Multiphysics Model of the NovaSure Endometrial Ablation Procedure

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Introduction

The NovaSure Endometrial Ablation System® is designed to remove the endometrial lining in the uterine cavity of women who suffer from menorrhagia. The NovaSure disposable device consists of a 2-pole, 4 electrode array that is inserted into the uterine cavity and deployed. A prescribed level of constant RF power from 28 to 180 Watts is delivered to the tissue at 482 KHz. The power level is determined based on the measured length and width of the uterine cavity that will provide a power density of 5.5 W/cm^2 inside the cavity wall. The device also includes a suction line to reduce the cavity pressure which insures good electrical contact between the tissue and the electrodes and removes any liberated steam. The system controller monitors the total tissue impedance and stops energy delivery when the impedance reaches 50 Ohms or the procedure time reaches 120 seconds whichever comes first.

The NovaSure ablation is a complex bioheat and mass transfer process. Electrical energy from the bipolar RF electrodes is dissipated in the tissue as heat. The power density is sufficient to induce water phase change and cause desiccation of the tissue as steam is liberated and removed via the vacuum port. The reduction in the tissue water content increases the electrical impendence of the tissue. This change in impedance alters the distribution of dissipated electrical energy in the tissue as the NovaSure RF controller maintains a constant power level during the procedure. The 50-Ohm impedance limit and the time limit control the depth of ablation into the uterine tissue.

A better model of the NovaSure ablation should aid in the understanding of key parameters that affect the procedure. Human studies are difficult to perform and yield limited information and animal models are not suitable to mimic human anatomy. *Ex vivo* tissues are widely used to investigate ablation, however these models are limited in their ability to help study the effects of anatomy, tissue blood flow and other significant parameters. In order to address some of these limitations, we have developed a COMSOL Multiphysics model of the NovaSure ablation process.

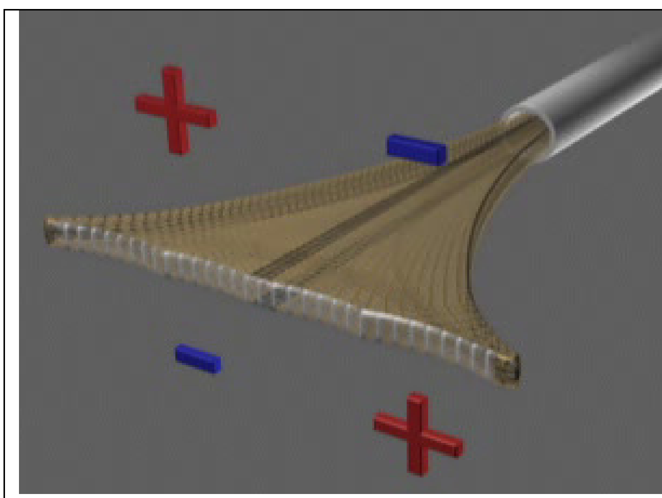

Figure 1: The NovaSure bipolar, 4-electrode array

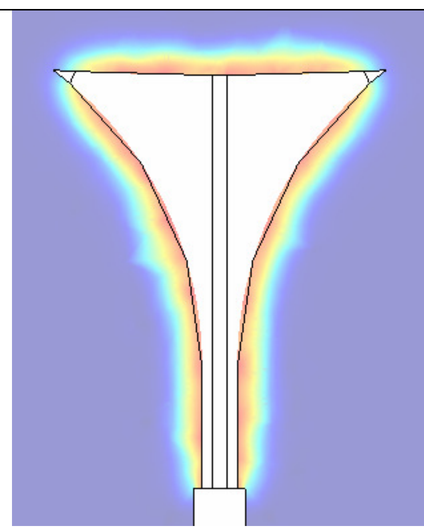

Figure 2: Thermal field from the ablation

Use of COMSOL Multiphysics

The model utilized COMSOL Multiphysics modules (Version 3.5a) for DC conductive media to solve for the resistive heating from the RF energy, the bioheat transfer module to solve for the temperature distribution and the diffusion module to solve for the transport of water vapor out of the tissue. Since the electrical conductivity of tissue is dependent on the liquid water concentration and this concentration decreases with phase change, these modules are solved as a coupled multiphysics set.

For the electrical part of the model, it was assumed that the capacitance effects in the tissue were negligible, thus the resistive heating is assumed to be induced by a DC voltage at the electrodes. Electrical conductivity is initially assumed to be uniform throughout the tissue, however conductivity is modeled as a function of the local tissue liquid water concentration and therefore changes in space and time as phase change and the ablation process proceeds.

For the thermal part of the model, it is assumed that thermal properties are uniform and constant. The phase change is modeled with a modified heat capacity that is a function of temperature to account for the latent heat of vaporization.

For the water transport (diffusion) part of the model, water vapor is created as a diffusion species in tissue locations that are above the phase transition temperature. In order to maintain mass balance, liquid water, as a diffusion species, is destroyed at the locations where water vapor is created. It is the liquid water concentration that determines the electrical conductivity and couples this module to the electrical multiphysics module. The water vapor diffuses along the gradient toward the uterine cavity where it is removed out via the vacuum line. The mass transport of water vapor out of the tissue creates an evaporative cooling that is coupled to the bioheat transfer module.

During ablation and the increase in tissue impendence, the NovaSure RF controller maintains a constant power level throughout the treatment and this is also modeled. While the Integration Coupling Variable in COMSOL is available to model this type of coupling, it was found that this approach greatly lengthened the computational time. Rather, it was found that by using 2 repeated solutions of the model, a constant power solution could be obtained faster. In the first solution, the electrodes were assumed to have a constant voltage initially set to dissipate 180 Watts but with diminishing power over time as the tissue impendence increases. This first result is then post-processed to determine the functional relationship between the total tissue impedance and the total tissue liquid water content and these data are used to create a Global Function of tissue impedance. This function is used in the second solution, along with the total tissue water content, to set the electrode voltage to maintain the power at the constant set point of 180 Watts in the face of changing impedance. A third solution may also be iteratively used to improve the power control to better than 0.5 Watts.

Expected Results

The depth of ablation predicted by COMSOL will be compared to experimental *ex vivo* ablation of porcine liver. Preliminary results indicate that the COMSOL and experimental ablation depths agree to about 1 mm. The model will also be used to assess the sensitivity to tissue blood flow, thermal properties and the initial electrical properties.

Conclusion

The multiphysics modeling of complex bioheat and mass transfer processes such as the NovaSure procedure is now possible. Preliminary results indicate that the prediction of accurate ablation depths is possible. After further validation of this modeling tool, it could be used to evaluate new ablation procedure parameters or electrode designs that can optimize the prescribed thermal therapy.