**Clinical Biostability of Poly(carbonate urethane) Insulation in Neurostimulation Leads**

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**Statement of Purpose:** The purpose of this study was to characterize the biostability of poly(carbonate urethane) (PCU) insulation from deep brain stimulation (DBS) leads that had been implanted in human patients for up to 4 years. Neurologic and cardiac stimulation leads have traditionally employed either silicone or poly(ether urethane) (PEU) insulation. Silicone is extremely biostable, but has moderate mechanical properties. PEU has excellent mechanical properties, but may be susceptible to oxidation under some circumstances. PCU was designed to provide improved oxidative stability over PEU, while retaining similar mechanical properties by replacing the susceptible polyether soft segment with a more biostable polycarbonate.

**Methods:** 15 DBS leads that had been implanted in patients for up to 4 years (range: 1 week – 4.1 years, mean: 2.1 years, median: 1.2 years) were analyzed. Results from explanted leads were compared to results from 20 non-implanted leads. The DBS leads analyzed in this study consist of a proximal end that plugs into an extension or implantable pulse generator, an elongated lead body, and a distal end that provides electrical stimulation to the brain. The proximal and distal ends have metallic electrodes separated by 55D durometer PCU tubes. The lead body is insulated by a 90A durometer outer PCU tube. Both the 55D distal and 90A proximal outer tubing components were characterized in this study. The PCU used in these leads is sold under the trade name Bionate$^{TM}$ (DSM Biomedical, Berkeley, CA). Bionate$^{TM}$ is comprised of a methylene di(p-phenyl isocyanate) hard segment chain extended with butane diol and a poly(1,6 hexyl 1,2-ethyl carbonate) soft segment. The tubing surfaces were inspected for frosting, pitting, cracking, abrasion, etc. using an optical microscope at 20X and scanning electron microscopy (SEM) at 20-200X. The surface chemistry of the tubing samples was investigated using attenuated total reflectance Fourier transform infrared spectroscopy (ATR-FTIR). The bulk properties of the tubing samples were evaluated using tensile testing. Due to size constraints, tensile testing was only performed on the 90A tubings.

**Results:** For explanted 90A samples, 4/15 samples exhibited cosmetic surface cracking (**Figure 1**). There was a significant correlation between implant duration and surface cracking. However, cracking severity (surface coverage or depth) did not increase with implant duration, indicating that high biostability was retained through 4 years of implantation. There was no surface cracking observed in explanted 55D samples. The ATR-FTIR spectra of explanted 90A samples exhibited moderate decreases in the carbonate oxygen linkage peak near 1250 $cm^{-1}$ and the non-hydrogen bonded carbonyl from carbonate peak near 1740 $cm^{-1}$ as well as the appearance of new peaks near 930 $cm^{-1}$ and 1175 $cm^{-1}$ (**Figure 2**). These changes are consistent with minor to moderate soft segment loss in the first 1 µm of the surface of the samples. Explanted 90A samples also demonstrated weak decreases in the urethane C-N peak near 1220 $cm^{-1}$ and amide peak near 1530 $cm^{-1}$ as well as the appearance of a new peak near 1650 $cm^{-1}$. These changes are consistent with minor hard segment loss in the first 1 µm of the surface of the samples. Explanted 55D samples exhibited weak decreases in the peaks near 1250 $cm^{-1}$ and 1740 $cm^{-1}$ with no appearance of new peaks near 930 $cm^{-1}$ or 1175 $cm^{-1}$. There were no changes in the peaks near 1220 $cm^{-1}$ or 1530 $cm^{-1}$; however, new peaks appeared near 1650 $cm^{-1}$. Explanted 90A samples had an average ultimate tensile strength (UTS) of 8366 ± 1571 psi and an average elongation at break of 359 ± 96%. The UTS of explanted 90A samples was 5% less and the elongation was 16% than non-implanted samples. These differences are not practically significant because of batch-to-batch material variation and inherent variability in tensile testing results. Demonstrating high biostability, the explanted samples retained high UTS and elongation values.

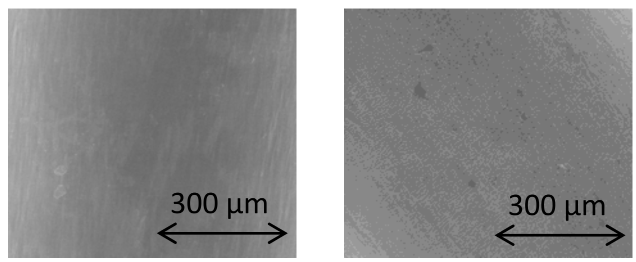


**Figure 1.** 200X magnification SEM images of a typical explanted 90A sample without surface cracking (left) and a typical explanted 90A samples with shallow surface cracking (right).

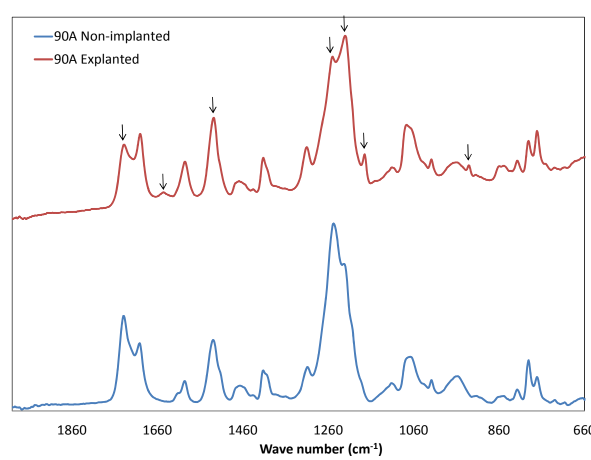


**Figure 2.** Typical FTIR-ATR spectra of a non-implanted 90A sample (blue) and an explanted 90A sample with shallow surface cracking (red).

**Conclusions:** The results of this study indicate that the clinical biostability of 55D and 90A PCU in DBS leads is extremely high through 4 years of implantation, with leads exhibiting only minor cosmetic surface oxidation.