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Modeling Diffusion Through Fibrous Capsules That Form Around Implanted Medical Devices

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Implanted medical devices can form fibrous capsules around them due to the foreign body response. This biological response can reduce inflammation that may be caused by mechanical movement or chemicals leached from an implanted medical device. These capsules are typically tough, fibrous, and avascular. As a result, they have a different elastic modulus and transport properties than the tissue that they replace. The amount of potentially hazardous materials that may be leached from a medical device over time can present a safety concern. For implanted polymeric devices, the quantity of leachables released into the body can be predicted using mathematical models as part of a toxicological risk assessment. The amount of material released will depend on the properties of the leachable, the polymer, and the surrounding tissue. Prior work examined material release quantities over the first 24 hours after implantation to estimate the maximum daily exposure. We now seek to examine release over longer periods of time (weeks, months, years). To accomplish this goal, changes in tissue properties that occur as a response to wound healing must be accounted for in the model.

In this research, computational models were developed to characterize changes in tissue properties and diffusion of leachables through tissue. Tissue property changes were modeled in Python using FiPy, a phase field modeling package produced by the National Institutes of Standards and Technology (NIST). For the initial model, a binary approach is taken, and the tissue is characterized as either “normal” or “fibrous capsule”. When fibrous capsules develop, they begin to form at the implant-tissue interface. Over time, these capsules can grow in thickness. Phase field modeling, which was originally developed to capture the complex phenomenon of metal solidification is well suited to model the histomorphological tissue changes. The model captures the evolution of the tissue from normal to fibrous capsule as a wave that radiates from the implant surface. This approach enables the properties of each volume element to change as the tissue transforms, which is an advantage over other methods. Diffusion of leachables through the tissue depends on the phase, so the leachable calculation utilizes the phase transformation in the analysis.

Initial results show that the capsule substantially reduced diffusion through the tissue. Using a constant concentration source, without a capsule, the system reached steady state (linear) within the timeframe of the analysis (50 days). In contrast, for the analysis with the capsule, the system was still developing at the end of the analysis with the leachable concentration decreasing with distance from the implant surface. Ongoing work is being performed to integrate explicit polymer diffusion, phase solubility, and more physiologically accurate morphology evolution into the analysis.

While this research focuses on leaching of potentially hazardous materials from an implanted medical device, the findings are also relevant to medical devices that rely on chemical release to perform their function. For example, an implanted insulin pump may form a fibrous capsule around it. Rather than being protective, the capsule effectively slows the release of insulin into the body, adding a time delay to the device’s response. Similarly, the response rate of glucose sensors can also be delayed by slower diffusion through a fibrous capsule.