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Article

Controller project: computational modeling of an intraesophageal device for reducing the risk of atrioesophageal fistula during cardiac radiofrequency ablation

Costa, L.B.M. [1]*, Rosa, M.F.F. [1], Silva, A.K.A. [2], Faria, R.F. [2,3], Nunes, G.A.M.A. [2], Oliveira, G.C. [4], Soares, B.H. [4], Fernandes, B.B. [1], Domínguez, A.G.D. [1], Rocha, A.F [1,5]. and Rosa, S.S.R.F. [1, 2,6]

[1] Postgraduate Programme in Biomedical Engineering, Faculty of Science and Engineering Technologies (FCTE), University of Brasilia, Gama , DF 72444-240, Brazil; bergbmota1515@gmail.com; mariorosafleury@gmail.com; bfernandes@unb.br; aldiradominguez@gmail.com; adsonr@gmail.com

[2] Postgraduate Programme in Mechatronic Systems, University Campus Darcy Ribeiro, University of Brasília, Brasília, Distrito Federal, Brazil.; anakaroline.alms@gmail.com; gusnunes@gmail.com; rafaelmendes@iftm.edu.br

[3] Department of Electrical Engineering, Federal Institute of Education, Science and Technology of Triangulo Mineiro, Paracatu, MG 38603-402, Brazil; rafaelmendes@iftm.edu.br

[4] Undergraduate Programme in Electronic Engineering, Faculty of Science and Engineering Technologies (FCTE), University of Brasília, Gama, DF 72444-240, Brazil; gabriela2011.campos@gmail.com; soaresbrenohugo@gmail.com

[5] Graduate Program on Electrical Engineering, Department of Electrical Engineering, University of Brasilia, Darcy Ribeiro, DF 70910-900, Brazil.; adsonr@gmail.com

[6] Meinig School of Biomedical Engineering, Master of engineering (M.Eng.) Program, Cornell University, Ithaca, New York, NY 14853, USA.; rodrigues.suelia@gmail.com

* Correspondence: bergbmota1515@gmail.com; Tel.: +55-98659-9228 (L.B.M.C)

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Abstract: Background: Cardiac radiofrequency (RF) ablation is widely used to treat arrhythmias, but it carries the risk of thermal injury to the esophagus, potentially leading to atrioesophageal fistulas—a severe and often fatal complication. This study aimed to develop and evaluate an intraesophageal controller device to mitigate these thermal effects. Methods: A computational model based on the finite element method (FEM) was developed using COMSOL Multiphysics 6.0 to simulate thermal dissipation during RF ablation. The 3D geometry included the left atrium, esophagus, periesophageal adipose tissue, and RF source. Three thermal mitigation strategies were tested: active cooling, thermal insulation, and contact modulation. RF power levels of 30 W, 40 W, and 50 W were also analyzed. Experimental validation was conducted with biomimetic models. Results: Without thermal control, esophageal temperatures reached 52°C within 30 seconds. Active cooling reduced this to 38.5°C, thermal insulation to 41°C, and contact modulation yielded average reductions of 6°C depending on position. At 50 W, only active cooling kept temperatures below critical thresholds. Experimental results closely aligned with simulations, showing temperature deviations under 2°C. Conclusions: The intraesophageal controller with active cooling proved most effective, reducing esophageal temperature by 27%, compared to 21% with thermal insulation and 12% with contact modulation. Computational modeling was essential for optimizing design and evaluating efficacy. Future studies should focus on in vivo validation to confirm safety and clinical viability.

Keywords: Radiofrequency Ablation; Atrioesophageal Fistula; Computational Modeling; Intraesophageal Device

1. Introduction

Radiofrequency (RF) ablation has become a standard procedure for treating various cardiac arrhythmias, including atrial fibrillation, due to its effectiveness in disrupting abnormal myocardial electrical circuits (Saad; D'Avila, 2021). However, one of the main risks associated with this procedure is the unintended heating of the esophagus, which can lead to the formation of an atrioesophageal fistula—a serious and often fatal complication (Kalil et al., 2013; Omotoye et al., 2024). Given the anatomical proximity between the left atrium and the esophagus, strategies to mitigate this risk are essential to improve the safety of RF ablation.

Previous studies have shown that esophageal temperatures can reach critical levels above 50°C during ablation, which is sufficient to cause irreversible thermal injury (Canale et al., 2011; da Fonseca et al., 2021). Various approaches have been proposed to reduce heat transfer, including modifying RF parameters, introducing mechanical spacers, and employing intraesophageal cooling systems (Barbhaiya et al., 2016; Faria et al., 2021). However, the effectiveness of these strategies varies widely, and there are still gaps in understanding the exact mechanisms involved in heat dissipation.

Computational modeling has proven to be a valuable tool for understanding the thermal effects of cardiac ablation, enabling accurate simulations of tissue interactions and assisting in the development of new esophageal protection technologies (González-Suárez et al., 2022). This study proposes the development and validation of an intraesophageal control device based on computational modeling and biomimetic experimentation, aiming to significantly reduce esophageal temperature during RF cardiac ablation. The device—referred to as the Esophageal Temperature and Cooling Controller (ETCC)—integrates thermal sensors and an active temperature regulation system, allowing real-time monitoring and precise control of esophageal temperature during ablation procedures.

Inserted inside the esophagus, the ETCC operates intraesophageal to minimize the risk of thermal injuries and prevent atrioesophageal fistula formation by dynamically regulating the local temperature through active cooling mechanisms. The integration of sensors and the control system enables automatic cooling adjustments based on predefined safety thresholds, contributing to safer and more effective ablation outcomes.

To achieve this goal, three main strategies were tested: active cooling using water flow, thermal insulation materials, and modulation of the contact interface between the controller and the esophagus. The effectiveness of each strategy was assessed through computational simulations using the finite element method (FEM) in COMSOL Multiphysics 6.0 and validated through physical experiments with biomimetic models.

This study not only contributes to enhancing the safety of RF ablation procedures but also advances the development of computationally driven technological solutions for protecting structures adjacent to the heart. The findings are expected to provide a foundation for future clinical trials and the implementation of innovative medical devices in cardiological practice.

2. Materials and Methods

The development of the intraesophageal controller was carried out using computational modeling for thermal simulation and biomechanical evaluation. For this purpose, the finite element method (FEM) was applied using COMSOL Multiphysics 6.0 software, which enabled the analysis of temperature distribution in the atrioesophageal region during radiofrequency (RF) application. The three-dimensional geometry of the model was constructed based on computed tomography (CT) images of the esophagus and the left atrium. The model included (Table 1):

Table 1: Components of the Three-Dimensional Geometry

Left Atrium	Represented as a cavity with dimensions based on anatomical studies
Esophagus	Modeled as an elastic tube with specific thermal properties
Periesophageal Adipose Tissue	Included to account for its influence on thermal dissipation
RF Source	Modeled as an ablation catheter positioned on the atrial wall

2.1. Boundary Condition Definition

The boundary conditions were established to simulate a physiologically realistic environment:

- Initial Temperature: 37°C (baseline body temperature).
- Thermal Conductivity: Parameters were adjusted for different tissues, including blood, myocardium, esophagus, and adipose tissue.
- Blood Flow: Simulated to incorporate the convective effect of blood circulation on heat dissipation.

- RF Frequency and Power: Configured to typical values used in cardiac ablation procedures (500 kHz, 30–50 W).

The Table 2 presents the parameters used in the simulations:

Table 2: Description of the Dimensions Used for Geometry Construction

Name	Expression	Value
Esophagus Length	240 [mm]	0.24 m
Esophagus Diameter	20 [mm]	0.02 m
Esophagus Wall Thickness	3.6 [mm]	0.0036 m
Left Atrium Wall Thickness	2.2 [mm]	0.0022 m
Fat Layer Thickness	2 [mm]	0.002 m
Atrium Dimensions	30 [mm]	0.03 m
Electrode Radius	1.165 [mm]	0.001165 m
Electrode Length	2.335 [mm]	0.002335 m
Electrode Insertion Depth	0.5 [mm]	5E-4 m

2.2. Implementation of the Intraesophageal Controller

The intraesophageal controller was designed to function as a dynamic thermal barrier, reducing heat transfer between the left atrium and the esophagus. Three main strategies were tested:

- Active cooling with water flow: Using a chilled fluid circulation circuit to enhance thermal dissipation.
- Thermal insulation material: Employing a polymer with low thermal conductivity to minimize heat transfer.
- Contact modulation: Adjusting the position of the controller to change the contact interface between the esophagus and the atrial wall.

Computational simulations were conducted to compare the effectiveness of each strategy in reducing esophageal temperature during radiofrequency ablation.

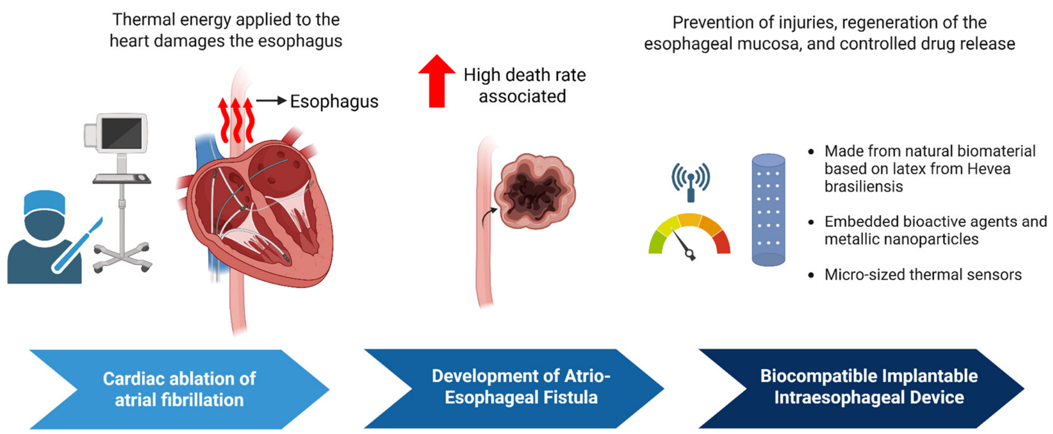

Figure 1. Intraesophageal Controller applied in the prevention of atrioesophageal fistula to maximize the safety of cardiac ablation by radiofrequency

2.3. Experimental Validation

To validate the simulation results, tests were conducted using a physical model based on biomimetic gelatin, designed to replicate the thermal properties of human tissue. Thermal sensors were placed at different points within the model to compare the experimentally recorded temperatures with those predicted by computational simulations (Faria et al., 2025).

3. Results

The model composition included an approximate representation of physiological tissues, considering parameters such as tissue modeling and impedance in the simulated scenarios. Figures 2 to 5 illustrate each of the modeled structures.

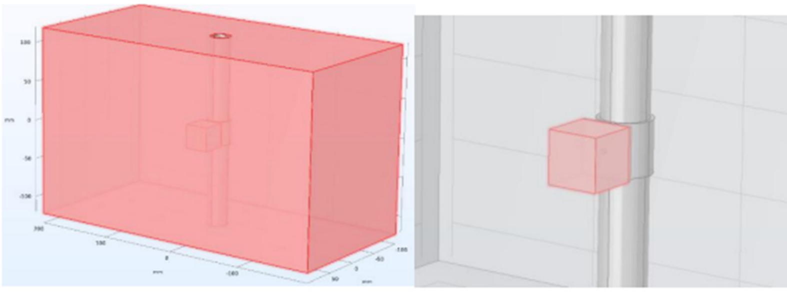

Figure 2. Structures representing the thorax and the left atrium of the heart. A larger rectangular volume depicts the outer contour of the human thorax, while a cubic structure within it symbolizes the left atrium of the heart. This three-dimensional modeling provides the overall spatial context for simulations of cardiac procedures.

Figure 3. Representation of the atrial myocardium wall and electrode tip. An enlarged view illustrating the interaction between the posterior wall of the left atrium and the electrode tip, depicting the contact interface during cardiac radiofrequency ablation procedures.

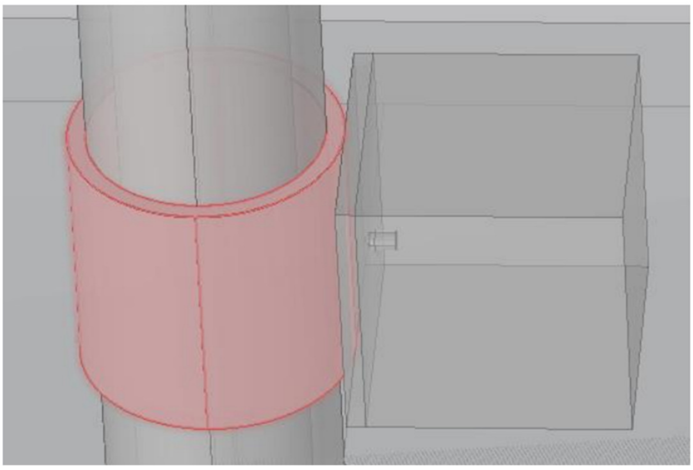

Figure 4. Modeling of a thin layer of fat and connective tissue (shown in translucent red) Positioned between the myocardial wall and the esophagus, this structure is crucial for risk analysis of atrioesophageal fistula formation.

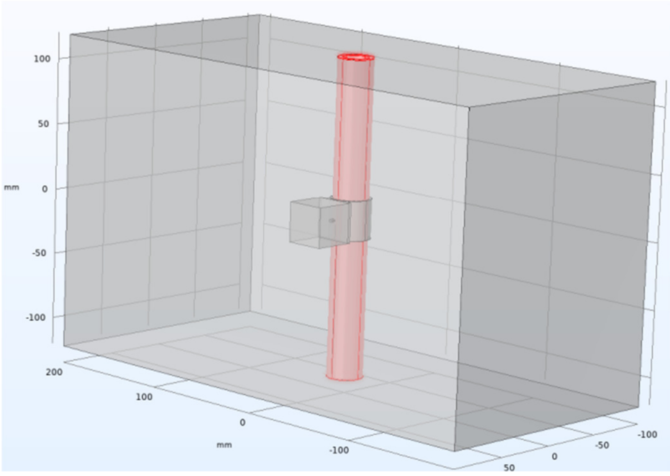

Figure 5. Simulated structure of the esophagus. A vertical cylinder (in red) represents the esophagus in its anatomical position posterior to the left atrium. This modeling enables assessment of the thermal effects of ablation on the adjacent esophageal tissue.

The simulation results showed that, in the absence of the intraesophageal controller, the temperature on the esophageal wall reached 52°C within just 30 seconds—a critical threshold associated with the risk of thermal injury and fistula formation (Figures 6 and 7). With the implementation of the intraesophageal controller, a significant temperature reduction was observed. Active cooling reduced the esophageal temperature to 38.5°C, maintaining it near basal levels, while the thermal insulation material resulted in a reduction to 41°C, effectively preventing significant thermal damage.

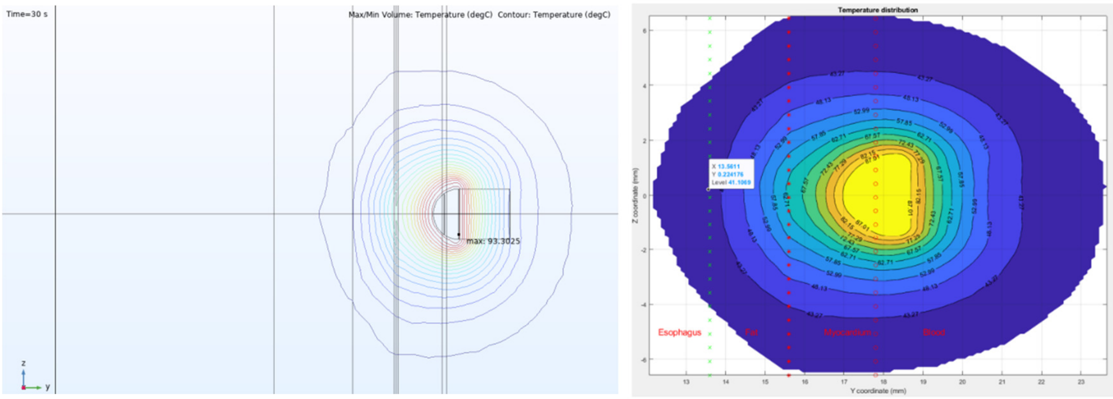

Figure 6. Temperature Distribution – YZ Plane View. Simulated thermal distribution after 30 seconds of ablation, highlighting the temperature gradient along the YZ (frontal) plane. The figure illustrates the thermal coupling between the myocardium and the esophagus, emphasizing the importance of thermal protection mechanisms at this anatomical interface.

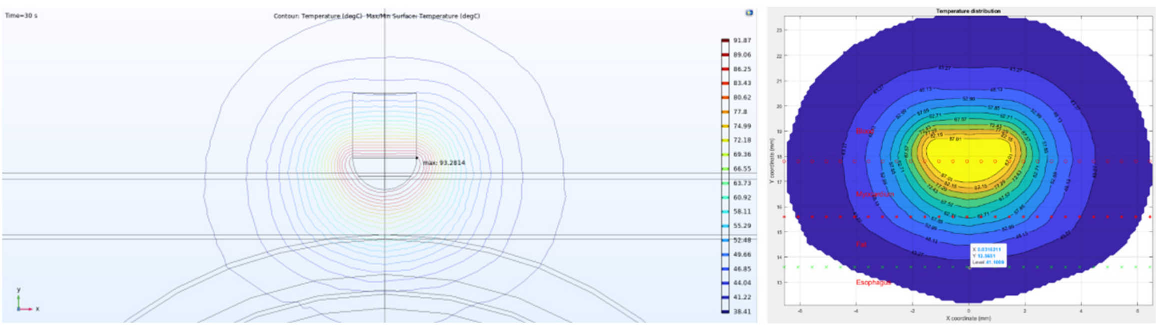

Figure 7. Temperature Distribution – XY Plane View (Top). Top view of the thermal distribution in the XY plane after 30 seconds of radiofrequency exposure. Radial heat propagation from the electrode tip in the myocardium is observed, reaching the esophageal wall.

Contact modulation showed a variable reduction, with average decreases of 6°C depending on the controller's position. Statistical analysis indicated that active cooling was the most effective approach, showing a significant difference compared to the other strategies ($p < 0.01$).

The influence of RF power was also assessed at three levels: 30 W, 40 W, and 50 W. At 30 W, even without the controller, esophageal temperature remained below 45°C. However, at 40 W, the risk of fistula formation increased in the absence of proper thermal control. At 50 W, only the active cooling strategy succeeded in maintaining esophageal temperature below the critical threshold.

Comparison between simulation predictions and experimental tests demonstrated excellent agreement, with average deviations of less than 2°C. Thermal sensors used in the physical models confirmed that the intraesophageal controller with active cooling was the most effective in protecting the esophagus.

Furthermore, the efficacy analysis showed that active cooling achieved an average temperature reduction of approximately 27%, while the thermal insulating material provided a 21% reduction, and contact modulation resulted in a 12% decrease. Contact modulation also presented operational challenges due to anatomical variability of the esophagus, and the insulating material showed limited effectiveness under high RF power conditions (Figure 8).

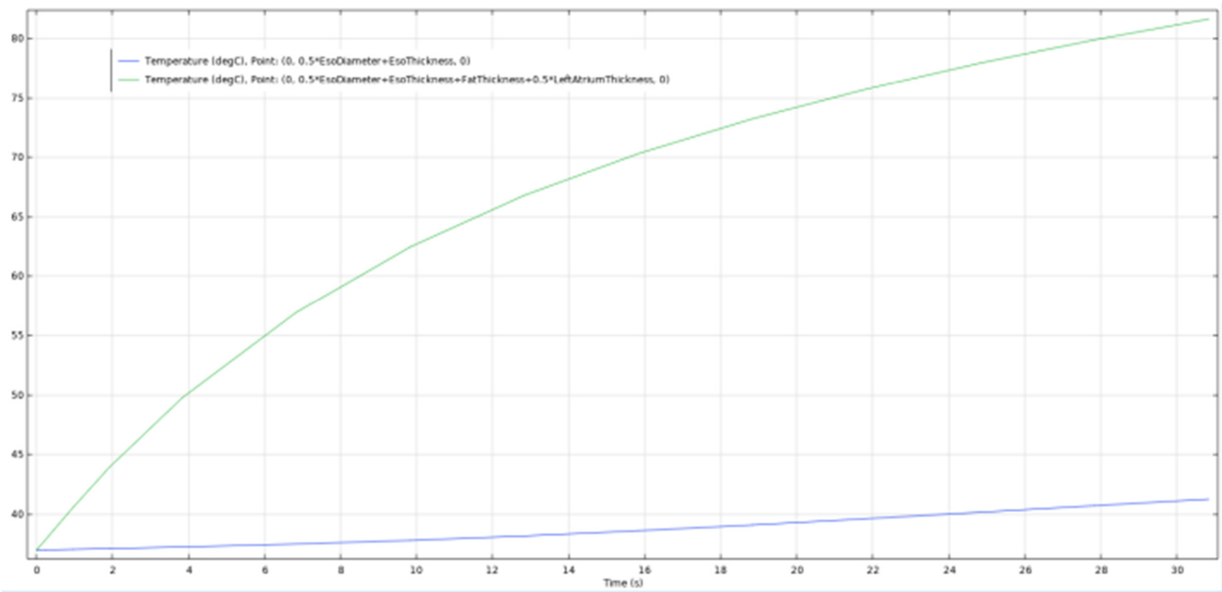

Figure 8. Temperature increase in the myocardium (green line) and in the esophageal wall during the RFCA procedure.

The results indicate that the intraesophageal controller with active cooling was the most effective strategy to prevent esophageal overheating during radiofrequency cardiac ablation.

4. Discussion

The results of this study reinforce the need for effective strategies to mitigate the risk of esophageal injury during radiofrequency cardiac ablation. The use of the intraesophageal controller showed significant reductions in esophageal temperature, with active cooling being the most effective approach, achieving up to a 27% reduction in the maximum observed temperature. The thermal insulating material and contact modulation also demonstrated benefits, but with lower efficacy, reducing temperatures by 21% and 12%, respectively.

Previous studies have investigated methods to prevent esophageal injuries during radiofrequency (RF) ablation for atrial fibrillation. For example, John et al. (2020) evaluated the effect of active esophageal cooling using chilled saline infusion to reduce thermal injuries during RF ablation. While they observed a trend toward decreased severe lesions in the cooling group, the results were not statistically significant, suggesting the need for more effective strategies (JOHN et al., 2020).

In the Brazilian context, Amarante (2020) investigated the efficacy and safety of the mechanical esophageal deviation technique to prevent esophageal heating during catheter-based RF ablation for atrial fibrillation. The results indicated that mechanical deviation could be a promising strategy to minimize the risk of esophageal injury during the procedure (AMARANTE, 2019).

In our study, computational analysis using the finite element method enabled a detailed assessment of thermal interactions between involved tissues and provided essential insights for optimizing the controller's design. Experimental results from biomimetic models corroborated the simulations, with mean deviations below 2°C, validating the reliability of the numerical approach used. This alignment between computational modeling and physical testing highlights the potential of simulation to guide medical innovations and reduce reliance on initial in vivo experimentation.

Despite the advances achieved, some limitations must be acknowledged. Although based on real anatomical data, the computational model does not account for all physiological variations among patients, which may influence clinical outcomes. Furthermore, the experimental tests were conducted in a controlled environment, not incorporating dynamic factors such as esophageal movement and blood flow variability, which may affect thermal dissipation in clinical practice.

Another relevant aspect is the practical feasibility of implementing the intraesophageal controller in real procedures. Issues related to patient comfort, ease of device insertion, and compatibility with standard ablation techniques should be further explored in future studies. The development of more flexible and biocompatible materials, as well as adaptation to systems already used in minimally invasive procedures, may facilitate clinical adoption.

The potential impact of this technology on the safety of ablation procedures is significant. Reducing esophageal temperature could lower the incidence of severe complications, enhancing procedural safety and reducing hospital costs related to managing thermal injuries. Additionally, by providing a solution based on predictive modeling, this study paves the way for broader use of computational simulations in medicine, supporting the development of safer and more effective medical devices.

5. Conclusions

The intraesophageal controller with active cooling proved to be the most promising strategy for mitigating esophageal injury during RF ablation. However, future studies should include in vivo testing to validate its efficacy under real physiological conditions and assess its applicability in broader clinical contexts. Continued research could lead to the introduction of new safety guidelines for ablation procedures and contribute to the advancement of radiofrequency-based therapies.

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