Endovenous Laser Treatment for Occlusion of Varicose Veins

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BEE 4530 Computer- Aided Engineering: Applications to Biomedical Processes
Spring 2016

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1.0 Executive Summary

Endovenous laser treatment (ELT) is a minimally invasive technique that uses laser energy to treat varicose veins. An optical fiber is inserted under the guidance of ultrasound and laser light is shone into the interior of the varicose vein. The optical fiber is withdrawn at a constant rate as, simultaneously, contraction of the vein occurs in response to heating induced by laser light exposure. Our goal is to model heat transfer between the laser and the vein wall and optimize laser power and pullback speed for ELT.

Modeling was performed in COMSOL using Navier--Stokes fluid flow and transient state heat transfer. The problem geometry was simplified to a 2-D axisymmetric model consisting of a lumen, vein wall and perivenous tissue. By modeling the ELT process, we were easily able to observe temperature changes and quantify cell death, a measure of tissue damage, in the vein wall and perivenous tissue while manipulating laser power and pullback speed.

We analyzed cell death in the vein wall, where permanent damage is desirable, as compared to the perivenous tissue, where it is not, at various laser powers and pullback speeds. Our results indicate that several optimal laser power and pullback speed combinations exist for different criteria. For minimum damage to the perivenous tissue we recommend a laser power of 15 W and a pullback speed of 2 mm/s. If damage to approximately 100 mm^2 of perivenous tissue is acceptable, the maximum amount of vein wall tissue can be destroyed using a laser power of 30 W and a pullback speed of 4 mm/s.

Our model supports the effectiveness of the ELT procedure and enhances discussions on best treatment methods. Optimization of laser power and pullback speed improves the efficacy of the treatment and decreases risk associated with damage to the perivenous tissue. By improving the efficacy and safety of ELT we hope to improve treatment options for the vast number of people suffering from varicose veins. Our results may also be used as foundation for further comparative studies of ELT procedure.

2.0 Introduction

2.1 Background

More than 40 million people in the United States suffer from varicose veins [1]. Varicose veins are twisted, enlarged veins that commonly occur on the leg [2]. When veins become varicose, valve leaflets in the veins no longer meet properly, causing blood backflow and accumulation that further enlarges the veins. Known as spider veins, varicose veins obviously cause cosmetic concerns. Other than cosmetic problems, they can be painful and in severe conditions can lead to leg swelling, skin inflammation, skin thickening and skin breaks [3].

Treatment for varicose veins may be either conservative or active. Conservative treatments include compression stockings, elevation of the legs, exercises and medications for venous symptoms. Active treatments range from invasive vein stripping surgery to non-invasive treatment like sclerotherapy. Minimally invasive treatments include radiofrequency ablation and endovenous laser treatment (ELT) [4]. Among these treatments, ELT is quickly gaining popularity and becoming the gold standard in the treatment of varicose veins for its efficiency and efficacy. Use of ELT avoids the scarring, higher symptom recurrence rate, and postoperative pain common to the vein stripping procedure.

During the ELT procedure, a laser fiber is inserted into the vein under ultrasonic guidance through a small puncture. Dilute local anesthesia is injected around and along the vein to prevent pain and help to protect the perivenous tissue by absorbing heat from laser. The laser is activated while the laser fiber is being pulled back at a constant speed, resulting in vein obliteration along its entire length [5]. The appropriate amount of laser energy per surface area applied is essential to the procedure, so that targeted vein wall tissue can be destroyed while not damaging adjacent perivenous tissue. Our goal is to analyze the heat transfer between the laser and the vein wall and the resultant tissue damage. The purpose of this study is to simulate the ELT procedure and find the optimal laser power and pullback speed combination.

2.2 Literature Review

In most initial ELT studies, the pulsed wave mode of the procedure was used. In pulsed wave mode, the amount of laser energy administered depends on the distance between laser energy pulses (0.3–2 cm), pulse duration (0.5–2 s) and amount of energy administered (10–15 W) [6]. However, the majority of recent studies focus on continuous mode, in which the laser fiber is pulled back at a constant speed. Compared to pulsed-wave mode, continuous mode is associated with shorter treatment duration, easier procedure standardization, and lower risk of venous perforation [7].

The most important parameter in laser therapy is fluence, or the amount of energy administered over a specified area. In continuous mode ELT, fluence depends on the wattage, or power, of the laser and the duration of treatment, which is determined by pullback speed [6]. Because the surface area of a varicose vein is difficult to estimate, Proebstle *et al.* have suggested the use of an endovenous laser fluence equivalent taking the diameter of the vein into consideration [8,9]. Several studies on the appropriate energy dose for effective treatment have been conducted [9,10,11]. Proebstle *et al.*'s group showed that 60 J/cm or more is associated with durable greater saphenous vein (GSV) occlusion after 12 months [9]. Timperman's 2005 report suggests that an energy dose greater than 80 J/cm resulted in a success rate of 100% [10]. Morden *et al.* build a mathematical model which suggests that 65 and 100 J/cm is needed for varicose veins of 3 and 5 mm, respectively, to irreversibly destroy the vein wall [11]. The variety in these findings highlights the need for further study of the ELT process.

3.0 Problem Statement

Using COMSOL, we generated a 2-D axisymmetric model of a laser moving through a cylindrical varicose vein at a constant pullback speed. Our goal was to analyze the heat transfer between the laser, the vein wall, and the perivenous tissue beyond the vein as well as the resulting tissue damage in the vein wall and perivenous tissue at a variety of laser power and pullback speed combinations. We incorporated the effect of blood flow disruption caused by the moving laser in our heat transfer model in order to increase the accuracy of our results.

4.0 Design Objectives

The design objective of this project was to model heat transfer to the vein wall and perivenous tissue during ELT. We used the temperature profile throughout treatment to quantify tissue damage in the vein wall and perivenous tissue. We aimed to:

(1) Model ELA treatment in a cylindrical vein while incorporating variations in blood flow due to the effect of a moving laser.

(2) Optimize damage to the vein wall while minimizing damage to the perivenous tissue by varying laser power and pullback speed.

5.0 Design Schematic

We built a 2-D axisymmetric model to describe the underlying physics of the optical-thermal interaction on the laser irradiated tissue. During treatment, laser energy is absorbed by the vein wall and the perivenous tissue beyond, causing heating of the tissues. Additionally, a secondary source of heating in the tissue is heat conducted from blood heated by the laser. In our model the laser moves linearly through the center of the vein at a constant pullback speed. Heat energy from the laser is absorbed by the blood and tissues, and heat energy from the blood is also transferred to the vein wall and the perivenous tissue via conduction and convection. As shown in Figure 1 below, such heating causes closure of the varicose vein.

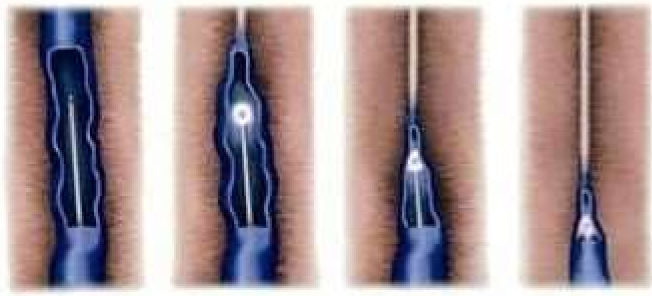

Figure 1. Cartoon of the ELA process in a varicose vein. As the laser tip is pulled back, vein wall tissue is damaged and the enlarged varicose vein closes.
http://www.nazveincenter.com/vein.html [20]

Our 2-D axisymmetric model of the ELT process includes a layer of blood in contact with the laser and the vein wall, as well as the vein wall and the perivenous tissue beyond it. Laser energy is emitted from a rectangular segment, representing the laser tip, that retreats at a specified pullback speed as treatment progresses. Heat is also transferred through the flowing blood to the vein wall by conduction and convection. Heat conduction occurs between the vein wall, where cellular damage is desired, and the perivenous tissue, where it is not. Figure 2 shows the schematic for our model of ELT.

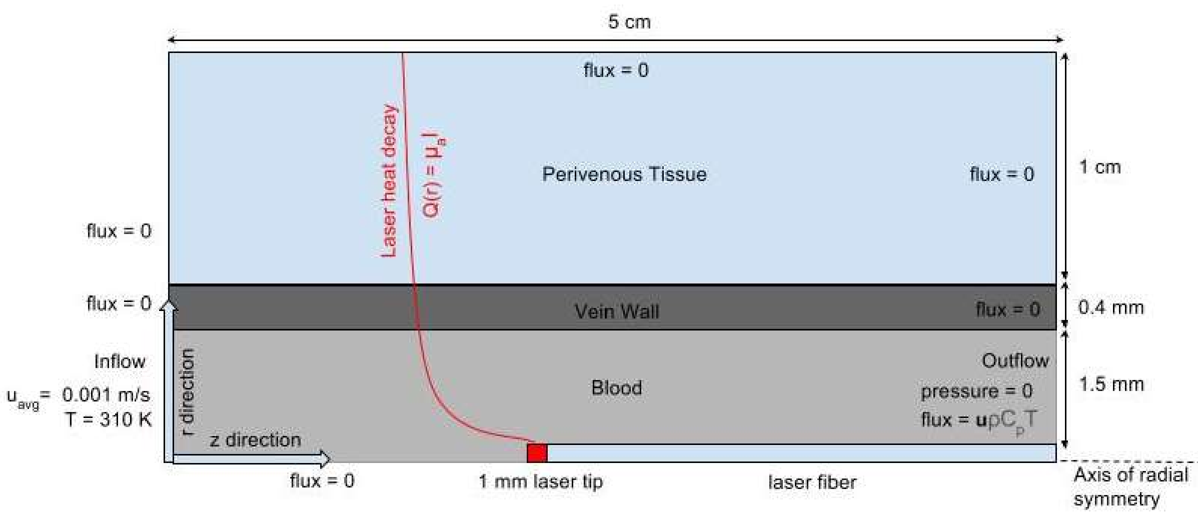

Figure 2. Schematic of our model for heat transfer in ELA of varicose veins. Laser heat energy is absorbed by each of the three domains: blood, vein wall, and perivenous tissue.

The schematic above depicts the geometry built in COMSOL for our model. Note that our model is axisymmetric about the center of the vein and that heat transfer largely occurs in the radial direction from the laser tip out to the vein wall and the surrounding perivenous tissue.

6.0 Governing Equations

The governing equations necessary for our model include laser energy absorption, heat transfer in three domains- the blood, the vein wall, and perivenous tissue- and Navier-Stokes fluid flow and continuity in the blood.

Laser energy is emitted from the optical fiber and may be modeled as an isotropically radiating point source. Energy is calculated via the equations for scattering processes [12]. The laser intensity, I, from an isotropic point laser source can be expressed as

$$I(r) = \frac{P_{laser}\mathrm{e}^{-\mu_{eff}r}}{4\pi Dr} \tag{1}$$

Where P_{laser} equals laser power, μ_{eff} is the effective attenuation coefficient, r equals radial distance from the source, and D is optical diffusion distance, calculated as

$$D = \frac{\mu_a}{\mu_{eff}^2} \tag{2}$$

With μ_a equal to the absorption coefficient in tissue.

Since our model is primarily concerned with temperature changes during the ELT procedure, we calculate volumetric heat generation, Q, from the laser as

$$Q = \mu_a I(r) \tag{3}$$

Values of physical parameters used for numerical simulation are listed in Appendix A.

In addition to direct laser heating, heat transfer due to convection and conduction occurs throughout the blood, vein wall, and perivenous tissue domains. The governing equation for heat transfer in the blood, where convection occurs due to blood flow, is

$$\rho C_p \frac{\partial T}{\partial t} + \nabla \cdot \left(\rho C_p \boldsymbol{u} T\right) = k\nabla^2 T + \rho_b c_b \dot{V}_b (T_a - T) + Q_{met} \tag{4}$$

This equation includes two terms for bioheat generation: blood perfusion and metabolic heat generation. In this expression $\dot{V}_b$ equals volumetric blood flow rate in the tissue, T_a is arterial blood temperature, and Q_{met} equals metabolic heat generation. In the tissues, no convection occurs so the governing equation for heat transfer in these domains is

$$\rho C_p \frac{\partial T}{\partial t} = k\nabla^2 T + \rho_b c_b \dot{V}_b (T_a - T) + Q_{met} \tag{5}$$

Recognizing that the moving laser perturbs the flow of the blood in the vein, thereby affecting heat transfer in this region, we use Navier-Stokes and continuity to govern fluid flow in the vein. The Navier-Stokes equation is

$$\frac{\partial \boldsymbol{u}}{\partial t} + \boldsymbol{u} \cdot \nabla \mathbf{u} = -\frac{\nabla P}{\rho} + \mathrm{v}\nabla^2 \boldsymbol{u} \tag{6}$$

where v is kinematic viscosity, u is velocity of the blood, P is pressure and ρ is blood density. The continuity equation for conservation of mass is

$$\nabla \boldsymbol{u} = 0$$

Finally, the governing equation for cell death in the vein wall and perivenous tissue is

$$\frac{dt_{43}}{dt} = R^{43-T} - tln(\quad \frac{dT}{dt} R^{43-T} \tag{7}$$

With t_{43} equal to a thermal damage threshold based on equivalent minutes of heating at 43 ºC. The constant R is defined as follows

$$R = \begin{cases} 0.25 & T \leq 43℃ \\ 0.5 & T > 43℃ \end{cases} \tag{8}$$

7.0 Boundary Conditions and Initial Conditions

Blood flow is laminar since the Reynold’s number has a value of 0.07, which falls within the range of laminar flow. Therefore, the boundary condition at the vein inlet is an average blood velocity. At the vein outlet pressure is zero.

Heat transfer boundary conditions include incoming blood at body temperature, 310 K. At the vein outlet heat is carried with the blood as it leaves the domain. Along the axis of symmetry at the center of the vein a no flux condition applies. We assume most heat transfer occurs in the radial direction so no flux conditions may be applied at the left and right boundaries of the tissues. Lastly, a semi-infinite model is assumed so that no heat flux occurs at the upper boundary of the perivenous tissue.

Initially the temperature throughout the whole domain is body temperature, 310 K. Additionally, the laser tip is initially located at the bottom boundary of the domain near the vein outlet.

8.0 Results and Discussion

After running our ELA model over a 20 second time span, we produced a temperature profile of the blood, vein wall tissue, and perivenous tissue. Figure 3 below depicts the temperature profile in the blood, vein wall, and perivenous tissue after 20 seconds of laser heating with a pullback speed of 2 mm/s and laser power set to 12 W.

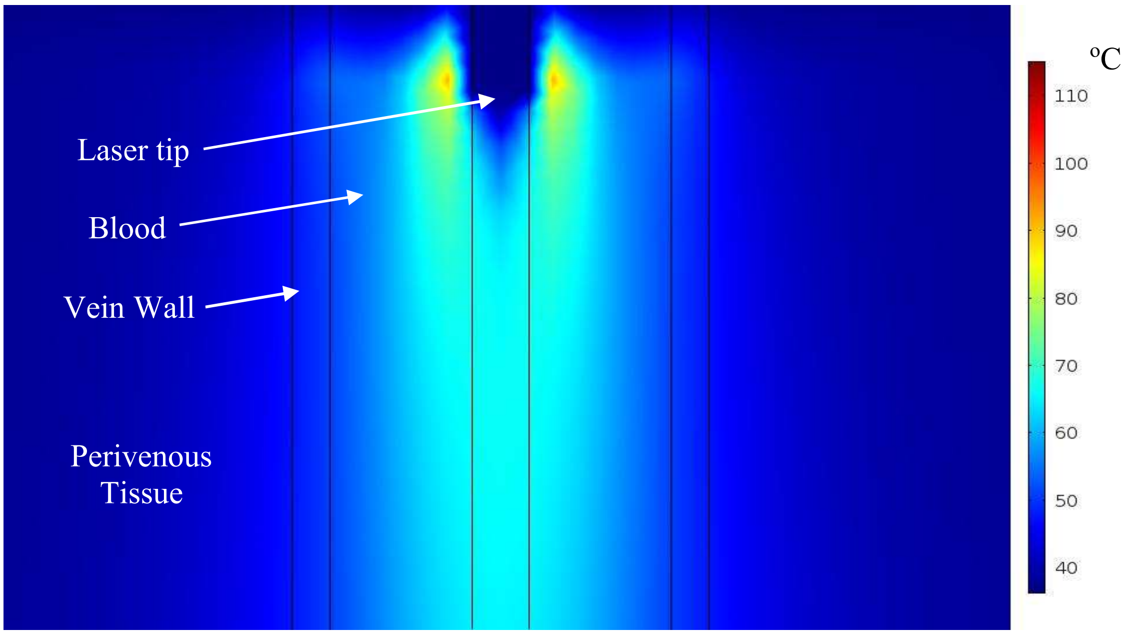

Figure 3. Temperature profile after 20 seconds of laser treatment. The region of yellow color represents the most intense heating nearest to the laser tip. Lighter blue coloration indicates more moderate heating in the vein wall and slight heating of the perivenous tissue.

In order to translate heating to a quantifiable measure of tissue damage we determined where the thermal damage threshold was reached (Equation 7). Cell death is shown in Figure 4.

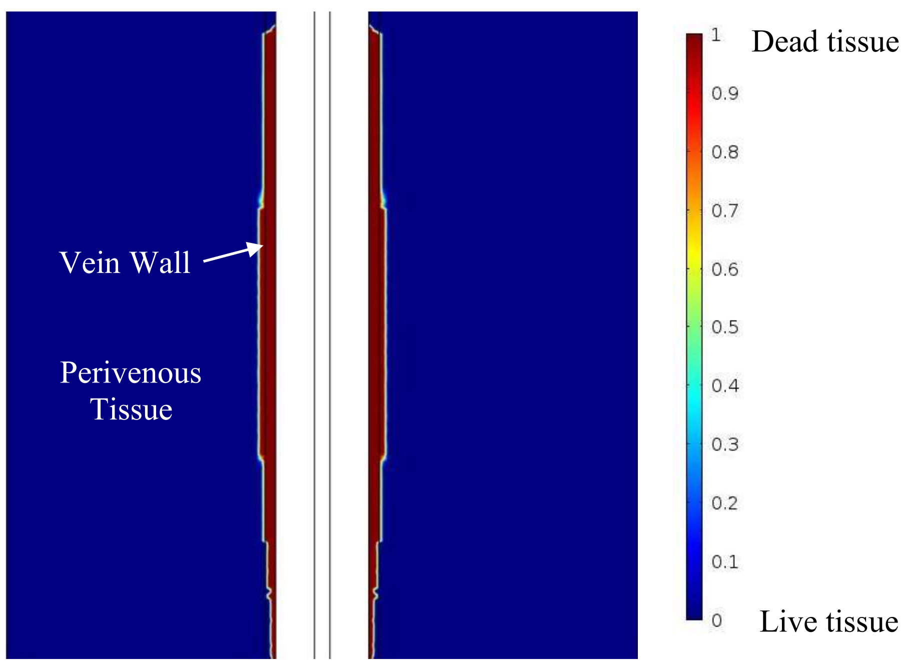

Figure 4. Cell death after 20 seconds of laser heating at a laser power of 12 W and a pullback speed of 2 mm/s. Red color represents dead tissue while blue tissue is not permanently harmed. Gradations in the color scale are an artifact of discretization error.

8.1 Optimization

In order to find the optimal combination of laser power and laser pullback speed, we performed optimization of cell death in the vein wall and perivenous tissue. The objective function we sought to maximize is defined as the difference between the volume of cell death in the vein wall and the volume of cell death in the perivenous tissue. We quantify the cell death volume by integrating the volume that reaches the thermal damage threshold, or critical value for cumulative equivalent minutes (CEM43) at a temperature of 43 °C (Equation 7). We found the critical value of CEM43 for the vein wall and perivenous tissue to be 240 s [17].

We implemented the optimization in COMSOL via a parametric sweep for laser power and laser pullback speed. According to recommended laser dosage values found in the literature [13], we selected the range for laser power to be 10 W, 15 W, 20 W and 30 W, and range for pullback speed to be 0.5 mm/s, 1 mm/s, 2 mm/s, 4mm/s and 20 mm/s. The result of parametric sweep is reported in Table 1.

Volume of wall death – Volume of perivenous tissue death (mm^3)		Laser Power			
		10 W	15 W	20 W	30 W
Pullback Speed	0.5 mm/s	167.37 - 1518.50= **-1351.13**	78.12 - 4929.42 = **-4851.30**	34.57 - 8067.09 = **-8032.52**	200.22 - 13967.66= **-13767.44**
	1 mm/s	294.24 - 93.87= **200.37**	314.67 -1177.58= **-862.91**	238.60 - 2690.80 = **-2452.20**	115.03 - 5220.86 = **-5105.83**
	2 mm/s	0 – 0= **0**	230.90 - 3.40 = **227.50**	398.84 - 415.70 = **-16.68**	370.19 - 1705.37 = **-1335.18**
	4 mm/s	0 – 0 = **0**	0 – 0 = **0**	5.30 - 0 = **5.30**	388.55 -101.43 = **287.13**
	20 mm/s	0 – 0 = **0**	0 – 0 = **0**	0 – 0 = **0**	0 – 0 = **0**

Table 1. Optimization of laser power and pullback speed. Less negative values of the optimization function indicate greater relative damage to the vein wall and as compared to the perivenous tissue. Highlighted in red are several optimal combinations of laser power and pullback speed.

Our optimization results indicate that several comparably effective combinations of laser power and pullback speed exist. From among the three options we've identified, a combination of 4 mm/s pullback speed and 30 W laser power optimizes destruction of vein wall tissue. However, a combination of 2 mm/s pullback speed and 15 W laser power minimizes damage in the perivenous tissue. Using a 1 mm/s pullback speed and 10 W laser power represents a compromise between maximum destruction in the vein wall and minimal damage to the perivenous tissue. A physician might choose between these procedure options based on the criteria they feel are most important for successful occlusion of varicose veins with limited side effects.

8.2 Mesh Convergence

In order to generate a temperature profile and cell death plot after ELT (Figures 3 and 4) we used a COMSOL-generated unstructured 'finer' mesh with approximately 10,000 elements. Figure 5 below shows a cut of the mesh elements used for computation.

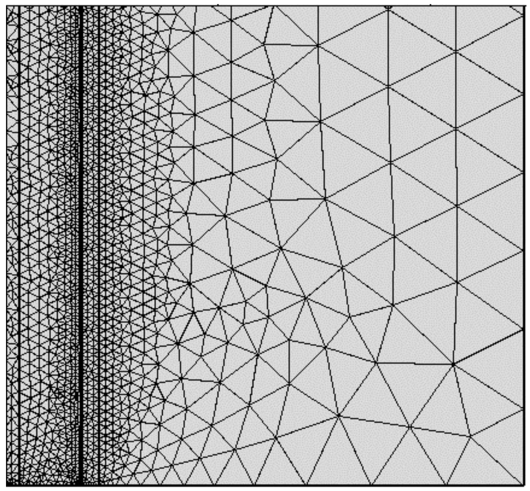

Figure 6. Mesh elements used to generate the model solution. Note that mesh elements are finest in the region of interest at the vein wall.

In order to verify that our mesh was fine enough to adequately capture regions of cell death, we compared cell death plots over the first 30 seconds of treatment using COMSOL's 'coarse' and 'finer' physics-controlled mesh options.

a) b)

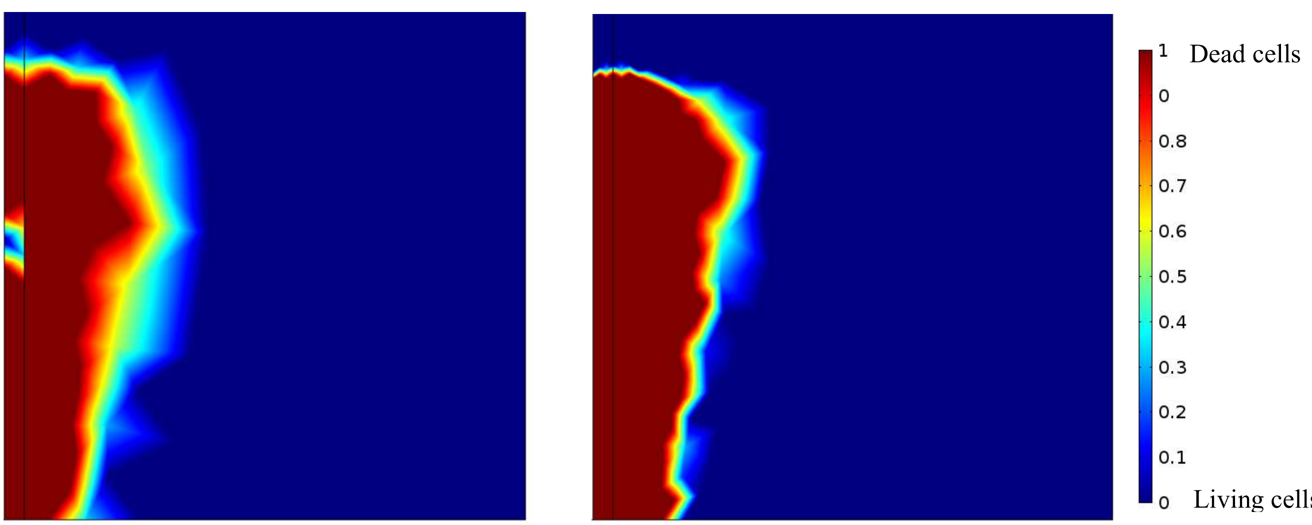

Figure 7. Cell death plots with a) a coarse mesh of 2634 elements and b) a finer mesh of 11,681 elements after 30 seconds of treatment. Note that the boundary at the thermal damage threshold for cell death becomes much cleaner using a finer mesh and the unphysical 'hole' of living cells in the vein wall in (a) is eliminated.

8.3 Validation

Our model may be verified by comparing our COMSOL-generated temperature profile to recent experimental results. Malskat *et al.*'s 2014 experiment mimicked ELT by drawing a laser fiber through a 'vein' of pig's blood within a cylindrical core of potato representing human tissue [18]. Thermocouple probes were placed at 0, 1, and 2mm from the 'vein' within the potato tissue and the following temperature series was generated.

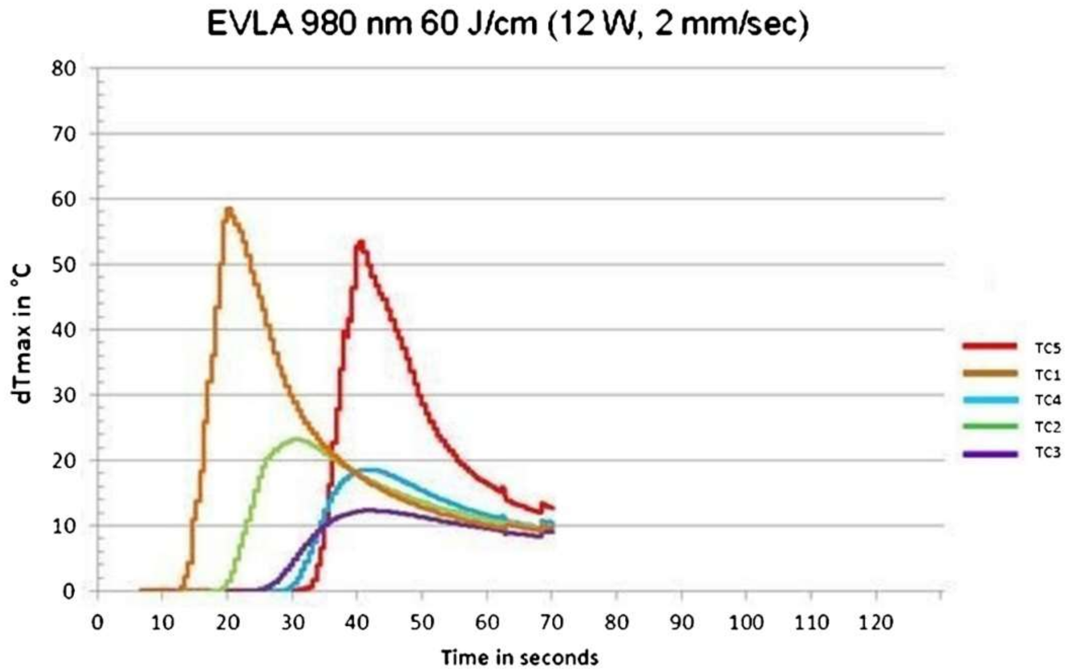

Figure 8. Experimental results tracking temperature increase at 0mm (TC5 and TC1), 1mm (TC4 and TC 2), and 2mm (TC3) from the 'vein' in the potato tissue [18].

To replicate experimental conditions we changed our model's initial temperature to room temperature and removed metabolic heat generation and blood perfusion terms. Additionally, we increased our laser fluence by a factor of 5 to account for a potentially greater laser tip size used in the experiment. We were then able to compare temperature readouts from COMSOL probes as our model ran (Figure 9) with the temperature increase recorded by the thermocouples in the experiment (Figure 8).

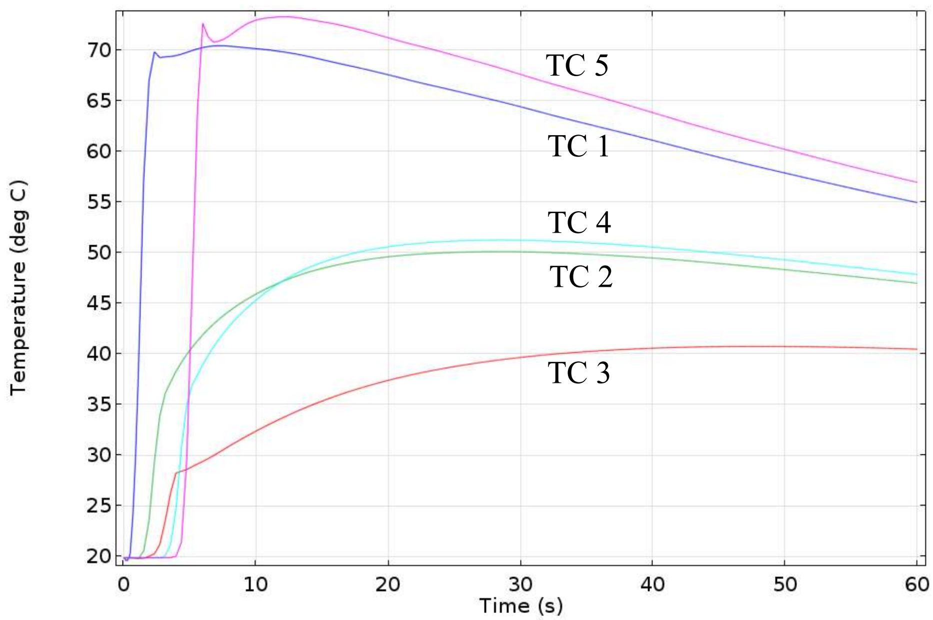

Figure 9. Model results tracking temperature increase at 0mm (TC5 and TC1), 1mm (TC4 and TC 2), and 2mm (TC3) from the vein wall. Note that temperatures in all probes are within several degrees of temperatures recorded from the experiment.

The maximum temperature achieved at the vein wall in the experiment was approximately 80 °C, which is very comparable to the maximum temperature at the same location after running our model, 74 °C. Our model's temperature profile is in line with that found in the experiment, so we have confidence that our measures of cell death, which depend on a temperature threshold, are accurate as well.

8.4 Sensitivity Analysis

We performed a sensitivity analysis in order to better understand our model. Sensitivity analysis gives us information about how our model works when parameters are varied by showing the influence of a certain parameter on the vein wall temperature. Temperatures here are measured at a location 2 mm from the center of the vein, near the vein wall, after 30 s of treatment. Physical parameters for the blood, vein wall and perivenous tissue were increased and decreased by 20% and the percent influence on temperature near the vein wall was recorded. The parameters varied include specific heat, density, conductivity, absorption coefficient, laser pullback speed, and laser velocity. The result, percentage change in temperature at the vein wall, is illustrated below (Figure 8).

Figure 8. a) Sensitivity analysis for temperature with respect to changes in the perivenous tissue parameters. b) Sensitivity analysis for temperature with respect to changes in the vein wall parameters. c) Sensitivity analysis for temperature with respect to changes in the blood parameters. d) Sensitivity analysis of laser tip velocity at time, t=60 s

9.0 Recommendations for Future Research

Our model builds upon previous literature seeking to optimize Endovenous Laser Treatment (ELT) [6,7,9,10,11]. Our work contributes to the body of knowledge on ELT by providing a readily change-able model that allows researchers to predict the impact of tweaking parameters like pullback speed and laser power on treatment outcome. The computer modeling approach is advantageous due to the difficulty of accurately replicating the human vein environment in experiments and the ethical concerns involved in using humans as study organisms during treatment.

Limitations of our model include the simplicity of our geometry and inaccuracies in assumptions of material properties and parameters. Actual varicose veins are twisted and their diameter may vary along the length of the vein. Additionally, human tissues are not completely homogenous, as we've assumed, and the local vein environment may change depending on the patient. Fluctuations in metabolic heat generation, blood perfusion, and blood flow resulting from laser heating may occur and are not accounted for in our model. Finally, our model fails to include heat absorption by the anesthetic fluid commonly injected into the perivenous tissue prior to treatment.

Regardless of these drawbacks, our model is still a useful tool in guiding future research on ELT methods. The model may be used as a first test of proposed treatment procedures since, as previously mentioned, a host of parameters are easily manipulated via COMSOL. After using the model to screen for promising preliminary results researchers could move forward to implement changes either in more labor-intensive experiments or through clinical trials.

10.0 References

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[20] ELT process cartoon: **http://www.nazveincenter.com/vein.html**

11.0 Appendix

Parameter	Domain	Symbol	Value	Unit	Source
Thermal Conductivity	Blood	k_b	0.492	W/(m*K)	[12]
	Vein Wall & Perivenous Tissue	k_s	0.56		
Density	All domains	ρ	1.05E+03	kg/m^3	[14]
Specific Heat	Blood	Cp_b	3820	J/(Kg*K)	[14]
	Vein Wall & Perivenous Tissue	Cp_s	3780		
Absorption Coefficient	Blood	$\mu_{a,b}$	0.28	1/mm	[14]
	Vein Wall	$\mu_{a.VW}$	0.1		
	Perivenous Tissue	$\mu_{a,P}$	0.03		
Effective Absorption Coefficient	Blood	$\mu_{eff,b}$	0.86	1/mm	[14]
	Vein Wall	$\mu_{eff,VW}$	0.79		
	Perivenous Tissue	$\mu_{eff,P}$	0.3		
Volumetric Blood Flow Rate	Blood	$\dot{V}_b$	$8.30\cdot10^{-6}$	$m^3/(kg\cdot s)$	[15]
Laser Power	Laser Heat Source	P_{laser}	15	W	[13]
Metabolic Heat Generation	Bioheat Source	Q_{met}	911	W/m^3	Calculated from textbook p. 421 assuming average body volume of 65.22L, surface area of $1.8m^2$
Arterial Blood Temperature	Blood	T_a	310	K	Normal body temperature
Thermal Damage Threshold	Vein Wall & Perivenous Tissue	t_{43}	240	s	[17]

Table 2. Parameters used for the simulation