Cardiac Lead Retrieval Analysis: Insulation Degradation Hinders Long Term Performance

Mariya Tohfafarosh, Alex Sevit, Jasmine Patel, Arnold Greenspon, Jordan M. Prutkin, and Steven Kurtz.
Drexel University, Philadelphia, PA, Thomas Jefferson University Hospital, Philadelphia, PA, University of Washington, Seattle, WA.

Introduction

Cardiac lead is a critical component still hindering the long-term performance of cardiac rhythm management systems with a 20% removal rate at 10 years implantation time [1]. Lead insulation polymers such as polyurethanes (PU) or polydimethylsiloxane (PDMS) degrade over time causing lead failure. PU undergoes metal ion oxidation *in vivo* [2], while PDMS is prone to surface hydrolysis [3]. Both are susceptible to environmental stress cracking. Such degradation could give rise to lead failure; however, little *in vivo* analysis of explanted leads is available. We systematically analyzed retrieved pacing and implantable cardioverter defibrillator (ICD) leads using Attenuated Total Reflectance - Fourier Transform Infrared Spectroscopy (ATR-FTIR) and Scanning Electron Microscopy (SEM) for chemical and physical degradation, respectively.

Methods

Polymer insulation from control non-implanted and retrieved >4 years leads were sectioned from 3 sites along the length of the lead body. Both inner and outer surfaces were analyzed for signs of degradation. Chemical degradation of PUs was quantified by calculating the ether index (EI), which is the ratio of 1111 cm^{-1} peak (C-O-C stretching) to 1413 cm^{-1} peak (C-C stretching) found in urethanes. A reduction in EI corresponds to PU oxidation caused by hydroxyl radicals *in vivo*. Hydrolysis of PDMS was characterized by presence of hydroxyl group (3200-3600 cm^{-1} peak) in the ATR-FTIR spectrum.

Results

Of the fifty-five leads retrieved from thirty-one patients, the indications for removal varied from dislodgement, infection, lead defect to elective replacement. Out of the fifteen leads that were analyzed, 5/5 PU and 6/10 PDMS leads (implantation time: 8.5 ± 3.3 yrs) demonstrated chemical degradation. EI decayed over time in PU leads (Fig. 1) such that ether content decreased by 46% at 8.4 yrs post implantation. The Fidelis leads in our study (n=2), which is a 2007 FDA recalled lead responsible for causing several deaths due to lead fracture, showed EI reduction of 50-72% at 5-6 years.

ATR-FTIR spectra analysis of the outer surface of PDMS confirmed presence of hydroxyl groups. The hydroxyl peak was only present on the outer surface of the leads implanted on an average of 7.8±4 years. Furthermore, two leads removed for electrical failure exhibited both chemical and physical degradation. Environmental stress cracking was observed under SEM (Fig. 2) for both the polymer coatings, which correlated with the spectral analysis.

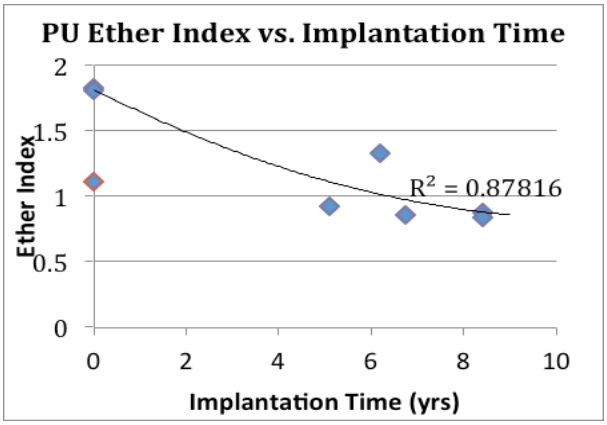

Figure 1. Ether Indices of Polyurethane leads based on ATR-FTIR spectra.

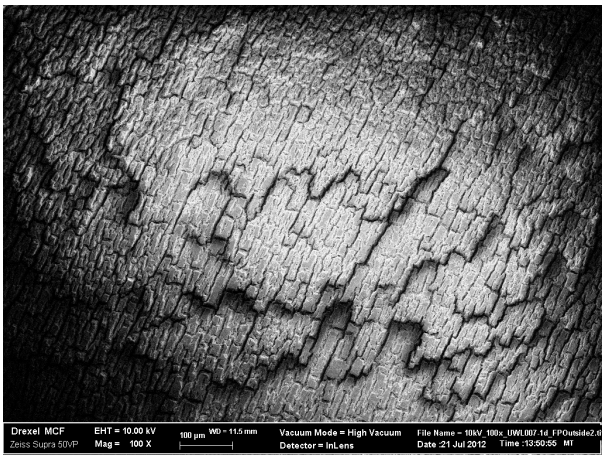

Figure 2. SEM image showing environmental stress cracking of a polyurethane lead.

Conclusions

Systematic analysis of retrieved leads yields important information regarding lead performance and biodegradation. PDMS and PU both degrade in unique ways, potentially causing lead malfunction. Continued analysis of retrieved leads is warranted.

References

1. Kleemann, T. Circulation. 2007;**115**(19): 2474-80.

2. Wiggins, M.J. J Biomed Mater Res. 2001;**58**(3): 302-7.

3. Kaali, P. J App Polymer Sci. 2010:**115**(2): 802-810.