Computational modeling for high-frequency surgery

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Abstract: This project explores the use of Finite Element Modeling (FEM) to support regulatory approval processes for high-frequency (HF) surgical devices. By refining an existing model and conducting ex vivo tests, the study investigated the influence of mesh refinement, tissue deformation, and electrode-tissue contact on heat propagation and necrosis formation. Results showed among others that finer mesh sizes and accurate modeling of tissue deformation improve simulation accuracy, particularly in predicting necrosis spread.

I. Introduction

Electromedical devices have been integral to modern medical practices for decades, particularly in high-frequency (HF) surgical applications, where they are used for controlled tissue damage. Despite their long-standing use, manufacturers face significant challenges in proving both the safety and efficacy of these devices to meet regulatory approval standards [1]. These validation processes often require extensive experimentation, which is both time-consuming and costly. To address these challenges, this project investigates the potential of computational modeling and simulation as a tool for supporting and streamlining the regulatory approval process for HF surgical devices. By developing an advanced Finite Element Model (FEM), the project aims to create a reliable, cost-effective alternative to traditional experimental methods.

The research focuses on improving an existing model [2] by incorporating more detailed physical interactions between electrical energy and biological tissue changes, such as temperature propagation and electrical conductivity. Key questions being addressed in this project include determining how to optimize the physical interactions represented in the model, understanding the influence of electrode pressure on tissue effects, and assessing whether the model is sufficiently complex to represent clinical applications. Additionally, ex vivo tests are being performed alongside the simulations to provide comparative analysis and ensure that the model accurately reflects real-world results. This combined approach of simulation and experimental validation is expected to help define the required level of optimization needed to produce representative simulation results while reducing the number of ex vivo tests.

II. Material and methods

The project (IP10 SmartMed B / HAP 2) utilized a comprehensive approach that combines FEM simulations with ex vivo tests to model and validate tissue behavior during monopolar HF coagulation. FEM simulations were conducted using COMSOL Multiphysics®, a platform that allows for the simulation of multiphysics processes in biological tissue. These simulations focused on tissue necrosis caused by HF electrical currents applied during soft coagulation (see Fig. 1).

The simulation model was based on an axisymmetric representation of liver tissue. A ball electrode was used to simulate the contact between the HF surgical instrument and the tissue. The modeling process was divided into two main steps. First, the mechanical problem of electrode-tissue interaction was solved by simulating the deformation of the tissue when pressed by the electrode. This step is critical because the tissue's deformation affects the contact area, which in turn influences the heat distribution during the coagulation process. The tissue was modeled as a hyperelastic material, utilizing the Neo-Hookean model. A series of electrode displacements were tested to simulate different pressure levels so that the effect of changing the contact area on heat transfer during coagulation could be investigated [3, 5].

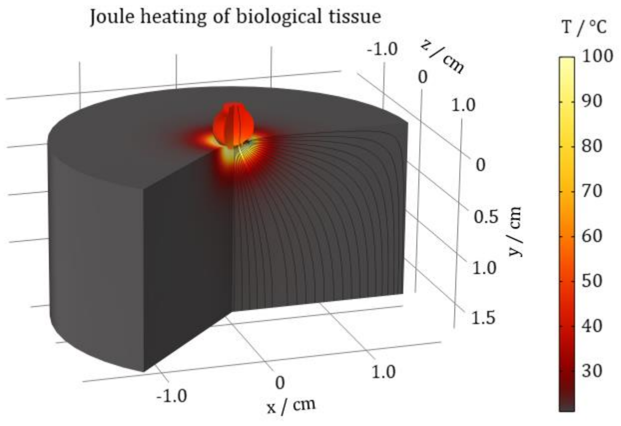

Figure 1: Simulated Joule heating in liver tissue by soft coagulation with a ball electrode including consideration of mechanical, electrical, and thermal effects.

The second step of the simulation involved solving the thermally and electrically coupled problem. This simulation phase involved applying a constant voltage to the electrode and modeling the resulting Joule heating within the tissue. Joule heating is the primary mechanism by which HF currents generate heat in biological tissues, leading to cellular damage and necrosis. The heat equation was solved using temperature-dependent parameters for heat capacity, electrical conductivity, and thermal conductivity, ensuring that the simulation accurately reflected the changes in tissue properties as it was heated. Different mesh sizes (coarse, medium, and fine) were used to examine the effects of mesh refinement on the accuracy of the simulation. Mesh refinement is crucial in FEM simulations because the mesh size determines the spatial resolution of the simulation, with finer meshes providing more accurate results at the cost of increased computational resources [4].

III. Results and discussion

The results of the FEM simulations provided significant insights into the influence of mesh refinement, tissue deformation, and electrode contact area on the accuracy of simulations for HF surgical applications. Mesh refinement was found to play a critical role in determining the accuracy of the necrosis prediction. The study used three different mesh sizes—coarse, medium, and fine—and found that finer meshes improved the accuracy of the simulation, particularly with regard to the lateral spread of tissue necrosis. Coarser meshes led to significant deviations in lateral necrosis spread, with errors reaching up to 44.3%. In contrast, finer meshes produced more precise results, though at the expense of higher computational costs. Notably, the use of exponential regression to compensate for coarse mesh errors proved effective in reducing the deviation in necrosis depth, although lateral errors remained more challenging to compensate [5].

In addition to mesh refinement, the study also examined the role of tissue deformation in influencing the heat distribution within the tissue. The simulations demonstrated that as the electrode pressure increased, the contact area between the electrode and the tissue expanded, leading to slower heat propagation. This phenomenon is crucial in clinical applications where deeper tissue coagulation is desired. The larger the contact area, the more gradually the heat propagates into the tissue, allowing for a more controlled coagulation process. This finding highlights the importance of accurately modeling tissue deformation in FEM simulations for HF surgery, as it directly influences the effectiveness of the procedure in achieving the desired clinical outcomes [3].

The simulations also revealed that the size of the electrode-tissue contact surface plays a central role in determining the extent of tissue necrosis. When the same voltage was applied to varying contact areas, the necrosis spread was found to decrease linearly as the contact surface area increased. This result suggests that even small variations in electrode pressure or positioning can significantly alter the extent of tissue damage during HF surgery. The linear relationship between contact surface area and necrosis depth provides a valuable parameter for optimizing HF surgical procedures, as it offers a predictable means of controlling the tissue effects through careful manipulation of electrode pressure [4].

IV. Conclusions

The findings of this project demonstrate the significant potential of FEM simulations for HF surgical devices. The results highlight the importance of mesh refinement, tissue deformation, and electrode contact area in determining the accuracy of simulations for predicting tissue necrosis and heat propagation. Finer mesh sizes offer more accurate results, though regression techniques can be applied to coarser meshes to improve their precision. The study also underscores the critical role of tissue deformation and electrode contact in influencing the thermal effects of HF surgery, with larger contact areas leading to slower, more controlled heat propagation and deeper tissue coagulation.

Nevertheless, ex-vivo tests for comparative analyses to the FEM simulations are absolutely necessary to confirm the validity of the simulation results. This validation is an essential step toward integrating computational modeling into the regulatory approval process for HF surgical devices. By reducing the reliance on extensive experimental testing, FEM simulations can help streamline the approval process, making it faster and more cost-effective for manufacturers.

Future research will focus on refining the control algorithms for power delivery in HF devices and further validating the models through additional ex vivo tests. The ultimate goal is to establish FEM simulations as a reliable, efficient tool for predicting the effects of HF surgical procedures, thus improving the design and approval of electromedical devices in clinical applications.

AUTHOR'S STATEMENT

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