DEVELOPMENT AND VALIDATION OF NUMERICAL MODEL SIMULATION FOR RF ABLATION USING THE ISOLATOR SYNERGY CLAMP

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BACKGROUND

Thermal ablation is rapidly becoming a standard of care for the treatment of atrial fibrillation (AF), a cardiac disorder characterized by irregular heart rhythm and estimated to impact more than 33 million people worldwide [1]. AtriCure is a company that specializes in epicardial ablation for AF and here we describe the development of a numerical model to study the performance of the Isolator® Synergy™ Clamp bipolar radiofrequency (RF) device. The clamp device features two jaws with embedded electrode pairs, which are used to secure the tissue by clamping across the left atrium (as shown in Figure 1). Energy is applied between the bipolar electrodes at approximately 460 kHz through an impedance-based control algorithm and is additionally duty-cycled between the pairs to further distribute the heating. Patient anatomies vary greatly and measured impedance will depend on atrial wall thickness, epicardial fat, electrode-tissue engagement, and structural variations. Further, tissue conductivity (inversely related to impedance) increases as the tissue is heated, leading to a complicated process, where the heat generation depends on the impedance, which in turn is a strong function of temperature. Energy delivery continues until a phase change in the tissue’s water content occurs, producing a sharp increase in impedance and termination of the ablation. Therefore, since tissue impedance and heating drive the device’s performance, a majority of the effort described here focuses on the validation work done to ensure the model is based on an accurate description of the tissue properties and response. While previous modeling of RF ablation often does include temperature-dependence of tissue properties, the referenced values vary notably and rarely include direct validation of modeling results to benchtop data. Variations in anatomy and fat content can dramatically impact the energy delivery and patient-to-patient treatment efficacy, so an accurate description of the tissue response is critical to understanding the limitations of current energy delivery algorithms and provides an invaluable tool in designing more efficacious ablation devices and algorithms.

METHODS

Benchtop validation experiments: Validation experiments were conducted with a simplified power algorithm (constant power with no duty cycle switching between the electrode pairs) on bovine ventricular tissue. A general experimental description is included in Figure 2. Two tissue models were used – two stacked slices of 5mm myocardium (n=20 runs) and two stacked
slices of 6mm fatty epicardium (n=20 runs). Detailed dimensional data was recorded for the tissue on each run (pre-ablation clamped thickness and engagement length and the tissue was then cross-sectioned for additional thickness measurements and lesion characterization post-ablation). Generator data during the ablation was recorded, including tissue impedance, power, voltage, and current. Finally, a fixture with an array of thermocouples was placed between the two tissue slices for half of the runs on each tissue model (representing the endocardial temperatures).

Numerical model: The ablation process is simulated in COMSOL Multiphysics® 5.3 through the AC/DC Electromagnetics and Heat Transfer modules. The device is relatively uniform along its engagement length (< 65mm), so the geometry is modeled as a 2D cross-section of the clamps and atrial tissue. A quasi-static approach is assumed for the electromagnetic physics due to the relatively large wave-length at 460 kHz.

Accurate electrical and thermal properties for the tissue are critical model inputs. The functions for electrical conductivity were developed based on literature review and fitting to the validation experiments. Reported values for electrical conductivity of myocardium and fat both vary across a fairly wide range at 0.12 to 0.6 S/m and 0.02 to 0.2 S/m, respectively (at approximately room temperature to 37°C) [2,3]. Further electrical conductivity is reported to increase with temperature by 1-2% per °C [2]. Finally, it is expected that the water content undergoes a phase transition around 100°C leading to a 1-2 order of magnitude drop in the electrical conductivity [4]. The critical parameter related to this phase change is the latent heat of vaporization, which is estimated based on the water content of the atrial muscle and fat. Finally, as the clamp produces significant compression (up to 40%), the potential impact of changes to the properties of the tissue between the jaws was also studied. It is assumed that the dominant effects of compression will be driven by water loss in the tissue. Similar to the latent heat of vaporization, tissue water content has been shown to correlate directly with other tissue thermal properties (thermal conductivity, specific heat capacity, and density) [5]. The potential impact of changes to water content in the compressed section was studied in context of the experimental validation data. All other material properties are assumed constant, based on literature values.

A constant power simulation was used to compare to the experimental results. Once a basis for the tissue properties was confirmed, simulation of the Synergy power control algorithm was achieved through a Terminal boundary condition on the electrode faces, which switches between constant power, current, and voltage modes, based on a global equation with indicator states that are triggered by events determined by the calculated tissue impedance. Electrode pair switching is simulated with a time-averaged power approximation. This assumes that no significant thermal transfer occurs at the switching time-scale, an assumption that is still being validated. However, solve times are two to three orders of magnitude slower with direct simulation of switching (minutes versus days). Finally, exposed tissue and device surfaces are subjected to natural convective cooling in air. The coupled physics is solved based on the electromagnetic heat source multiphysics and the transient solution is run until the impedance spike is achieved.

RESULTS

The results of the validation experiments were used to investigate sensitivity and fitting of the tissue properties described above. Initial focus was on the myocardial tissue properties. The average tissue geometry (thickness, engagement length, and compression) was used to set the model geometry baseline. A parametric solver was then used to iterate and find the optimal fit for the room temperature electrical conductivity and rate of increase with temperature, based on the tissue impedance data measured by the generator. Further, the time to impedance spike was used to investigate the model sensitivity to the myocardial water content. This process was then repeated, by fixing the “best fit” myocardial properties and looking at the properties of fatty layer only. The electrical conductivities for
myocardium and fat used in the model are shown in Figure 3, as well as a comparison of the model’s predicted impedance versus the experimental data in Figure 4.

**Figure 3.** Room temperature values and temperature rate of change for electrical conductivity of myocardium and fat were fit against the benchtop validation data. The resulting trends with temperature are shown and were used for the basis of modeling device behavior.

**Figure 4.** Simulated impedance response shows good agreement with the decreasing trend observed in both the myocardial (top) and fatty epicardium (bottom) experiments, but under predicts the time to impedance spike. Measured impedance is from the ASU RF generator and is normalized to the initial impedance value. The generator times out after 40 seconds and is restarted with a 2 second delay.

**INTERPRETATION**

It is apparent from Figure 4, that the model is under predicting the time to create the impedance spike. This was investigated in the context of the impact of compression and water content on the tissue thermal properties. Figure 5 shows the modeled impact of water content and the overall trends observed. It can be seen that reducing the water content (baseline water content of myocardium is expected to be around 80%) leads to even earlier predictions for the time to impedance spike, dominated by the reduction in latent heat of vaporization. So the “best fit” model assumes the native water content of 80%, but still under predicts the time to the impedance event. While this is a limitation of the model, Figure 5 also demonstrates an incredibly valuable agreement in the trends observed. The proportional trends do agree closely with those observed in the experiments, which is still incredibly effective at evaluating the relative impact of potential design changes and experimental factors. While the model does take into account the potential phase change of the water, we hypothesize that there may be an impact of water transport occurring as the tissue is heated and membranes breakdown; this is a potential effect that will be studied further through continued model development.
reasonable value for myocardial tissue (80% water) gave the closest fit to measured impedance behavior. The simulation under predicts the time to impedance spike (bottom), but does provide an incredibly powerful tool for describing the proportional impact of design variables. For myocardium, the modeling was compared to the subset of data that ran to an impedance spike (n=10). For fatty tissue, the modeling was compared to the subset of data for only tissue with a continuous fat layer and that ran to an impedance spike (n=7).

Similarly, as shown in Figure 6, an offset is seen in the observed versus predicted endocardial temperatures. Model sensitivity to the thermal properties has been fully evaluated and is not expected to be a contributing factor. A potential lag in the thermocouple response and impact of capacitive power coupling to the tissue are still being evaluated as contributing factors. However, while it is important to acknowledge limitations in the model, it again shows useful agreement in the observed trends, which is critical for future work in evaluating thermal dosing and lesion formation.

Initial experimental validation shows very promising agreement with a detailed set of validation experiments. The work here largely focused on verifying the accuracy in description of the tissue response to heating, as the efficacy of the Isolator Synergy Clamp device relies on the complex response of tissue impedance. This baseline numerical modeling of our current device performance will provide an invaluable tool for understanding the physics and feasibility of next generation devices and energy control.

REFERENCES