Target-Drift Prevention Treatment for Implantable Electrodes

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Statement of Purpose: Implantable electrodes for pacemakers, defibrillators, sensing of brain waves and other physiologic signals, pain control, nerve stimulation, cochlear devices, and thermal treatment of tumors, as well as numerous emerging uses are subject to "target drift" of the electrical energy. This is because the usual "foreign body reaction" around the tissue-embedded electrode creates insulating scars, which enclose the electrode in a salt-water moat that diverts current, requires greater energy, and drains battery reserve. Thus, the electrode is not adequately retained adjacent to the tissue that is targeted for stimulation or sensing. This investigation (O'Connor 2010) evaluated surface energy enhancement of electrodes, via pre-implantation Radio Frequency Glow Discharge Treatment (RFGDT), to promote tighter tissue binding directly to the electrodes and limit electrode movement in order to more efficiently deliver electrical signals to/from only the targeted tissue volumes (Figure 1).

Methods: All project work involving animals was approved by the Institutional Animal Care & Use Committee of Roswell Park Cancer Institute. In a pilot study, reference polydimethylsiloxane (PDMS) and commercially pure titanium (cpTi) were implanted subcutaneously in Balb/C mice. After 30 days, the implants and their associated tissue capsules were retrieved. Histological analyses of the tissue reproduced previously published findings of thick, dense poorly attached scar capsules around the reference, low-critical surface tension PDMS, in contrast to more cellular and strongly attached tissue layers that were difficult to delaminate from the higher-surface-energy cpTi. For the main study, cpTi, capacitor-grade Tantalum (Ta), and synthetic heart valve-quality pyrolytic carbon (PyC) were selected as representative potential high-surface-energy implant electrode materials. Surface characteristics of the 3 materials were determined as-manufactured and after RFGDT, including comprehensive contact angle analyses, scanning electron microscopy (SEM), energy dispersive X-Ray spectroscopy (EDS), and electron spectroscopy for chemical analysis (ESCA). Replicate samples were implanted subcutaneously in Balb/C mice and harvested after 7, 28 and 56 days. The recovered, preserved conductive implant/tissue specimens were examined by Electrical Impedance Spectroscopy (EIS) over the range from 100Hz to 100,000Hz, in Bode plot and Nyquist plot formats, before extracting the implants for their surface examination by SEM and histological examination of the mating separated tissue capsules in hematoxylin and eosin (H&E)-stained light microscopic thin sections.

Results: The differential findings were that the RFGDT'd PyC and Ta implants had significantly increased surface resistance and capacitance over their sterilized-only controls. Histological analyses showed that the scar capsules that formed around RFGDT'd PyC and Ta specimens had more-flattened cellular layers. The cpTi specimens, previously identified as promoting good tissue-to-surface integration in dental implants, showed only marginal improvements in soft tissue attachment following RFGDT. These experimental findings were confirmed in the requirement for conversion of the standard Randles model equivalent circuit with constant phase elements (which described the pre-implant materials) to a modified Randles model with additional resistance and capacitance to describe the implants with well-integrated surface coatings (Figure 2).

Figure 1. Schematic drawings of the ideal tissue/electrode integration, the typical (loosely attached) scar capsule, and scar capsules previously observed around RFGDT'd implant materials.

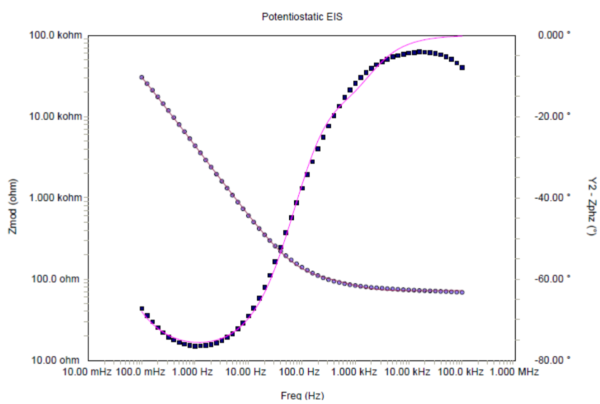

Figure 2. Electrical impedance spectrum for RFGDT Pyrolytic Carbon after 56 days subcutaneous implantation

Conclusions: Implanted RFGDT electrodes for biomedical signal sensing or tissue stimulation had thinner scar capsules with less surrounding dense collagenous lamellae and source fibroblasts, minimizing the problematic spurious current paths and non-target layers observed for electrodes that are only weakly retained at their target sites. A modified Randles model with additional resistance and capacitance was required to describe the implants having the well-integrated tissue coatings. Future work with RFGDT-modified electrode materials must include actual signal acquisition and stimulation trials in host tissues, to assess predicted improvements in electrical energy-transfer efficiency and battery lifetime extensions.

Reference: O'Connor LM, Ph.D. Dissertation, State University of New York at Buffalo, 2010.