A Method for the *In Vitro* Testing of Cardiac Ablation Catheters

Steve S. Hsu, Lawrence Hoh, Richard M. Rosenbaum, Arye Rosen, *Fellow, IEEE,* Paul Walinsky, and Arnold J. Greenspon

Abstract—**We have developed a flow-phantom model in order to measure the temperature profile of radio frequency (RF) and microwave (MW) catheters. The model consists of a muscle equivalent phantom in a perfusion chamber with constant saline infusion of 4 L/min immersed in a 37°C saline bath. RF (4 or 8 mm, 550 kHz) or MW (12 mm helical antenna, 915 MHz) catheters were placed on the surface of the phantom and various energies were applied. Temperature measurements were obtained with fiberoptic thermometry probes placed at various distances from the catheter. Temperature contours were generated, and lesion volumes were estimated using 47°C isotherm ($\Delta T \geq 10°C$). The dosimetry of power versus ΔT was linear. A 2.59 fold increase in power density was required to achieve a similar surface temperature with the 8 mm versus 4 mm electrode tip. The volumes of lesions created with an 8 mm electrode were 2.5× larger than those made with a 4 mm electrode at a similar surface temperature. The RF phantom data compared favorably with the lesion volumes seen in the *in vivo* canine left ventricular model. The temperature profile of the microwave electrode showed heating along the length of the catheter due to imperfect tuning of the antenna. Deeper heating was seen with 8 mm RF and MW electrodes than with an RF 4 mm electrode given the same surface temperature. Measurements obtained with both a static and flow-phantom model demonstrated the cooling effects of flow on surface temperature measured during power delivery. Conclusions: The flow-phantom model accurately predicts the lesion geometry but underestimates the lesion volume at higher temperature when compared to the *in vivo* left ventricular canine model. Static phantom models will overestimate lesion size due to the surface cooling effects of cardiac blood flow. Changes in microwave catheter design may be carefully analyzed with the flow-phantom model prior to *in vivo* testing.**

I. Introduction

RADIO FREQUENCY (RF) catheter ablation has become the nonpharmacologic treatment of choice for patients with a variety of supraventricular arrhythmias [1]–[3]. Small discrete lesions are produced by delivering 20–40 W of unmodulated 550 kHz RF energy to the tip of a standard 4 mm tipped electrode catheter. Resistive heating of cardiac tissue occurs at the point of electrode contact [4]–[6]. Radio frequency ablation using 4 mm electrodes produces cardiac lesions with volumes of up to 460 ± 150 mm^3 [7]. Such lesions, when correctly placed, are capable of preventing episodes of recurrent supraventricular tachycardia in greater than 90% of patients treated with this technique [1]–[3].

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The efficacy of RF catheter ablation for the treatment of ventricular tachycardia is variable [8]. In patients with idiopathic left ventricular tachycardia, ventricular tachycardia arising from the right ventricular outflow tract, and ventricular tachycardia secondary to bundle branch reentry, the results of catheter ablation are quite good. The efficacy rate is similar to that found in the treatment of supraventricular tachycardia. In these tachycardias the focus of the tachycardia or the area required for ablation is small. In patients with ventricular tachycardia post myocardial infarction the results of catheter ablation have been much poorer, with efficacy rates of approximately 50%. In these patients, the tachycardia arises from an area between normal and scar tissue. Based on data derived from the surgical treatment of these tachycardias, a larger area of tissue must be ablated to successfully interrupt the tachycardia.

One of the limitations of the current catheter approach to the treatment of ventricular tachycardia post myocardial infarction is the size of the lesion produced [9] and [10]. Various energy sources including dc current [11], RF energy [8], [12]–[14], and microwave energy [15]–[18], have been investigated in an attempt to create larger lesions. In addition, various designs of the electrode tip have been investigated [7] and [19]. Most studies have utilized either *in vivo* or *in vitro* animal preparations. These investigations require repeated animal surgery, with its added expense, each time there is a change in catheter design. Phantom material has been used in radiation oncology and hyperthermia to analyze the tissue heating profile and to guide therapy [20]. A phantom model has the advantage of allowing repeated measurements in a stable environment, without the biologic variability of animal preparations. The effects of changes in catheter design may be easily studied. Previous studies of cardiac ablation catheters have utilized static phantom models which do not take into account the cooling effects of blood flow [13]–[15] and [18].

We created a flow-phantom model to simulate the endocardial environment present in catheter ablation. The model consists of phantom material which simulates cardiac muscle suspended in a saline perfusion chamber. Flow across the surface of the phantom, simulating blood flow, is controlled by a perfusion pump. Each catheter design was analyzed by placing the catheter in the perfusion chamber on the surface of the phantom material. The goal of the study was to characterize the temperature profile and lesions produced by various RF and microwave catheters using the flow-phantom model. These

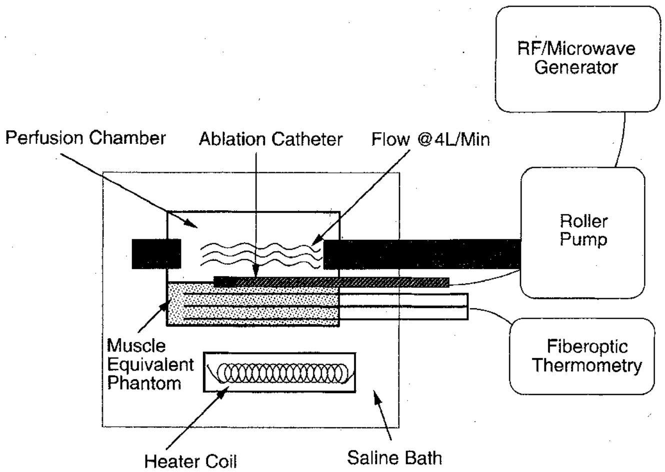


Fig. 1. Diagram of the flow-phantom model for the evaluation of cardiac ablation catheters. The catheter to be evaluated is placed on the surface of the phantom which is immersed in a perfusion chamber. Cardiac output is simulated by perfusing saline across the surface of the phantom by means of a roller pump.

data were then correlated with data obtained from whole animal preparations to test the validity of the results obtained from the phantom model.

II. Methods Flow-Phantom Model

A. Perfusion Chamber

A perfusion chamber was constructed from 3/8-in clear acrylic slabs. It consists of 2 halves, which are each 10 cm in length, 4 cm in width, and 1.5 cm in depth. The lower half is filled with phantom material through which fine glass capillary tubes are placed every 5 mm along the length and every 2.5 mm along the depth. The phantom is separated from the top chamber by a thin layer of cellophane to prevent it from being dissolved by the chamber flow. The catheter of interest was placed at the center of the chamber, and adequate contact of the entire catheter tip with the phantom was verified by visual inspection. The complete perfusion chamber was immersed in a saline bath maintained at a constant temperature of 37°C. The top portion of the chamber was perfused with 37°C saline at 4 L/min via the two side ports (Fig. 1).

B. Phantom Preparation and Ablation Catheters

Muscle equivalent phantoms for RF or microwave were made from mixtures of TX150, polyethylene powder, NaCl, and water and poured into the lower half of the perfusion chamber [15] and [21]. The phantom material was allowed to set for 30 minutes prior to evaluation. The RF ablation catheters evaluated were a 4 mm tip Steerocath and a large tip 8 mm catheter (EP Technologies, Sunnyvale, CA).

A catheter for microwave ablation was constructed with a 12 mm helical antenna [16]. The microwave ablation catheter consists of a steerable 10 F catheter with a central flexible coaxial cable with an overall diameter of 2.413 mm (0.095 in). At the tip of the catheter the coaxial cable terminates in a helical antenna. [The coaxial cable has an attenuation of approximately 29 dB/100 ft.] Before the catheter was tested in the phantom material it was evaluated on a network analyzer to confirm that the catheter radiated energy at 915 MHz. The RF generator delivered an unmodulated waveform at 550 kHz at powers of up to 100 W (EP Technologies, Sunnyvale, CA). A microwave generator was developed for delivering powers of up to 150 W at 915 MHz (Microwave Medical Systems, Littleton, MA). Constant power was delivered for 30 s during each run.

C. Temperature Measurements

Temperature measurements were obtained using a 12 channel Luxtron fiberoptic thermometry system. The fiberoptic probes were inserted into the fine glass capillary tubes at various positions to record the temperature. These measurements were taken at depths of 0, 2.5, 5, and 7.5 mm; at lengths of −5, 0, 5, 10, 15, 20, 25, and 30 mm from the tip along the length of the catheter; and at distances of 0, 2.5, 5, 7.5, 10, 12.5, and 15 mm from the catheter at each side. Data were recorded for a total of 90 s during each run: 30 s at baseline, 30 s during power delivery, and 30 s during cooling.

D. Dosimetry and Lesion Volume Calculations

A dosimetry of power versus maximal temperature change ($\Delta T_{\max}$) was measured for each catheter. Power was varied from 5–50 W for RF and 10–150 W for microwave energy. Isotherm contour plots were constructed by measuring the temperature change at various distances from the catheter tip during power delivery. Since previous studies have shown that irreversible cell death occurs at temperatures above 47°C [1] and [4], estimated lesion volumes were calculated from isotherms of 47°C and higher (i.e., a $\Delta T \geq 10$°C).

In vivo lesions were created using previously described methods [8]. Briefly, following RF ablation, the animal was sacrificed, the left ventricle was dissected free of other structures, frozen at −70°C, and then sliced into 2 mm sections along the short axis. Sections were incubated in nitro-blue tetrazolium (0.5 mg/ml in Sorenson's Buffer [pH = 7.4]) at 37°C for 15 min and then fixed in a solution of 10% formalin. The perimeter of each lesion was traced onto plastic transparency sheets and the area planimetered using a digitizing pad. Lesion volume was then calculated according to

$$V = \Sigma A_n \cdot T_n$$

where

V total lesion volume;
A_n mean planimetered lesion area for each slice;
T_n thickness of the given slice.

These results were compared to the *in vitro* lesions calculated from the phantom model.

E. Statistical Analysis

Continuous variables are expressed as mean ± SD. Correlations between continuous variables were tested with use of the Pearson correlation coefficient (r). A p value <0.05 was considered significant.

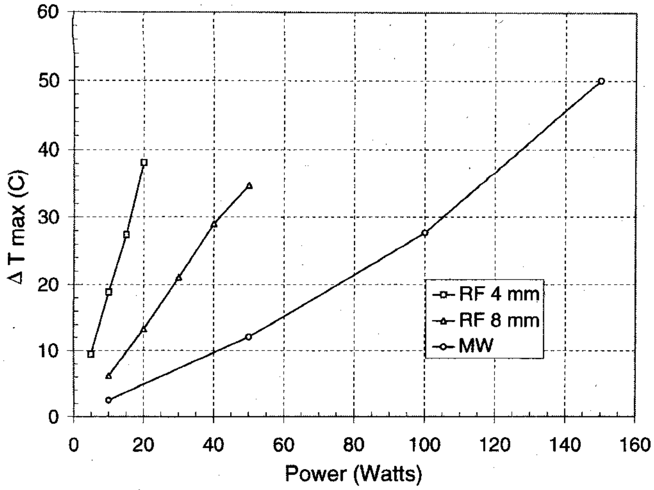


Fig. 2. Dosimetry of power versus temperature for RF and microwave catheters. The maximal change in temperature is at the surface, near the tip for RF catheters and at the base for the microwave catheter.

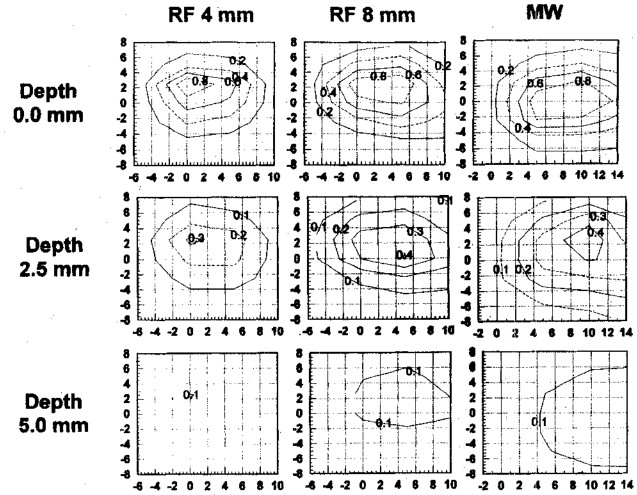


Fig. 3. Temperature profile at various depths for RF and microwave catheters. Contours are isotherms normalized to the maximal surface temperature. The ordinate and abscissa are distances in millimeters. The catheter tip is positioned at (0, 2.5) for both RF 4 mm and 8 mm and at (0, 0) for microwave.

III. Results

A. Dose Response Curve

The relationship between delivered power and tip temperature was evaluated for a 4 mm and an 8 mm RF catheter as well as for the microwave catheter with a 12 mm helical antenna. There was a linear relationship between power and the change in surface temperature (Fig. 2). The correlation coefficient (r) was 0.998 for the 4 mm electrode, 0.997 for the 8 mm electrode and 0.997 for the microwave catheter. More power was required to achieve the same change in temperature with an 8 mm as compared to a 4 mm catheter. The power density required to achieve a similar surface temperature was 2.59× higher for an 8 mm RF catheter. The microwave catheter required still higher power in order to achieve the same change in temperature.

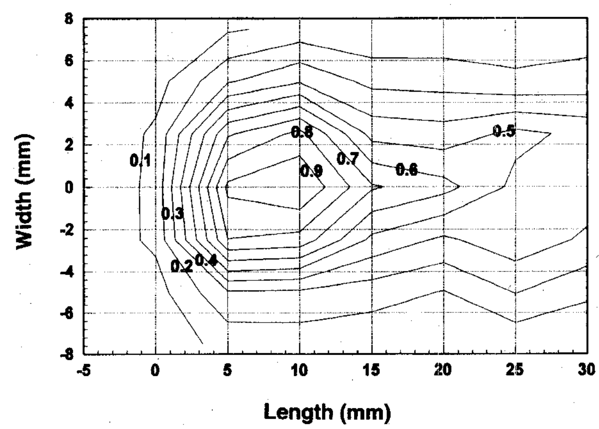


Fig. 4. Temperature profile of 12 mm helical microwave catheter at the surface. Contours are isotherms normalized to maximal surface temperature. The ordinate and abscissa are distances in millimeters. There is significant heating along the length of the catheter.

B. Temperature Contour

The higher power requirement for the large tip 8 mm RF catheter translated into wider and deeper heating. A contour plot of the change in temperature on the surface of the phantom in response to heating was generated for the three catheters (Fig. 3). Isotherms were normalized to the maximal surface temperature. Plots were also generated for depths of 2.5 and 5 mm beneath the surface of the phantom. At the surface the area of heating created by the 8 mm RF catheter was 1.67 times larger than that created by the 4mm RF catheter. The microwave catheter exhibited a still larger area of heating. Maximal heating occurred at the base of the microwave antenna, whereas with the RF catheters maximal heating occurred at the tip. A surface contour plot of the microwave catheter demonstrated that there was significant heating along the shaft of the catheter (Fig. 4). Fifty percent of maximal heating was seen 2.7 cm from the tip of the catheter. There was a marked diminution in heating at a depth of 2.5 mm. A larger area of heating was observed for the 8 mm RF and microwave catheter as compared to the 4 mm RF catheter. At a depth of 5 mm there was little heating observed with the 4 mm RF catheter. By contrast, both the 8 mm RF and microwave catheter showed a change in temperature at a depth of 5 mm but the change was only 10% of that seen on the surface.

C. Depth and Rate of Heating

The time course of heating at various depths was analyzed by plotting the change in temperature as a function of time (Fig. 5). The change in temperature was expressed as the percent of the maximal surface temperature achieved during power delivery. This permitted a comparison of the time course of heating among the three catheters tested. Following power delivery there was a 3–4 s delay in temperature rise for

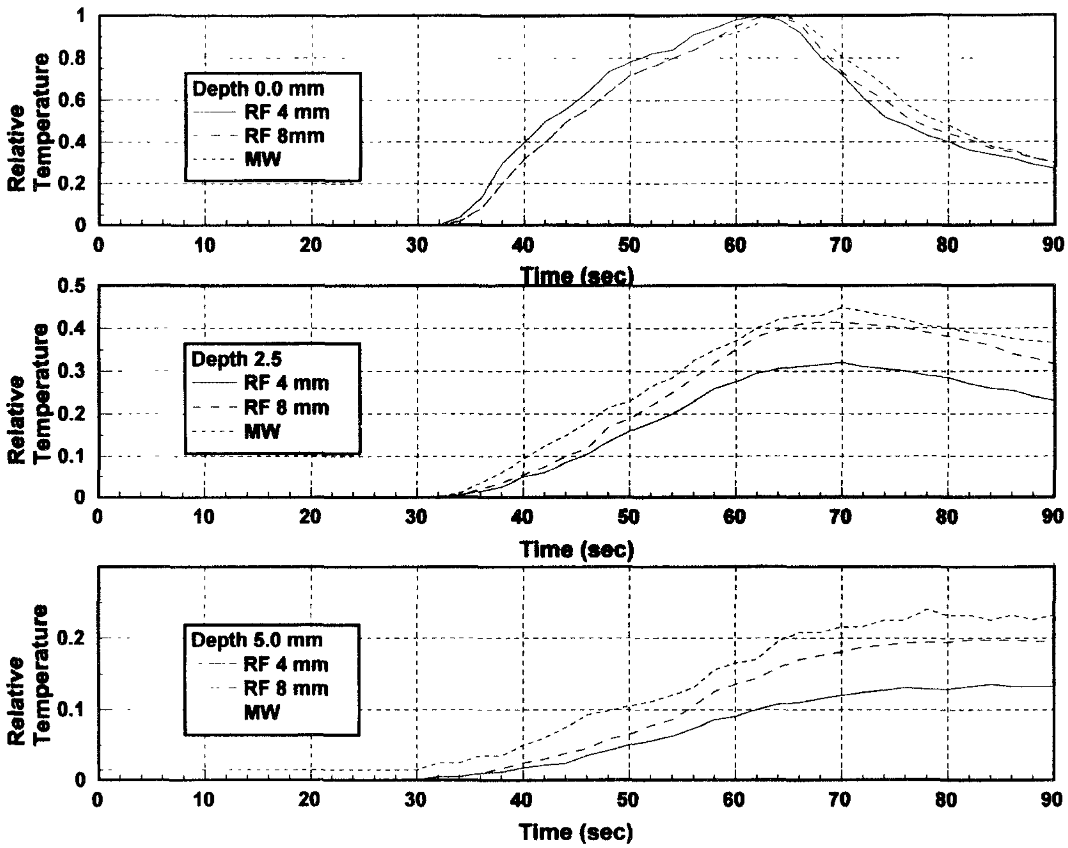


Fig. 5. Relative temperature at various depths before, during, and after power delivery. Relative temperature is $\Delta T/\Delta T_{\max}$. Power was delivered from 30–60 s. There is more depth heating for the RF 8 mm and microwave catheters than for the RF 4 mm catheter, given the same maximal surface temperature.

all catheters tested. Peak temperature was achieved several seconds after power was turned off. This effect was delayed at depths of 2.5 and 5 mm. A greater depth of heating was observed with both the 8 mm RF and microwave catheter. Following delivery of power, the surface cooled more rapidly than the deeper levels studied due to the flow of 37°C saline across the phantom surface.

D. Effects of Flow on Surface Temperature

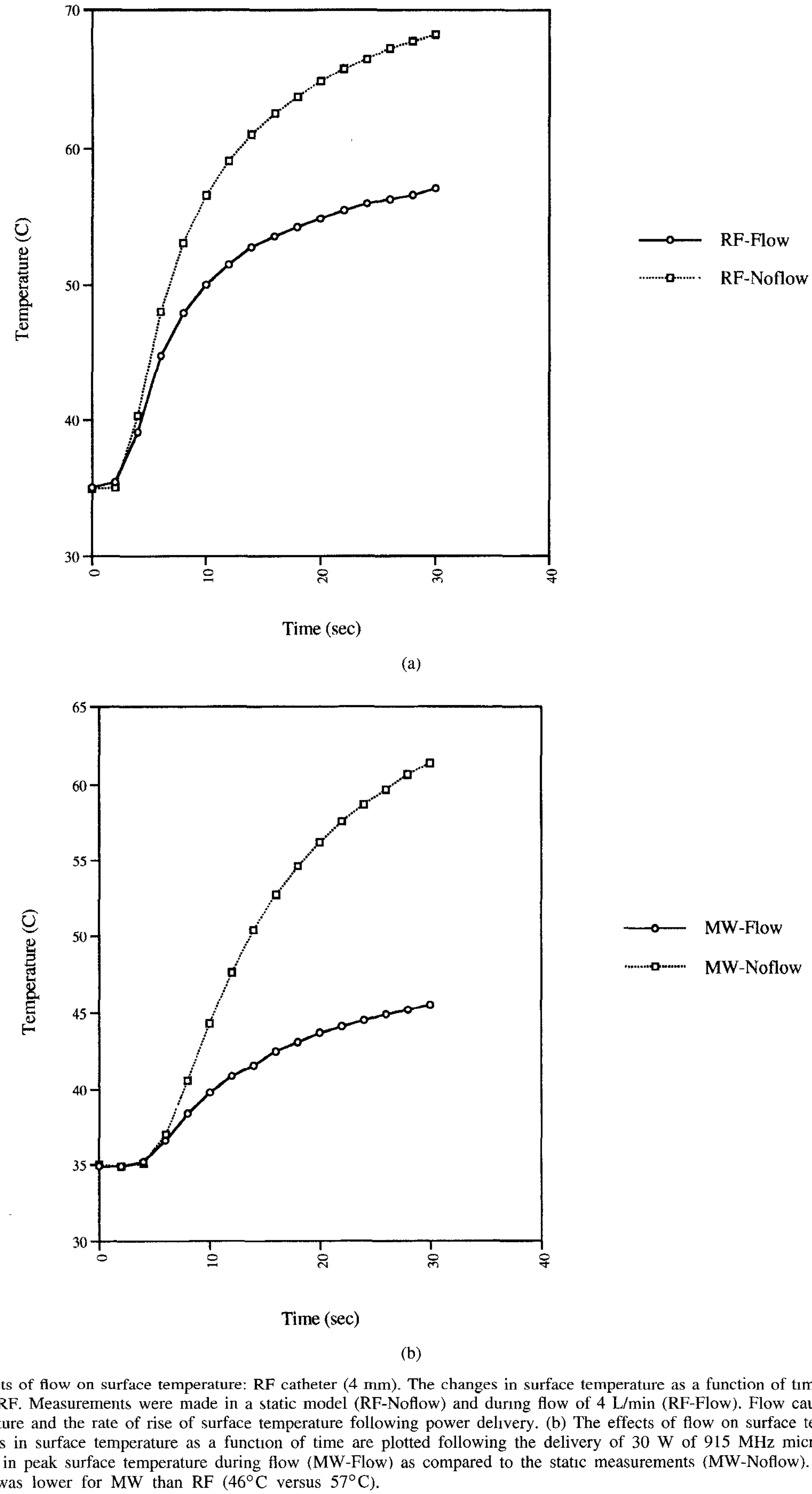
The effects of cardiac blood flow on surface temperature during cardiac ablation were evaluated by comparing a static and flow-phantom model. Static measurements were performed using the previously described phantom model but without perfusion of saline across the surface of the phantom. These values were compared to those obtained with saline perfusion of 4 L/min [Fig. 6(a) and (b)]. Perfusion of saline caused a marked reduction in surface temperature for both RF and microwave ablation catheters. In the static model, the peak surface temperature measured 30 s after delivery of 30 W of power was 68°C for the 4 mm RF catheter and 61°C for the microwave catheter. Flow caused a reduction in peak surface temperature to 57°C with the RF catheter and 46°C with the microwave catheter. In addition, the rate of rise of surface temperature was attenuated by flow. These data suggest that static phantom models will overestimate lesion size as lesion size is proportional to surface temperature during ablation [6].

E. Lesion Volume

Lesion volume was plotted as a function of power for both RF and microwave catheters. Volumes were obtained from *in vivo* ablation of canine left ventricular myocardium as well as from measurements taken during phantom experiments. There was a direct relationship between lesion volume and delivered power for each electrode tested. Power delivery and hence lesion size was limited in the RF catheters by the development of a rise in impedance seen at higher power. A higher power was required to optimize lesion size with the 8 mm versus the 4 mm RF electrode (80 W versus 40 W). The maximal lesion volume with an 8 mm RF electrode was approximately twice that achieved with a 4 mm electrode (914 ± 362 versus 446 ± 150 mm^3, $p < 0.01$).

Lesion size was also calculated following the delivery of microwave energy. Microwave energy was delivered at a power setting of 80 W for a total of 5 min. Mean lesion size measured 435 ± 236 mm^3. This is similar to the size of lesions created with the smaller tipped RF electrodes.

The size of lesions created *in vivo* were compared to estimated lesion size in the phantom model (Fig. 7). There was a good fit between the phantom and animal data obtained from the 4 mm RF catheter. For the 8 mm catheter, the phantom model underestimated lesion size when power was increased beyond 20 W. However, the phantom model accurately predicted that it would take approximately twice the delivered



(b)

Fig. 6. (a) The effects of flow on surface temperature: RF catheter (4 mm). The changes in surface temperature as a function of time are plotted following delivery of 30 W of RF. Measurements were made in a static model (RF-Noflow) and during flow of 4 L/min (RF-Flow). Flow caused a decrease in both peak surface temperature and the rate of rise of surface temperature following power delivery. (b) The effects of flow on surface temperature: Microwave Catheter. The changes in surface temperature as a function of time are plotted following the delivery of 30 W of 915 MHz microwave. Similar to RF, there was a decrease in peak surface temperature during flow (MW-Flow) as compared to the static measurements (MW-Noflow). During flow, the peak surface temperature was lower for MW than RF (46°C versus 57°C).

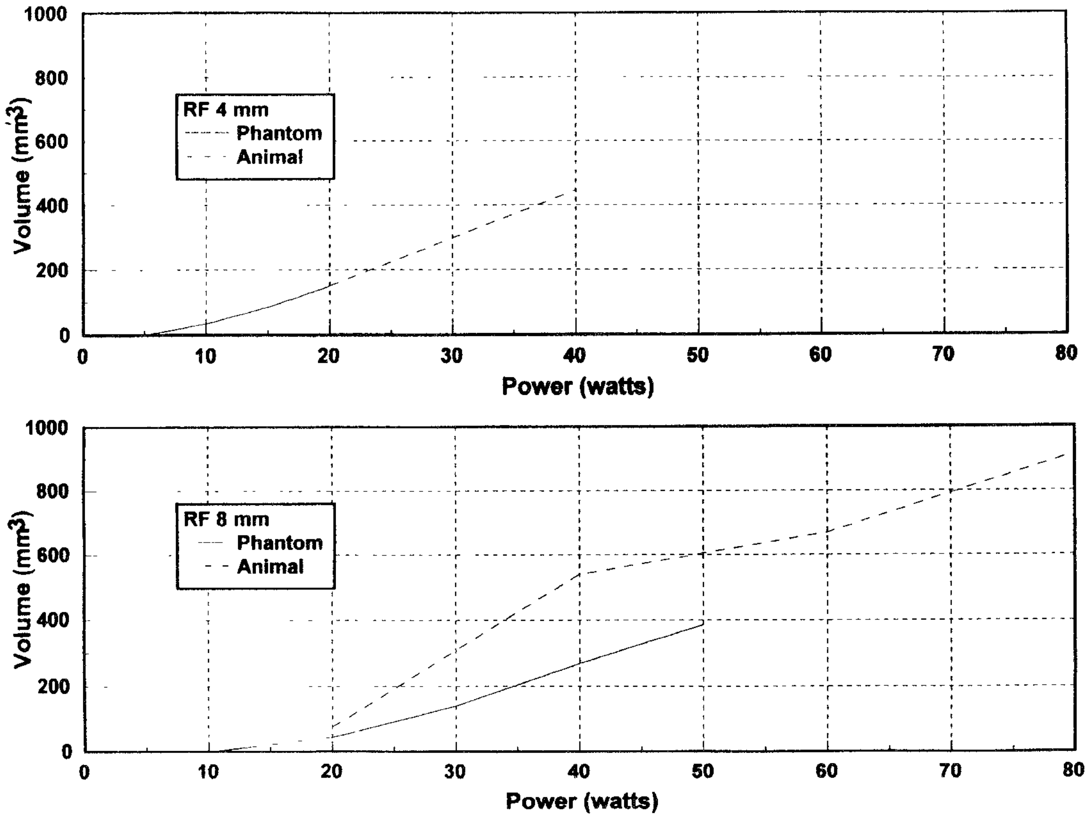


Fig. 7. Comparison of the lesion volumes obtained with the phantom and canine left ventricular models for the RF catheters.

power for an 8 mm catheter to create a lesion similar in size to a 4 mm catheter.

IV. Discussion

The flow-phantom model provides a simple *in vitro* method for analyzing cardiac ablation catheters. Heating of cardiac tissue to a level of cell death is the principal mechanism of successful cardiac ablation [1], [2], [4], and [6]. Therefore, understanding the temperature profile of a particular catheter design is important in order to assess its effects on lesion size. The advantages of the present phantom model are the linear response of temperature to delivered power, the ability to measure the temperature at any point along the catheter shaft, and the control of chamber flow with its effects on surface cooling. This flow-phantom model is superior to previously described static phantom models which do not take into account the surface coolong effects of cardiac blood flow.

With RF ablation, there is resistive heating at the contact point between the catheter tip and cardiac tissue. More power is required for the larger 8 mm tip RF catheter to achieve the same surface temperature. However, this additional power requirement translated into deeper heating and larger lesion size. The area on the surface heated to the maximal temperature is greater allowing more heat to be conducted to deeper tissue layers. The microwave catheter also demonstrated heating below the surface. However, in the present design of the helical antenna, there also was heating along the shaft of the catheter which suggests that there may not have been proper tuning of the microwave antenna. A poorly designed microwave catheter would heat tissue by conduction but not achieve volume heating effects secondary to the radiation of energy.

A. Limitations

The lesion size derived from the phantom model was only an estimate of the lesion size *in vivo*. The measurement in the phantom assumed that the myocardium was flat. In addition data points were only obtained at 2.5 and 5 mm below the surface of the phantom. More closely spaced thermometry probes would likely have yielded more accurate information. However, closer spacing of the thermometry probes is not feasible in this model. Furthermore, we assumed that a temperature of 47°C resulted in irreversible cell death. This assumption also influenced the results. Nonetheless, the present system accurately reflects trends in temperature profiles that result from changes in catheter design or type.

B. Conclusion

The flow-phantom model is a predictable method for testing changes in catheter design for cardiac ablation. It may be particularly suited for the study of microwave catheters where optimal antenna design is currently being studied. The flow-phantom model is useful for characterizing the temperature profile of an ablation catheter and will aid in future catheter design prior to *in vivo* testing.

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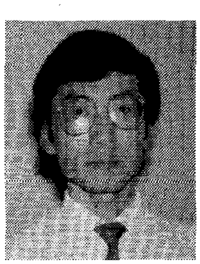

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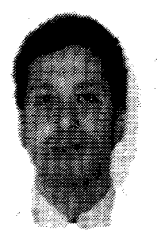
Lawrence Hoh, photograph and biography not available at the time of publication.



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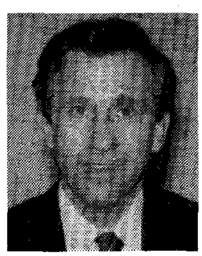

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