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Precision test apparatus for evaluating the heating pattern of radiofrequency ablation devices

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Abstract

Radiofrequency has established itself as a useful technique for managing cardiac arrhythmias and treating soft tissue tumors. However, despite its pervasive use, many of the biophysical principals needed to fully understand and optimize the radiofrequency ablation technique have not been explored. We have designed a test rig that is useful for studying the heat transfer mechanisms that affect the outcome of radiofrequency ablation devices. Using both solid and liquid phantom materials, which simulate body tissues and blood, the test rig is designed for systematic testing of the effects of predictable flow patterns on the temperature profiles generated within the solid phantom.

The test rig consists of a custom built thermistor array, a linear test chamber, and a radiofrequency generator. We calibrate the flow of a liquid phantom material to demonstrate that predictable laminar flow profiles are generated. To demonstrate the performance of the ablation system, we present preliminary data attained using a commercially available cardiac ablation catheter.

The advantages of this test system are its flexibility, its reproducibility, its precision, and its low cost. Thus, it is ideally suited for studying a variety of complex ablation problems involving multiple tissues types and complex blood flow geometries. Published by Elsevier Science Ltd on behalf of IPPEM.

Keywords

Radiofrequency ablation; Measurement techniques

1. Introduction

The term ‘radiofrequency ablation devices’ refers to a class of medical devices operating between 460 and 550 kHz that deliver therapeutic energy into soft tissues with the goal of eradicating diseased or tumorous tissues. In clinical treatment, energy is injected through a metallic electrode, through surrounding tissue, to an electrode on the surface of a patient that completes an electric circuit [1].

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Although radiofrequency ablation has been used widely and is the standard of care for several treatment modalities, the physics of radiofrequency ablation remains a difficult course of study. While dosimetry and heat transfer are well-explored sciences [2], a plethora of research topics relating the two fields is needed to complete our understanding and to optimize the design and performance of ablation devices.

We offer an experimental tool that carefully controls the key physical parameters that are essential to understanding how radiofrequency ablation works. It consists of temperature measurement probes that minimally perturb electric and thermal effects of ablation, solid-tissue simulating and liquid-blood stimulating materials, plus a means for creating simulated blood flow to account for convective cooling of the ablated region. This test system produces highly reproducible results, can be flexibly configured, is easily constructed, and is affordable. We present the design and calibration of this test system. For purposes of demonstration, we have modeled the behavior of a cardiac ablation electrode in this report.

2. Design considerations

Although commercial radiofrequency ablation systems operate at a relatively narrow band of frequencies (460–550 kHz), a design goal in the test system was to afford a wide range of frequencies for study [3]. Since the heat deposition from ablation devices occurs in two modes, conductive and dielectric heating, a flexible test system that allows for wide frequency adjustment can allow for more detailed study of the heating characteristics. Conductive heating, or Joule heating, occurs at lower frequencies where the heat generated is equivalent to the electrical power being dissipated in the tissue due to an induced current that is produced when a potential is applied across two electrodes (ablation probe and ground plane) [4]. Dielectric heating, or capacitive heating, occurs at higher frequencies where heat is generated by the vibration of particles in response to the presence of a changing electrical potential applied across two electrodes [5]. Both modes of heating exist simultaneously and the dominance of one mode over the other is influenced by the frequency of the stimulus, the dielectric properties of the tissue, and the dimensions of the ablation probe. In the majority of cases, commercial radiofrequency ablation systems are dominated by conductive heating, since tissue impedance between 460 and 550 kHz is largely dominated by the electrical conductivity of tissue and not its dielectric permittivity [6].

Radiofrequency ablation is frequently applied in settings that involve multiple tissue types and multiple phases (i.e. gas, liquid, solid) [1]. For example, in liver tumor ablation, procedures are frequently applied percutaneously, and thus are in contact with several tissue types (e.g. muscle, skin, fat, and liver) [7]. In cardiac examples, ablation electrodes are deployed in the atria and ventricles, where they are in contact with both myocardial tissue and blood [2]. To study these problems effectively, we developed phantom materials that exhibit the properties of both tissue and blood.

It is widely known that the flow of blood over the surface of tissue creates a cooling effect which can greatly affect the shape and size of an ablated region when radiofrequency energy is applied [8,9]. While experimentally establishing the bulk flow rate of blood is not

difficult, establishing the velocity profile of blood close to the surface of the tissue is typically complicated. The effects of tissue cooling have been difficult to characterize precisely, since the velocity profile close to the tissue surface must be known to exactly account for forced convection. We avoided the experimental complications associated with empirically determining heat transfer coefficients by establishing laminar flow in our test rig. Although we recognize that laminar flow bears little resemblance to flows that one would expect in the heart, we chose laminar flow for two reasons. First, by studying heat transfer patterns under laminar flow conditions at high and low flow rates, we can bracket the expected clinical conditions. Second, by using a laminar profile that is both reproducible and predictable, we are able to study the effects of surface cooling with higher precision.

3. Materials and methods

The test rig consists of a custom array of thermistor probes, a system for establishing laminar flow profiles, a custom built radiofrequency ablation generator, and phantom materials. These systems are described below.

3.1. Thermometry

The thermistor probes used to measure the temperature distribution in the solid (tissue) phantom material were constructed by inserting the shank of a miniature glass encapsulated thermistor assembly (approx. 0.26 mm in diameter) into the tip of a glass capillary tube (approx. 0.28 mm in diameter). The diameter of the thermistor bead, located at the end of the thermistor assembly, was slightly larger than the glass capillary tube (0.30 mm) to prevent the thermistor bead from retracting into the glass capillary (see Fig. 1). To allow for thermal expansion of the glass components due to large temperature changes, the thermistor assembly was not bonded to the glass capillary, creating a 'slip' fit. This design feature did not alter the measurement characteristics of the thermistor probe since all of the internal subcomponents were electrically insulated, preventing fluid penetration into the assembly. The completed assembly has a thermal time constant of 14 ms.

An array of 12 custom-built thermistor probes were arranged into three columns of four probes each placed in the tissue phantom at distances of 0, 1.5, 3.0, and 4.5 mm directly below the catheter (see Fig. 2). For each probe, a Wheatstone bridge circuit was constructed such that the thermistor was inserted into one leg of the bridge. An amplifier circuit was connected across the bridge so that the differential voltage between the test and reference arms of the bridge could be amplified and then recorded with a 16-bit analog to digital conversion card into a computer.

A voltage source of 0.2 V was applied to each of the thermistor bridge circuits so that the resistance of each thermistor could be recorded and converted to temperature. The total power applied to the thermistor probe was approximately 1–3 μ W, thus thermistor self-heating was considered to be a minimal source of error. The temperature probes were then calibrated to an accuracy of 0.01°C using a standard thermometer which is traceable to NIST calibration.

Since the stimulation frequency of the radiofrequency components of the test system were low, capacitive coupling to the thermistor leads was small and considered negligible. Given the relatively small dimensions of the probe, the low energy dissipated by self-heating, and the negligible capacitive coupling in our design, we concluded that the thermistor probes were minimally perturbing to the electrical and thermal events in the materials under study.

Fig. 3(a) is a photograph showing a detail of the thermistor array. Fig. 3(b) shows the position of the thermistor probes relative to an ablation catheter inserted into the linear test cell.

3.2. Hydrodynamic considerations

The main body of the test system is a linear test chamber constructed from 0.5-in. Plexiglas with an inner chamber dimension of $8 \times 8 \times 130$ cm (see Fig. 4). We were restricted to this length because we were not able to mill Plexiglas sections to lengths longer than 130 cm without incurring milling inaccuracies of more than 0.1 mm. The top of the ablation test chamber is a removable cover that is affixed to the cell by means of 0.375-in. screws placed every 10 cm. These screws can be removed to allow for the insertion of the tissue phantom material or for cleaning. A Teflon seal is used to prevent leaking. An access port is placed on the cover so that ablation catheters can be mounted into positions relative to the thermistor array. Access ports are placed on both sides of the tank so that the temperature probes and the ground wire could be made inside the linear test cell.

Flow is produced and maintained in the test cell by sustaining a differential pressure across the test cell using two constant pressure head tanks. Each constant pressure head tank was constructed from 0.24-in. Plexiglas and is configured as two concentric cylinders. The inner cylinder of each heat tank is the main flow area for that head tank. The outer cylinder is the overflow area. As seen in Fig. 5, fluid phantom material is pumped into the inner chamber of the constant pressure head tank on the left using a centrifugal pump at a rate that is faster than the rate at which it exits. The excess fluid pours into the outer chamber thereby maintaining a constant fluid height and pressure (P_1) in the head tank. The fluid phantom material then flows through the linear test cell and drains into the inner cylinder of the second head tank on the right. Once the fluid reaches the top of the second head tank, it overflows into the surrounding chamber, thereby maintaining a constant pressure in the second head tank (P_2). The pressure differential created by the two constant pressure head tanks creates a driving force for the movement of the fluid phantom, the center-line velocity of which was calculated based upon empirical measurement to be proportional to the square root of the mainstream pressure differential ($V \propto \sqrt{P_1 - P_2}$).

3.3. Radiofrequency generator

To generate the radiofrequency energy needed to heat the phantom material, a function generator (Hewlett Packard HP3314A) and a radiofrequency power amplifier (EIN Model 2100L) were used (see Fig. 5). The HP function generator was connected using a GPIB card so that the waveform, shape, frequency, and amplitude of the voltage produced by the function generator could be specified using a PC. The output of the function generator was connected to the power amplifier using a 50 Ω coaxial cable. The amplified output of the RF

power amplifier was connected by a second 50 Ω coaxial cable to the ablation probe and to the copper ground plate directly beneath the thermistor array. Current flowed from the tip of the ablation probe, through both the solid and liquid phantom materials to the ground plate. A pair of directional couplers (not pictured) was connected to the output of the RF power amplifier so that the forward and reflected power of the amplifier output could be measured. A 50 Ω power resistor was used to determine the function generator voltage needed to produce various power outputs.

Custom software was written in ASYST 4.0 to control the delivery of RF energy and to monitor the temperatures from the thermistor array. By specifying the amount of time prior, during, and after an ablation; the amount of power; and the frequency of the RF energy, a wide range of ablation parameters could be achieved. Our test rig was configured to sample data from the thermistor probes at 500 points/s, for stimulus frequencies of 10 kHz–12 MHz, at power output levels between 0 and 200 W.

3.4. Phantom materials

To model myocardial tissue, we added 4% high gel strength agar (Sigma A-6924) to a 0.1% sodium chloride solution. (All percentages by weight.) We heated this mixture to 100°C, dissolved the agar, and poured it into the linear test cell. Upon cooling, a solid phantom material formed with an electrical conductivity of 0.17 S/m, which is approximately the conductivity of myocardial tissue at 500 kHz [10]. Blood was simulated by adding 0.2% hydroxyethylcellulose to a 0.2% sodium chloride solution. This produces a soapy mixture with an electrical conductivity of 0.6 S/m, approximately blood, and a kinematic viscosity of 14.9 centistokes (mm^2/s) at 21°C.

The viscosity of the blood phantom is approximately 5 times greater than that of human blood [11]. Hydroxyethylcellulose is a polysaccharide that modifies the viscosity of the saline solution, but does not affect the electrical conductivity of the solution. The choice of increasing the viscosity of the blood phantom 5 times was motivated by the need to decrease the entrance length for laminar flow, which was approximated using RY Chen's expression for non-turbulent flows [12]:

$$\frac{L_e}{D} = 0.061\text{Re} + \frac{0.72}{0.04\text{Re} + 1}, \quad \text{Re} = \frac{\rho V D}{\mu} \quad (1)$$

where L_e is the entrance length, Re is the Reynolds number, ρ is the density, μ is the viscosity, V is the centerline velocity of the fluid, and D is the hydraulic diameter of a rectangular conduit. The hydraulic diameter is estimated as $D = 2HW/(H + W)$ where H and W are the height and width, respectively, of the effective interior dimensions of the linear test cell exposed to flow.

3.5. Calibration

To ensure that the experimental test system is producing a predictable laminar flow, we performed a series of validation tests to determine the shape of the velocity profile in the linear test cell. Dye was mixed with a small volume of blood phantom and injected into the

linear test cell through the access port in the laminar flow region. A Plexiglas block, measuring 7 cm in height, was inserted into the linear test cell such that the channel height was approximately 1 cm in thickness. Given a channel width/height ratio of 8, we approximated the flow as a two dimensional velocity profile between parallel surfaces. Thus, the velocity profile in the chamber is:

$$u = \frac{1}{2\mu} \frac{dp}{dx} (y^2 - Dy) \quad (2)$$

dp/dx is the pressure drop across the linear test cell, and y is the height in the linear test cell. It is clear from Eq. (2), that we expect the flow profile to resemble the shape of a parabola.

We validated the presence of laminar flow by injecting dye through the tip of a hypodermic needle, producing a streak emanating from a point. This was done at 1 mm spacing throughout the 1 cm channel height. Fig. 6 shows an example dye streak as viewed from the side and from the top with a flow rate of 4.0 l/min. The figure demonstrates that the dye streak does not change shape as it travels through the tank. This is an indication that laminar flow is present. We verified this for flows ranging from 0.1 to 6.0 l/min.

We demonstrated that the expected parabolic flow profile [in Eq. (2)] exists in the linear test cell by quickly injecting a bolus of dye into the linear test cell from a hypodermic syringe such that we disturbed the laminar flow. Fig. 7 shows that with a flow rate of 4.0 l/min, we re-establish laminar flow within 1 s and a parabolic profile forms due to frictional losses that form no-slip boundary conditions on the upper surface of the test cell and the Plexiglas block.

4. Results

We tested a wide range of power and flow settings using this apparatus. In these studies, we used a commercially available ablation catheter. Fig. 8 shows an example trace of temperature data recorded from the center column of thermistor probes in the thermistor array. In this example, a steady flow rate of 4.6 l/min was sustained and 10 W of power was delivered to the probe tip over a period of 20 s. Given the geometry of the probe, the geometry of the ground electrode, and the electrical conductivities of the blood and tissue phantom materials, the impedance of the 'blood/tissue' layer was approximately 42 Ω . Since the radiofrequency ablation generator was a 50 Ω system, the small impedance mismatch between the generator and the phantom materials caused approximately 12% of the delivered power to be reflected from the tip back to the radiofrequency ablation generator. Thus, the effective power output for our example is 8.8 W. The maximum temperature attained at the thermistor on the surface was 54.75°C. This experiment was conducted at room temperature.

Fig. 8 demonstrates that temperature changes faster near the surface of the tissue than in positions deeper in the tissue phantom. The data also shows latency in achieving peak temperature after power delivery has been terminated for temperature probes that are placed deeper into tissue. This finding is principally due to the forced convection on the surface of

the solid phantom which dissipates the heat away from the surface at a faster rate than the heat conduction that occurs deep in the tissue phantom.

The mean transient temperature data from a series of 6 experiments for all the thermistor probes in the array were extrapolated using a bi-cubic spline algorithm to generate an isothermal profile of a growing lesion. For this series of experiments, the power was maintained at 8.8 W and the flow rate was adjusted to 4.6 l/min. The ambient temperature for the experiment was 21°C; the variation of temperature in the series of experiments did not deviate by more than 2%. Fig. 9 shows the steady-state isothermal profile for this series. the narrowing of the thermal pattern near the surface is a result of surface cooling by the blood phantom.

5. Analysis

An understanding of the basic science associated with radiofrequency ablation is essential for the design of new ablation devices. Much of our understanding to date has drawn on clinical studies which report a wide disparity of lesion size data. [13–25] We have endeavored to create a test system that can be used to study the physical parameters that affect the performance of radiofrequency ablation devices.

To minimize changes of conductivity in the blood phantom, caused by diffusion over the course of the experiment, we used large quantities of phantom materials. In our study, we prepared approximately 40 l of blood phantom which was circulated and mixed throughout the experiment. The conductivity of our solution at the end of the experiments (approximately 2–3 h later) did not vary by more than 2%.

While it is possible to minimize the conductivity change in the solid tissue by flushing the linear test cell periodically with a large volume of saline solution that has an equivalent conductivity to the tissue phantom, we did not pursue this for the data presented in this study. Our experiments showed that the rate of diffusion in the tissue phantom were largely dependent on the percentage of agar used in the phantom material. As the percentage of agar was increased in the tissue phantom, the diffusion rate decreased. High concentrations of agar, however, were found to be difficult to cast into the linear test cell. The concentration of agar used in our experiments was approximately 4%. At this concentration, the liquefied agar could be cast without much difficulty, and the extent of ionic diffusion did not exceed 10% change within 1.0 mm of the surface of the tissue phantom during the first 2 h of experimentation. We experimentally determined that the temperature measurements under identical conditions applied over the course of 2 h did not vary more than 2%, demonstrating that the test method was highly reproducible.

While this test system is easy to assemble and produces highly reproducible results, it is worth mentioning that it is also affordable. The ablation test system presented in this manuscript is reasonably inexpensive and was constructed in our laboratory at a cost of \$700 and incurs an approximate cost of \$15 per experiment on average. When compared to the operation cost of attaining similar data using in vivo and in vitro tissue studies, it is evident

that ablation systems can be evaluated quickly, accurately, and inexpensively using this methodology.

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Fig. 1.
Thermistor probe assembly.

Fig. 2.
Thermistor array.

Fig. 3.
Detail of thermistor array and their position relative to an ablation probe.

Fig. 4.
Linear test cell design.

Fig. 5.
Experimental setup.

Fig. 6.
Validation of laminar flow profiles in the linear test cell at 4.0 l/min.

Fig. 7.
Validation of predicted parabolic flow indication the presence of laminar flow (flow: 4.0 l/min; time interval between pictures: 0.5 s).

Fig. 8.
Sample temperature trace at 8.8 W and 4.6 l/min.

Fig. 9.
Isothermal contours generated at 8.8 W and a flow rate of 4.6 l/min.