STRUCTURAL ANALYSIS OF THE POLYMERS USED AS INSULATION IN CARDIAC LEADS AFTER IMPLANTATION IN HUMANS

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Statement of Purpose: Recent studies have shown that accelerated high temperature *in vitro* testing is not applicable to multiphase co-polymers such as thermoplastic polyurethanes[1,2]. Since polyether polyurethanes (PUs), and polydimethylsiloxane (PDMS) based polyurethane copolymers (SPUs) are extensively used as insulation materials in cardiac leads a novel methodology to evaluate their biostability *in vivo* was developed in the present work.

Methods: Cardiac leads insulated by SPU (Elast Eon 2A (E2A) or Optim®), PUs (Pellethane55D (P55D) and Elasthane80A (E80A)), and silicone were explanted from humans and returned to the manufacturer between 2006 and 2012. After decontamination and cleaning, the leads were sorted by material and implantation period (0 [control], 2-3 and 4-5 years). A total of 196 leads provided samples that were visually, chemically and mechanically characterized for comparison. Scanning Electron Microscopy (SEM) was used to assess microscopic and macroscopic surface degradation. Fourier-Transform Infrared Spectroscopy with Attenuated Total Reflectance (ATR-FTIR) assessed changes in the chemical structure of the surface. Gel Permeation Chromatography (GPC) determined the average molecular weight and polydispersity of the bulk polymers. Mechanical (tensile) testing was performed to assess elongation and tensile strength of each material. All data was compared and statistically analyzed across different implantation periods and materials.

Results: Visual and SEM analyses showed no surface degradation for SPU and silicone samples even after 5 year of implantation. On the contrary, some surface cracking was noted for P55D and full breaches for E80A samples. The median SEM degradation scores (scale 1-6) were lower for SPU versus 55D and 80A PU leads, both at 2-3 years (2 *vs* 3 $p<0.001$) and at 4-5 years (2 *vs* 4 $p<0.001$) respectively. FTIR-ATR spectra analysis for peaks indicative of oxidation and hydrolysis showed low chemical degradation for each type of insulation. SPU samples showed weak oxidation of the polyether soft segment, accompanied by a weak increase in the characteristic absorption of carbonyl groups participating in hydrogen bonding and, thus, the degree of phase separation. PUs samples presented weak oxidation of the polyether soft segment and even higher increase in the degree of phase separation. Interestingly neither SPU nor PU samples showed evident signs of hydrolysis in contradiction to recent reports proposing SPU susceptibility to hydrolytic attack[3] (Figure 1).

Molecular weight analysis for SPU showed an initial drop after 2-3 years of implantation followed by plateauing, attributed to possible dissolution of the allophanate bonds formed during the processing of the SPU. The molecular weight for P55D did not show changes over the years despite observations of surface cracking. Similarly E80A polyurethane showed a small drop around 9% despite obvious visual signs of surface degradation. Lastly, the ultimate tensile strength (UTS) of all tested materials remained well above the international standard requirements at 4-5 years of follow up. SPU maintained over 700% of elongation without any difference between the 0 year and 4-5 year time points compared with approximately 300% for PUs. Silicone being a highly elastic material (~900% elongation) showed a slight decrease in UTS values (-12.6% $p=0.005$) after 4 years of implantation.

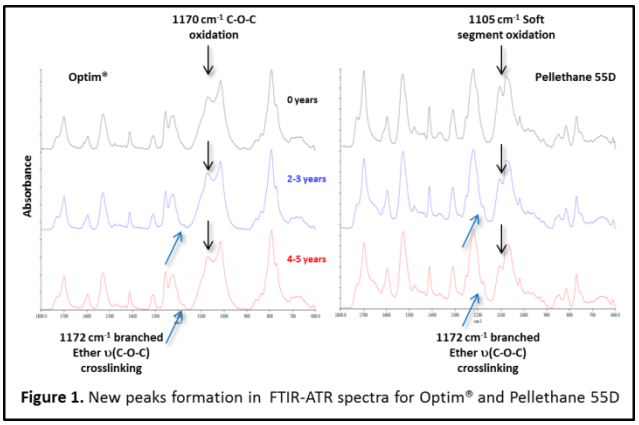

Figure 1. New peaks formation in FTIR-ATR spectra for Optim® and Pellethane 55D

Conclusions: A comprehensive biostability assessment utilizing this novel method is feasible for heterogeneous polymers. Analyzed SPUs provided robust data alongside industry standard PUs, when examined through mechanical, chemical and visual techniques after exposure to long term human biological stresses. We propose the systematic use of this methodology to study the biodegradation of polymeric insulation materials from returned products.

References:

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3. Chaffin, K. A., Buckalew, A. J., Schley J. L., et al. *Macromolecules* **2012**; 45: 9110-9120.