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Temperature field reconstruction for minimally invasive cryosurgery with application to wireless implantable temperature sensors and/or medical imaging ☆

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ABSTRACT

There is an undisputed need for temperature-field reconstruction during minimally invasive cryosurgery. The current line of research focuses on developing miniature, wireless, implantable, temperature sensors to enable temperature-field reconstruction in real time. This project combines two parallel efforts: (i) to develop the hardware necessary for implantable sensors, and (ii) to develop mathematical techniques for temperature-field reconstruction in real time—the subject matter of the current study. In particular, this study proposes an approach for temperature-field reconstruction combining data obtained from medical imaging, cryoprobe-embedded sensors, and miniature, wireless, implantable sensors, the development of which is currently underway. This study discusses possible strategies for laying out implantable sensors and approaches for data integration. In particular, prostate cryosurgery is presented as a developmental model and a two-dimensional proof-of-concept is discussed. It is demonstrated that the lethal temperature can be predicted to a significant degree of certainty with implantable sensors and the technique proposed in the current study, a capability that is yet unavailable.

Introduction

Cryosurgery is the destruction of undesired tissues by freezing. It was introduced as an invasive procedure for the first time in 1961, with the development of the cryoprobe by Cooper and Lee [4]. As a minimally invasive procedure, cryosurgery experiments were conducted in the mid 1980s, following technological developments in medical imaging. While cryosurgery has been applied to virtually any tissue of the body as a method of treatment, prostate cryosurgery was the first minimally invasive cryosurgical procedure to pass from the experimental stage to become a routine surgical treatment [13,4,15].

The minimally invasive approach created a new level of difficulty in cryosurgery, in which a well-defined 3D shape of tissue must be treated, while preserving the surrounding tissues. In an effort to gain better control over the cryosurgical procedure, the number of cryoprobes has been increased over the years so that more than a dozen cryoprobes can be applied simultaneously. If localized effectively, one of the potential benefits of the use of a large number of miniaturized cryoprobes is superior control over the freezing process [5,12,30,32,33].

With the dramatic increase in the number of cryoprobes, two new challenges in cryosurgery have arisen: (i) how to shape the frozen region and restrict the destructive freezing effect to the target area, and (ii) how to correlate the developing thermal field with established criteria for cryosurgery success. The current study is a part of an ongoing effort to address those challenges by developing means for real-time feedback to the cryosurgeon on the developing thermal field.

While the benefits of temperature measurements during cryosurgery are well documented and highly recommended in the literature [1,2,7,9,16,28,29,35], and modern cryodevice setups often offer the feature of real-time temperature sensing, temperature sensors are often not integrated into the procedure for various reasons. At the current state of cryosurgery technology, two principle means have been developed for temperature sensing as a means of monitoring and control, the cryoprobe-embedded sensor and the so-called "needle sensor". The cryoprobe-embedded sensor approach is as old as the first invasive cryoprobe, but with a diminishing use in recent years. It is the cooling capability and not the temperature that is often controlled in modern cryoprobe. For example, the surgeon would control the flow rate of the cryogen in order to control the rate of propagation of the freezing front, all in effort to match its final location with a predetermined contour (the organ contour, for example). Here, a higher flow rate in a nearby cryoprobe will drive the freezing front propagation faster,

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and the entire process is performed in a trial-and-error fashion, while the freezing front contour is monitored by means of medical imaging. This mode of operation, combined with the everlasting effort to miniaturize cryoprobes, has led to abandoning temperature sensors in some modern cryoprobes altogether.

An example for the use of needle temperature sensors in cryosurgery is the placement of one or two such sensors near the rectal wall, as feedback to prevent freezing injury to it—one of the most severe complications in prostate cryosurgery [16,29,35]. The needle sensor is frequently a hypodermic needle in a diameter similar to that of the minimally invasive cryoprobe. The thermocouple is often the choice of practice as the measuring principle for hypodermic sensors. When incorporated, the needle sensor and the cryoprobe are localized using a similar methodology in prostate cryosurgery—inserting either into a predetermined depth through an x–y grid, which is aligned with the organ but placed outside of the body. Unfortunately, despite its advantages as a safety measure, and despite the capability of modern cryosurgical devices to integrate such temperature sensors, the needle sensor is not frequently used in cryosurgery in recent years.

The current study is a part of an ongoing effort to develop means to improve cryosurgery planning and control. The current project is focused on developing miniature, wireless, implantable temperature sensors to reconstruct the temperature field in real time—a capability which is yet unavailable for routine practice. This project combines two parallel efforts: (i) to develop the hardware necessary for implantable sensors [11,23], and (ii) to develop a method for temperature-field reconstruction in real time, which is the subject matter of the current study. This is a proof-of-concept level study, which uses prostate cryosurgery as a developmental model. For that purpose, the analysis presented in this study focuses on a two-dimensional target, representing the largest cross-section of the prostate, while using a proprietary computerized planning algorithm, known as "bubble-packing" [30,31,33]. Finally, this study investigates input from three potential sources, imaging, temperature sensor-embedded cryoprobes, and implantable sensors.

While hardware development is the subject matter of a parallel effort [11,23], its current state of development is overviewed here in brief, for the completeness of presentation only. Hardware development is aimed at an ultra-miniature, wireless, battery-less, implantable temperature-sensing device, having a diameter of 1.5 mm and a length of 3 mm to enable minimally invasive deployment through a hypodermic needle. The new device consists of three major subsystems: a sensing core, a wireless data-communication unit, and a wireless power reception and management unit. Power is delivered wirelessly to the implant from an external source using an inductive link. To meet size requirements while enhancing reliability and minimizing cost, the implant is fully integrated in a regular foundry CMOS technology (0.15 μm in the current phase of development), including the implant-side inductor of the power link.

Mathematical formulation

It is customary to assume that heat transfer during cryosurgery can be modeled with the classical bioheat equation [12,17]:

$$C\frac{\partial T}{\partial t} = \nabla \cdot (k\nabla T) + w_b C_b (T_b - T) + q_{met} \tag{1}$$

where C is the volumetric specific heat of the tissue, T is the temperature, t is the time, k is the thermal conductivity of the tissue, w_b is the blood perfusion rate, C_b is the volumetric specific heat of the blood, T_b is the blood temperature entering the thermally treated area (typically the normal body temperature), and q_{met} is the metabolic heat generation.

The physical properties used for the current study are listed in Table 1. it is assumed in the current study that the specific heat is an effective property [34] within the phase-transition temperature range of −22 to 0 °C (the tissue is first-order approximated as an NaCl solution), where a detailed discussion about the application of the effective specific heat to phase change problems is given in [13]. The metabolic heat generation is typically negligible compared to the heating effect of blood perfusion [21], and is neglected in this study. While more advanced models of bioheat transfer are available in the literature [3,6], it is assumed in the current study that they would not guarantee greater accuracy in the cryosurgery simulation but will involve greater mathematical complications.

The blood perfusion rate in the unfrozen region (Table 1) and the step-like change in the blood-perfusion rate upon the onset of freezing represent the worst-case scenario in terms of transient effects. In practice, one would expect a gradual decay in blood flow with the decreasing temperature, potentially leading to a complete stasis before the freezing temperature is achieved. To the best of knowledge of the authors, the actual temperature dependency of blood perfusion in the prostate is unknown. The uncertainty in blood perfusion rate may contribute a few percent to the uncertainty in predicting the freezing front location [21]; this uncertainty is not taken into account in the current study. A detailed discussion on the propagation of uncertainty in measurements into heat transfer simulations of cryosurgery is given in [22].

Quasi-steady approximation

At least two principal approaches are available in effort to provide the clinician with feedback on the developing temperature field: (i) prediction-based, by applying a real-time simulation of the procedure, and (ii) reconstruction-based, using measured data at multiple locations. In the first approach, the bioheat transfer process is simulated using Eq. (1), while temperature data obtained from the cryoprobes is used as internal boundary conditions.

The real-time simulation process is typically very computationally expensive [10,24] and rarely is it practical as a real-time feedback. While available data from implantable sensors can be used to verify the quality of a real-time simulation, such data cannot be straightforwardly implemented to correct the simulated temperature field once a deviation between predicted and measured values is observed. Since temperature sensors do not drive any thermal effect, merely correcting a predicted temperature field to specific values at the sensor locations has no physical meaning. More appropriately, this deviation can be used to correct the model properties (i.e., thermophysical properties) by employing a parametric estimation procedure [19], after which a computer simulation can be attempted again in effort to get a better match between computer results and experimental data. This prediction–correction process of model properties using a full-scale simulation, data measurements, and parametric estimation could continue until the convergence of property values. Obviously, this process is even more computationally expensive than the cost of a single simulation, and the cost only increases as the cryoprocedure progresses, since every simulation with corrected parameter values must restart from the same initial condition at the beginning of the cryosurgical procedure.

The proposed alternative approach of temperature-field reconstruction attempts to use all available data at any given instant in order to generate a current temperature field. In the absence of more detailed information, one could take all the available data at discrete points and approximate the temperature field in the domain by applying some method of interpolation. Here, the method