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Effects of Heterogeneous Surroundings on the Efficacy of Continuous Radiofrequency for Pain Relief

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ABSTRACT
This numerical study highlights the deviation between the predicted lesion volume of the homogeneous and heterogeneous models of the continuous radiofrequency (RF) procedure for pain relief. A three-dimensional computational domain comprising of a realistic anatomy of the target tissue has been considered in the present study. A comparative analysis has been conducted for three different scenarios: (a) completely homogenous domain comprising of only muscle tissue, (b) heterogeneous domain comprising of nerve and muscle tissues, and (c) heterogeneous domain comprising of bone, nerve and muscle tissues. Finite-element-based simulations have been performed for computing the temperature and electrical field distributions during the continuous RF procedures for treating chronic pain. The predicted results reveal that the consideration of heterogeneity within the computational domain results in distorted electric field distribution and leads to the significant reduction in the attained lesion volume during the continuous RF application for pain relief.

CCS CONCEPTS
• Applied computing---Life and medical sciences • Computing methodologies---Modeling and simulation---Model development and analysis • Mathematics of computing---Mathematical analysis---Numerical analysis

Keywords
Continuous Radiofrequency; Pain Relief; Bioheat Transfer; Finite-element Method; Computational Modelling

1. INTRODUCTION
The application of RF (radiofrequency) has been gaining rapid progress and increasing popularity for treating different types of neuropathic pain, such as in management of low back pain, hip pain, knee pain and migraine [1, 5]. In general, the power delivery during such chronic pain management procedures is done using either a continuous or a pulsed mode [5]. In the conventional continuous power delivery mode, RF currents are applied in between the electrode (accurately placed on the target nerve) and the dispersive ground electrode (placed at patient's skin). While, in the pulsed delivery mode, short pulses of RF currents are applied from the RF generator to the neural tissue, followed by silent phases that allow time for heat dissemination [5]. Thus, the mechanism of action of both these modes is completely different. The continuous RF mode results in coagulation of the neural tissue above 50^{o}C that results in protein denaturation and destruction of the axons, which stops the transmission of nociceptive signals from the periphery, thereby mitigating chronic pain. Whereas, the pulsed mode is a theoretically nonablative procedure, since usually the maximum temperature during such procedures is not allowed to exceed 42^{o}C, thus making it less destructive as compared to the continuous RF. Although to date the exact explanation of the complete mechanisms of action involved during the pulsed RF procedure for treating chronic pain remains elusive, extensive research is undergoing to quantify its associated effects [1].

Computational modelling and simulations have become a vital tool for providing a quick, convenient and inexpensive evaluation of the treatment outcomes of the thermal ablative procedures. Computational modelling has been used in past at different stages of RF-based ablative procedures, that include design and development of new protocols, as well as optimization and improvement of existing protocols of clinical systems. Computational models also serve as a means of understanding the interaction between various physical phenomena and the effects of various extrinsic and intrinsic factors on the treatment outcomes of RF-based clinical techniques. The present study aims at quantifying the effects of heterogeneity in the computational domain of interest on the lesion volume attained during the continuous RF procedure for treating chronic neural pain. As part of our comprehensive analysis of this issue, three different computational domains have been considered: (a) completely homogenous domain comprising of only muscle tissue, (b) heterogeneous domain comprising of nerve and muscle tissues, and (c) heterogeneous domain comprising of bone, nerve and muscle tissues. Furthermore, a comparative study of continuous RF has been conducted with and without utilizing a temperature-controller. It is an automated control loop proportional-integral-derivative (PID) controller within the computational domain that continuously modulates the applied voltage to keep the maximum temperature below the predefined value for avoiding the occurrence of charring at the electrode tip.

2. COMPUTATIONAL MODELLING
A schematic of three-dimensional heterogeneous computational domain comprising of muscle, bone and nerve tissue [7], with an embedded 22-gauge monopolar RF electrode having 5 mm active tip length [3] has been shown in Figure 1. The continuous RF procedure has been performed by applying a constant voltage of

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15 V at the active tip of the RF electrode. Further, the dispersive ground electrode has been modelled by applying zero voltage on the outer boundaries of the computational domain. The initial voltage and initial temperature of the entire computational domain have been considered to be 0 V and 37°C, respectively, and the electrical and thermal continuity boundary conditions have been imposed at each interfaces. The thermo-electric and biophysical properties considered in the present study are summarized in Table 1 [3, 6, 7]. In what follows, the effect of heterogeneity on the efficacy of continuous RF procedure has been quantified considering three different cases of computational domain, as we mentioned earlier: (a)complete homogeneous computational domain comprising of only muscle tissue, (b) computational domain comprising of 4 mm cylindrical nerve embedded within the muscle tissue, and (c) completely heterogeneous computational domain comprising of bone, nerve and muscle tissues. Additionally, the computational model for temperature-controlled RF has been developed utilizing an automatic PID controller [8] to limit the maximum temperature to 85°C and its treatment outcomes have been compared with the model having constant voltage source of 15 V. In the present computational study, the treatment time of continuous RF procedure has been set to be 60 s.

Table 1. Thermo-electric and biophysical properties of different materials considered in the present study.

Material (Tissue/ Electrode)	Electrical conductivity σ [S/m]	Specific heat c [J/(kg·K)]	Thermal conductivity k [W/(m·K)]	Density ρ [kg/m^3]	Blood perfusion ω_b [s^{-1}]
Muscle	0.446	3421	0.49	1090	6.35×10^{-4}
Bone	0.0222	1313	0.32	1908	4.67×10^{-4}
Nerve	0.111	3613	0.49	1075	3.38×10^{-3}
Plastic	10^{-5}	1045	0.026	70	–
Electrode	7.4×10^{6}	480	15	8000	–
Blood	–	3617	–	1050	–

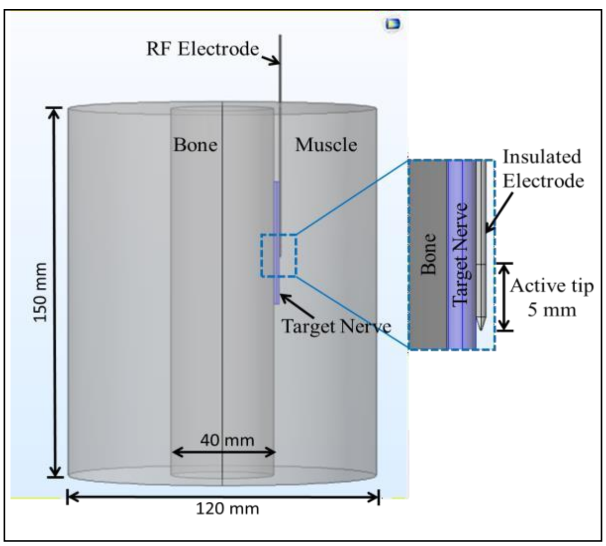

Figure 1. Schematic of three-dimensional heterogeneous computational domain comprising of nerve, bone and muscle tissue with an embedded monopolar RF electrode.

The RF procedure represents a coupled thermo-electric problem where electromagnetic energy is used to heat the biological tissue. In the lower frequency range of 500 kHz, as is generally used during the RF procedures, a simplified version of Maxwell's equations (known as the quasi-static approximation) can be used to compute the electric field distribution within the computational domain without compromising accuracy. It is given by:

$$\nabla\cdot(\sigma(T)\nabla V)=0, \tag{1}$$

where σ is the temperature-dependent electrical conductivity (S/m) that has been modelled by a linearly increasing (+2% per °C) function of temperature in the present study [8] and V is the applied voltage (V) that is related to the electric field "**E**" (V/m) by the standard potential field approximation given by:

$$\mathbf{E}=-\nabla V. \tag{2}$$

Further, the current density "**J**" (A/m^2) can be derived from the electrical conductivity and field as follows:

$$\mathbf{J}=\sigma(T)\mathbf{E}. \tag{3}$$

The volumetric heat generated, Q_p (W/m^3), within the biological tissue by electromagnetic field during RF procedure is given by:

$$Q_p=\mathbf{J}\cdot\mathbf{E}. \tag{4}$$

The Fourier-conduction-based Pennes bioheat transfer equation has been used to compute the temperature distribution within the computational domain during the continuous RF procedure for chronic pain relief. It is given by:

$$\rho c\frac{\partial T}{\partial t}=\nabla\cdot(k\nabla T)-\rho_b c_b\omega_b(T-T_b)+Q_m+Q_p, \tag{5}$$

where ρ is the density (kg/m^3), c is the specific heat (J/(kg·K)), k is the thermal conductivity (W/(m·K)), ρ_b is the density of blood, c_b is the specific heat capacity of blood, ω_b is the blood perfusion rate (1/s), T_b is the blood temperature (37°C), T is the unknown tissue temperature to be computed from Equation 5. The term $\rho_b c_b\omega_b(T-T_b)$ accounts for the heat sink effect caused by small capillary vasculature, Q_p is the volumetric heat source (W/m^3) computed using Equation 4, Q_m is the metabolic heat generation (W/m^3) that has been neglected in the present study due to its insignificant contribution as compared to Q_m [3], and t is the duration of the continuous RF procedure (s).

A temperature-dependent piecewise model of blood perfusion rate has been used in the present computational study. Accordingly, a constant predefined value of blood perfusion rate prevails below the tissue temperature of 50°C and beyond that it ceases due to the collapse of microvasculature [7], and is given by:

$$\omega_b(T)=\begin{Bmatrix}\omega_{b,0} & \text{for} T<50^{\circ}C\\ 0 & \text{for} T\geq 50^{\circ}C\end{Bmatrix}, \tag{6}$$

where $\omega_{b,0}$ is the constant blood perfusion rate of tissue domain given in Table 1 and T, as before, is the unknown temperature computed from Equation 5.

In the present numerical study, ablation volume ($\dot{V}$) has been quantified using the isotherm of 50°C (i.e. the volume of tissue having temperature ≥ 50°C post-RF procedure) [7], and is given by

$$\dot{V} = \int\int\int_{\Omega} dV(\text{mm}^3) \ \ (\text{where } \Omega \geq 50^{o}C). \qquad (7)$$

The coupled thermo-electric models of continuous RF application for treating chronic pain have been solved using a finite-element method (FEM) based COMSOL Multiphysics 5.2 software [2] utilizing an adaptive time-stepping scheme. The computational domain has been discretized using a heterogeneous tetrahedral mesh elements constructed with COMSOL's built-in mesh generator. A further refinement closer to the active tip of the electrode has been applied, where the highest electrical and thermal gradients are expected. Further, a mesh convergence analysis has been carried out to determine the optimal number of mesh elements that would result in mesh-independent solution. Figure 2 presents the meshed computational domain of the heterogeneous model comprising of 174486 elements and 476384 degrees of freedom. All simulations have been conducted on a Dell T7400 workstation with Quad-core 2.0 GHz Intel® Xeon® processors.

3. RESULTS AND DISCUSSION

The motive of the present numerical study is to quantify the effect of heterogeneous surroundings in the computational domain on the efficacy of continuous RF procedure for pain relief. The variations in temperature distribution and lesion volume have been computed for homogenous domain (comprising of only muscle tissue) and heterogeneous domain comprising of: (a) nerve and muscle tissue, and (b) bone, nerve and muscle tissue. In what follows, three point of interest (as shown in Figure 3(a)) has been defined to analyze the thermal performance of the continuous RF application for treating chronic pain. Importantly, point P1 lie 1 mm away from the tip of the electrode along the electrode axis, while P2 and P3 lie 1 mm away in a transversal plane in the opposite direction from the middle of the active part of the electrode. It is noteworthy to mention that point P2 lies on the nerve and bone side of the computational domain of the heterogeneous model, whereas point P3 lies on the side surrounded by muscles alone.

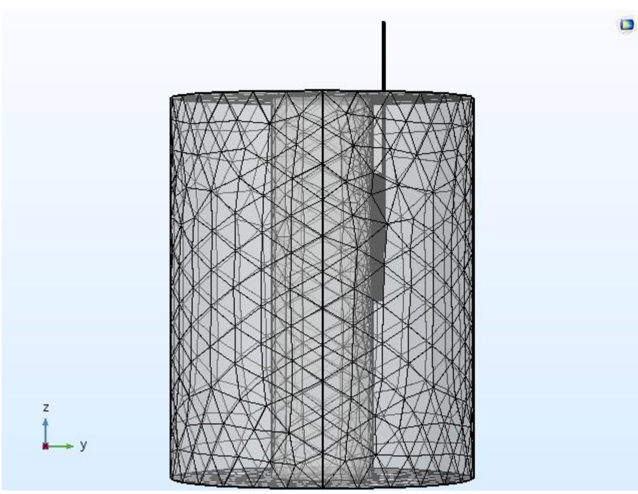

Figure 2. Meshed computational domain of the continuous RF procedure comprising of 174486 tetrahedral elements.

Figure 3(b) presents the variation in temperature with respect to time at point P1 for the considered cases. As evident from Figure 3(b), the introduction of heterogeneity within the computational domain results in significant decrease in the predicted temperature at a particular instance. The predicted temperature at point P1 at the end of 60 s of the continuous RF procedure has been found to be 75.70ºC, 70.73ºC and 67.03ºC for the homogenous muscle domain, heterogeneous muscle and nerve domain, and heterogeneous muscle, nerve and bone domain, respectively. The variations in the temperature distribution with respect to time at P2 and P3 points have been presented in Figures 3(c) and 3(d), respectively. Again, a significant decrease in the predicted temperature with introduction of heterogeneity in the computational domain can be clearly seen in these figures. This variation in the predicted temperature during the continuous RF procedure can be attributed to differences in the thermo-electric parameters of the muscle, nerve and bone tissues, as summarized in Table 1. The introduction of nerve in the homogenous muscle domain results in the lower electrical conductivity that leads to distorted electrical field distribution. In its turn, it results in lower volumetric heating as compared to the completely homogenous computational domain comprising of muscles alone. Furthermore, the introduction of bone, having lower electrical and thermal conductivities as compared to muscle tissue, does not allow the efficient heat conduction from the electrode during the continuous RF procedure for treating chronic pain.

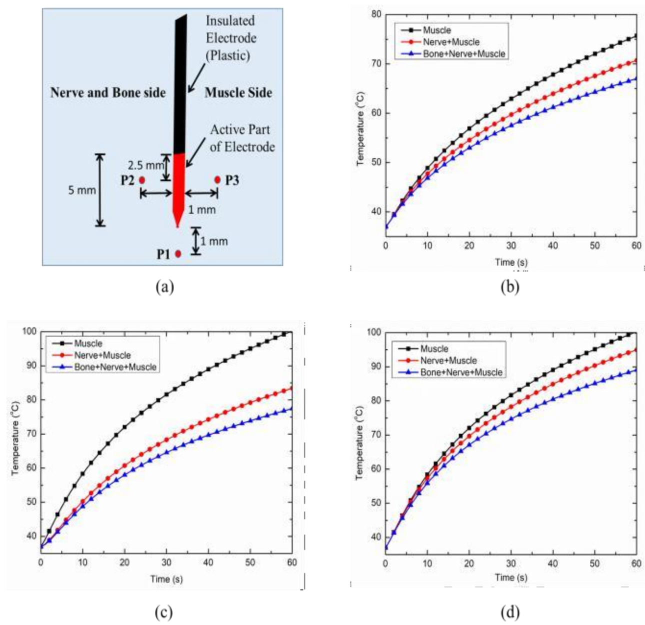

Figure 3. (a) Schematic of three points (P1, P2 and P3) chosen for the evaluation of thermal performance during the continuous RF procedure. Variation in temperature distribution as a function of time at: (b) P1, (c) P2 and (d) P3, for different cases considered in the present study.

The inclusion of nerve and bone within the muscle tissue domain significantly hampers the thermal and electrical performances of the continuous RF procedure for pain relief. Figures 4(a)-(b) represent the temperature distribution at points P2 and P3 for the case of heterogeneous computational domains of the muscle, i.e., including both nerve and bone, and including only nerve, respectively. The inclusion of the nerve and/or bone within the homogenous computational domain of the muscle (for simulating realistic anatomical situations) on one side of the RF electrode restricts the efficient conduction of the heat on that side owing to the lower thermal and electrical conductivities of bone and nerve in comparison to the muscle tissue. These variations result in asymmetric deviation in the temperature distribution on two equally spaced but oppositely placed points P2 and P3 on the transverse axis from the middle of the active part of the electrode, as shown in Figures 4(a)-(b). Importantly, for the homogenous computational domain comprising of the muscle tissue, the temperature profile at both points P2 and P3 is symmetric and completely coincide with each other. However, the decrement in temperature at points P2 and P3 after 60 s of continuous RF procedure have been found to be 12.15% and 13.02% for the heterogeneous computational domain of muscle tissue embedded with only nerve, and embedded with both nerve and bone, respectively. Thus, the consideration of heterogeneous surrounding within the computational model significantly effects the thermal performance of continuous RF procedure for chronic pain relief.

Further, the comparison between the electrode tip temperature for the constant voltage and temperature-controlled protocols of power delivery during the continuous RF procedure has been presented in Figure 4(c). As evident from Figure 4(c), the constant voltage source can result in attainment of 100^{o}C temperature close to the active tip of the electrode that can, in its turn, result in occurrence of charring. This is highly undesirable phenomenon during RF procedures that lead to an abrupt decline in electrical and thermal conductivities of the biological tissues, limiting efficient conduction of thermal energy and thereby reducing the lesion size. Thus, the utilization of temperature-controlled power delivery protocol during continuous RF procedures in clinical practices can completely mitigate the chances of occurrence of charring, whereby the applied voltage is varied between the electrodes to keep the maximum temperature at the tip of electrode to be 80-90^{o}C [4].

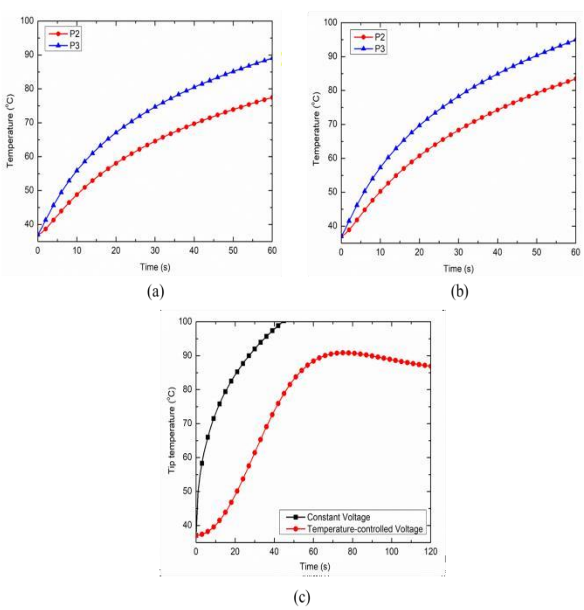

Figure 4. Variation in temperature distribution as a function of time at points P2 and P3 for heterogeneous computational domain comprising of: (a) nerve, bone and muscle tissues, and (b) nerve and muscle tissues. (c) Variation in the target tip temperature as a function of treatment time for constant voltage and temperature-controlled protocols of power delivery during the continuous RF procedure for pain relief.

The variation in lesion volume (the total coagulation volume) attained for different cases considered in the present study, viz., homogenous domain comprising of only muscle tissue and heterogeneous domain comprising of: (a) nerve and muscle tissues and (b) bone, nerve and muscle tissues, has been presented in Figure 5(a). As depicted in Figure 5(a), the attained lesion volume significantly decreases as the heterogeneity in the surroundings is introduced within the computational domain during the continuous RF procedure for pain relief. The propagation of nerve damage with respect to time in the heterogeneous computational domain during the continuous RF procedure has been presented in Figure 5(b). The introduction of bone within the computational domain results in 12.75% decrease in the nerve ablation volume after 60 s of continuous RF procedure. Thus, the consideration of heterogeneous surroundings to replicate the realistic anatomy becomes utmost important for accurately predicting the treatment outcomes of the continuous RF procedures for chronic pain relief. It is expected that the results presented in this study will assist the pain management clinicians and researchers to tackle the issue of variability of thermo-electric and biophysical properties in a better way by proper treatment planning and consideration of the impact of each parameter on the treatment outcomes. Future studies can be extended by incorporating the neural model to replicate the pain transmission and mitigation during the continuous RF procedures for pain relief. In addition, patient-specific models can be developed that can be integrated into the clinical workflow for quantifying *a priori* estimates of the treatment outcomes and the risks involved during such minimally invasive treatment procedures.

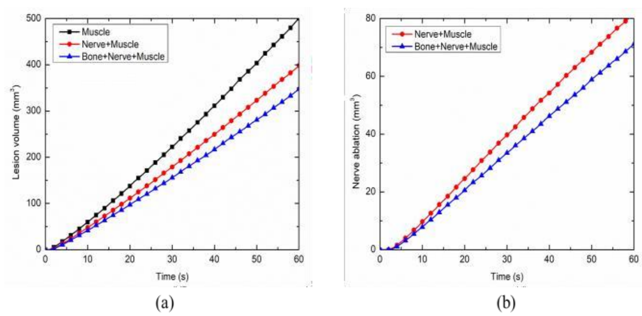

Figure 5. Variations in (a) lesion volume, and (b) nerve ablation, with respect to time during the continuous RF procedure for pain relief among different considered cases.

4. CONCLUSION

A finite-element-based numerical study has been conducted to quantify the effects of heterogeneities, such as nerve and bone tissues, on the efficacy of the continuous RF procedure for pain relief. A comparative analysis has been conducted to evaluate the impact of different heterogeneities in the surrounding of the computational domain on the temperature distribution and the attained lesion volume. Based on the results obtained from this study, it has been found that there has been a decrease of 30.64% in the attained lesion volume considering a heterogeneous domain comprising of bone, nerve and muscle tissues, as compared to a homogenous domain of the muscle alone. Further, it has been concluded that a significant variation prevails in the predicted temperature distribution among different cases considered in the present study. Subsequently, this study emphasizes the importance of consideration of heterogeneous surroundings on the predicted treatment outcomes of the continuous RF procedure for treating chronic pain.

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