Development of multi-modal characterization methods for drug-eluting matrices: the effect of processing on drug release from cardiac leads

Bing Luo, Chris Frethem and Greg Haugstad, Characterization Facility, University of Minnesota
Jeannette Polkinghorne, Boston Scientific

Medical devices often employ drug delivery systems to enhance device performance. From a materials-characterization standpoint these systems provide outstanding test cases for pushing the frontiers of analytical science. The Characterization Facility group has a recent history of developing new methodologies in confocal/Raman microscopy, scanning electron microscopy and atomic force microscopy to examine polymer-drug coatings (in situ and ex situ). First successes [1,2] provide strong impetus for expanding this line of research: further development of complementary techniques (e.g., cryo fracture) and additional case studies of biomedical materials (e.g., drug-loaded moldings). One example is cardiac leads, which connect medical devices such as pacemakers and defibrillators to the heart, as used to monitor the heart’s rhythm and provide therapy when needed. A drug delivery system is incorporated onto the end of cardiac leads to reduce inflammation and fibrosis at the lead-tissue interface and enable optimal lead performance.

In this project, cryo preparation coupled with scanning electron microscopy (SEM) and confocal Raman microscopy will be used to capture images of the drug delivery systems processed under different conditions. One goal is to elucidate the effects that processing changes can have on the drug system and ultimately on drug release. Preparation of samples using methods such as cryofracture can help to reveal internal characteristics upon SEM analysis. Raman spectroscopy provides chemical fingerprints of a material. Combining high resolution confocal optical microscopy and Raman spectroscopy, a 3-D chemical map can be obtained from a material with the ultimate resolution of $\frac{1}{4}$ micron laterally and $\frac{1}{2}$ micron vertically. The Raman image below demonstrates that the drug (dexamethasone acetate) is released through a porous network when it is immersed in a solvent. This research will provide insight into the mechanism of release to help guide design of refined devices for human use.
