREOUS AND PYROLYTIC CARBON-METALLIC ALLOY SURGICAL BIOMATERIALS

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Vitreous and pyrolytic forms of carbon have been used extensively as synthetic biomaterials for the replacement of, augmentation of, and attachment to biological tissues.[1,2] One such device involving the integrated use of carbon and metallic alloys, the vitreous carbon tooth root replacement system, is schematically illustrated in Figure 1. The biocarbons, in general, have demonstrated very acceptable biocompatibility and the prognosis for expanding clinical applications is quite good.

Biomaterial Analyses

Vitreous and pyrolytic carbon specimens received for limited clinical trials were subjected to laboratory examination. A number of the vitreous carbon devices,* when examined stereomicroscopically and radiographically, showed irregular surface and internal features. Many of these features appeared as cracks with some extending from the external carbon surface to the stainless steel core. Metallographic analyses of transverse and longitudinal sections showed surface to core interconnected features.[3]

To establish basic data on possible electrochemical influences of co-exposure of carbon and metallic alloy materials to biological environments, in vitro laboratory corrosion experiments were initiated.[4] Mixed-potential corrosion theory and accompanying potentiostatic polarization data were** used to determine corrosion rates of carbon-metal couples, and then compare these corrosion rates with those of the individual alloys. Anodic and cathodic polarization curves were generated in isotonic saline (0.9% NaCl) solution at a pH of 7.0 and a temperature of 37.0°C. The anodic dissolution curves of stainless steel (316L) and Tivanium (Ti-6Al-4V) alloys were measured in nitrogen-saturated solution. The cathodic polarization curves of the two alloys and pyrolytic carbon were determined in oxygen-saturated solution. Extrapolation of the Tafel regions of the cathodic polarization curves to their respective intersections with the anodic dissolution curves allowed corrosion rates to be graphically determined.

Results and Discussion

The number of vitreous carbon devices examined and the irregular features found are summarized in Table I. The first three groups were examined prior to the general release of this implant system. The last group examined stereomicroscopically, Group 10 showed no significant irregular features. In our opinion, this number of irregular features represents a significant statistic. It was previously proposed[3] that these type features could influence electrochemical (biodegradation) and mechanical (strength and fracture) properties.

The potentiostatic polarization curves for passivated Ti-6Al-4V and 316L stainless steel with pyrolytic carbon are shown in Figures 2 and 3 respectively. With these results and by application of mixed-potential theory, the effect of carbon-to-metal area ratio on corrosion rate was evaluated.

The investigation indicated that the Ti-6Al-4V alloy in a pyrolytic carbon-metal couple would not undergo corrosion at a significantly more rapid rate than the alloy alone in simulated body fluids, even if the carbon-to-metal area ratio was quite large. This result is taken from inspection of Figure 2 where it is noted that all curve intersections are located far below the apparent transpassive potential of Ti-6Al-4V. In the case of stainless steel, however, the results indicate that the presence of pyrolytic carbon would accelerate the corrosion rate through the pitting corrosion mechanism, and that the detrimental effect of carbon would grow worse as the carbon-to-metal area ratio increased. This result is drawn from inspection of Figure 3 where it is noted that the curve intersections are very close to or in the transpassive region of 316L stainless steel. Furthermore, pitting corrosion was observed on the sample surfaces at noble potentials as low as +0.1 volt.

The post clinical implantation vitreous carbon stereomicroscopic evaluations, Group 11 of Table I, showed two devices with irregular features. One device had fractured in vivo and showed pitting corrosion of the stainless steel core. The relative area ratio of carbon to metal was high in this situation. In our opinion, this example provides some support for previous predictions that certain types of carbon-to-metal alloy couples in biological environments can compromise biocompatibility criteria.

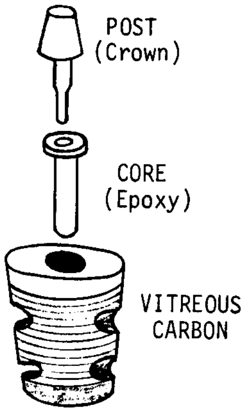

FIGURE 1. Schematic Drawing of Vitredent Tooth Root Replacement System.

GROUP	NUMBER OF SPECIMENS	IRREGULAR FEATURES	COMMENTS
1	85	5	Early design-no big grooves
2	71	7	Early design-no big grooves
3	48	10	Clinical design
4-7	85	18	Receiv. for clinic. place.
8-10	72	6	Receiv. for clinic. place.
11	9	2	Post clinical placement specimens(rec.from dentists)
1-3	47	8	3 view radiographic evalua.

TABLE I. Nondestructive Stereomicroscopic and Radiographic Examinations of Vitreous Carbon Tooth Root Replacement Systems.

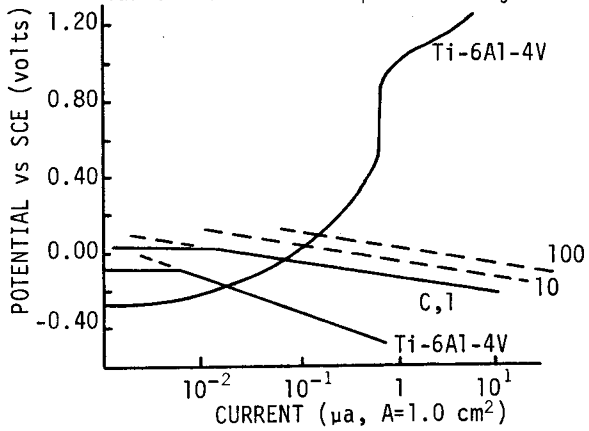

FIGURE 2. POLARIZATION RESULTS FOR Ti-6Al-4V and Pyrolytic Carbon.

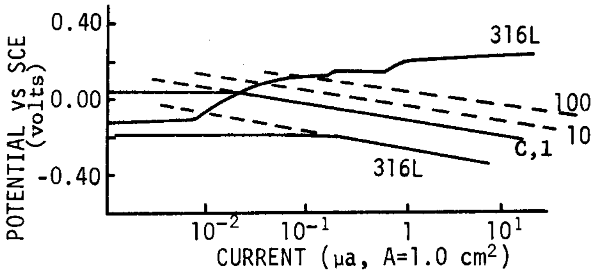

FIGURE 3. POLARIZATION RESULTS FOR Type 316L Stainless Steel and Pyrolytic Carbon.

References

(1) D.E. GRENOBLE and R. VOSS, Analysis of Five Years of Study of Vitreous Carbon Endosseous Implants in Humans, Oral Implantology, 6, 509-525 (1977).

(2) J.C. BOKROS, R.J. AKINS, H.S. SHIM, A.D. HAUBOLD and N.K. AGARWAL, Prostheses Made of Carbon, Chemtech., January, 40-49 (1977).

(3) J.E. LEMONS, Biomaterials Science Protocols for Clinical Investigations of Porous Alumina Ceramic and Vitreous Carbon Implants, J. Biomed. Mater. Res. Symp., 6, 9-16 (1975).

(4) N.G. THOMPSON, R.A. BUCHANAN, and J.E. LEMONS, In Vitro Corrosion of Carbon-Metal Galvanic Couples, Abst. No. 116, Society for Biomaterials Symp., 27 (1977).

* Samples furnished by Vitredent Corporation, Los Angeles, CA., USA.

**Pyrolytic carbon samples supplied by Medical Products Division, Gulf General Atomics, San Diego, CA., USA.