Improving Thermal Effect on Biological Tissue Using Multiphysics Simulation and Shape Optimization

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Abstract

As minimally invasive and robotic surgical devices get smaller, designing precise energy delivery to create the desired tissue effect becomes a key component in product development. With many interdependent physical phenomena occurring simultaneously, it becomes necessary to use tools such as the COMSOL Multiphysics® software to provide the insight needed to accurately describe the expected behavior in an interaction between the device and tissue.

In this example, a catheter-based balloon electrode with a saline flow used for cooling is optimized for use in a renal denervation procedure. The goal of a renal denervation procedure is to use energy to create a lesion at the depth of the hyperactive renal sympathetic nerves associated with hypertension. These nerves are at an average depth of 6 mm from the interior artery wall. An effective renal denervation procedure is also required to protect the artery wall from damage during energy application, preventing stricture or other complication. These dual requirements necessitate a balance between the delivery of electrical energy via the 500 kHz source to create the lesion and the ability of the saline cooling to maintain the wall of the blood vessel at temperatures below the damage threshold.

Using COMSOL® and fourth order Bernstein polynomials, the energy delivery was optimized to create the desired tissue effect through simulation. Starting with an electrostatics model to determine the field and resulting current density, the joule heating multiphysics determined the volumetric thermal effect. This modeling is coupled with heat transfer definitions that combine not only the conduction and convection mechanisms through the material and the fluid flow but also the impact of perfusion in the tissues surrounding the artery. Using this coupled model and variable biological tissue properties, the optimization was defined to maintain the desired lesion while minimizing the energy applied at the catheter.

With an initial assumption of constant power delivery, the Bernstein coefficients were used to modify the time dependent power delivery over a series of hundreds of iterations. By changing the model on a time-varying power delivery, the resulting optimized energy application adjusts for the changes in the tissue properties and other interactions in the system and results in creating the desired lesion without complicating the cooling system with delivery of excess energy.

Within medical device design, the ability to simulate the expected result (i.e. the effect on the tissue) opens a new pathway to device design with reduced tissue testing during development, resulting in time and cost savings on the path to device commercialization. With the complex interactions between devices and biological tissue, the insights provided

by multiphysics modeling will become ever more important in medical device development.