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Regulating Energy Delivery during Intracardiac Radiofrequency Ablation using Thermal Strain Imaging

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Abstract— **Tissue temperature is critically related to the success or failure of catheter ablation procedures. Temperature imaging using ultrasound techniques is attractive because of the potential to provide real-time information at low cost. The signal-processing methods used here were developed to investigate the feasibility of monitoring ablative therapy by identifying the point at which the slope of the thermal strain curve changes sign caused primarily by speed of sound variations with temperature. Previously, we have demonstrated the feasibility of this method in-vivo using porcine models. In this paper, we present recent results with temperature validation for this method in-vivo using an integrated intracardiac echocardiography (ICE) probe. Also preliminary results on thermal strain imaging using a cMUT array integrated into the ICE probe are presented.**

I. Introduction

Electrophysiology (EP) interventions have experienced increasing popularity as a treatment option for arrhythmias due to advances in technologies that enable more effective clinical procedures. Radio frequency ablation (RFA) is most commonly used in EP procedures to permanently alter the myocardium in locations which support aberrant electrical conduction pathways contributing to irregular heart rhythm. Regulating energy delivery to maximize safety is crucial for successful outcomes.

Currently, the effects of RF delivery can be monitored only indirectly by real-time analysis of impedance [1], electrogram amplitude [2], the electrophysiologic behavior of the tissue being ablated [3] and temperature at the tip of the electrode [4], [5]. Tissue temperature is critically related to the success or failure of catheter ablation procedures [6], [7]. To ensure irreversible injury, a tissue temperature of approximately 48-50 °C must be achieved [5]-[8]. Raising tissue temperature significantly beyond this point can be unnecessary and cause complications (Figure 1).

Because of the importance of tissue temperature monitoring, a standalone thermocouple or a thermistor embedded in the electrode is used during catheter RFA procedures [5], [7]. During energy delivery, a portion of the electrode is typically in contact with the tissue and the remainder in contact with surrounding blood. The electrode temperature recorded by the thermocouple represents not only contributions from tissue, but a combined interaction from the production of heat in nearby tissue by the RF field and convective heat loss to surrounding blood and tissue [7], [9]-[11]. Because of convective heat losses, the temperature recorded by the thermocouple is generally less than that at the hottest point in the tissue, misleading the operator to increase the energy delivered.

Temperature imaging using ultrasound techniques is more attractive because of the potential to provide 2-D real-time temperature information in a cost effective way. However, there are several limitations in ultrasound-based temperature measurement. Measurements over large temperature ranges are limited because the sensitivity to sound speed changes beyond 50 °C is low [12]. If a very high temperature rise is considered (tissue temperature rise of 15 °C or higher), as in the case of high-intensity focused ultrasound (HIFU), the effect is two fold: sound speed variations with temperature are not as sensitive and the tissue undergoes state changes that could fundamentally change the ultrasound backscatter signal character.

Sound speed variations with temperature introduce apparent shifts in scatterer position and thermal expansion of the medium introduces a physical shift in scatterer position. Beyond 50 °C, thermal expansion is no longer negligible and contributes to the total echo shift or delay in strain calculations. Thus, TSI may not be practical for ablation monitoring based on precise temperature measurements since it is more sensitive and unambiguous for small temperature changes in the temperature range below 50 °C. For ablation treatment of arrhythmia, however, a robust, reproducible indicator of tissue necrosis rather than absolute temperature monitoring is required. In particular, it is more important to know when tissue temperature has reached or exceeded 50 °C so ablation can be terminated.

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Considering thermally-induced strain as a function of time during the ablation procedure, we hypothesized that there is a point where the slope of the thermally-induced strain approaches zero. That is, by continuously tracking from a reference frame just prior to the start of ablation, the thermal strain will eventually plateau because the sound speed has reached its maximum value as a function of temperature.

The signal-processing methods proposed in this paper were developed to investigate the feasibility of monitoring ablative therapy by identifying a point at which the magnitude of the slope of the thermal strain curve reduces significantly, caused primarily by sound speed variations with temperature. The feasibility of this method for ablation monitoring was tested in-vivo using an animal model.

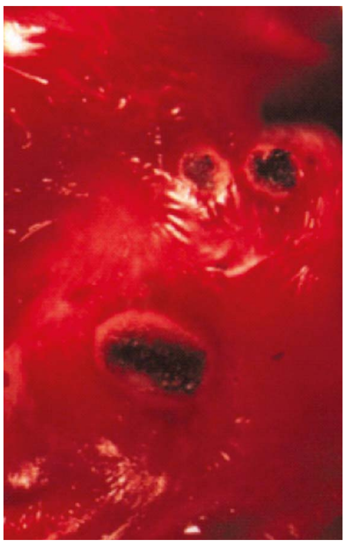

Figure 1. Coagulum formation on atrial endocardium from too much energy delivery

II. METHODS

For the in-vivo study, juvenile Yorkshire pigs were used as the animal model. Specially designed ultrasound compatible RFA electrodes were integrated into a prototype 9F forward-looking microlinear (ML) intracardiac echocardiography (ICE) catheter array to simultaneously image and ablate the right atrial wall [13]. Additionally, a thermocouple normally residing inside the electrode was pulled out to touch the tissue for thermal strain validation. Fig. 2 shows the approximate geometry for this configuration. The transmit frequency was 11 MHz with a transmit focus at 2 mm. Ablation was performed while the integrated imaging and ablation catheter was localized and guided by fluoroscopy.

The new 9-Fr forward-looking ICE catheter was constructed with three complementary technologies: a CMUT imaging array with a custom electronic array buffer, catheter surface electrodes for EAM guidance, and a special ablation tip which permits simultaneous TSI and RFA. In vivo imaging studies of five anesthetized porcine models with five CMUT catheters were performed.

Two-dimensional phase-sensitive correlation-based speckle tracking was applied to RF data from every frame in the sequence to estimate temporal strain along the axial direction. The tracking algorithm involves calculating complex cross-correlation coefficients between small windowed blocks from two consecutive frames, reducing the probability of peak hopping by filtering the correlation coefficient functions, and estimating the shift from the phase zero-crossing around the peak correlation coefficient. The correlation kernel size was about the full-width-half-maximum (FWHM) of a speckle autocorrelation function for optimal strain estimation. Reduced kernel size and correlation filtering significantly decreases peak hopping probability and increases the accuracy of displacement estimation.

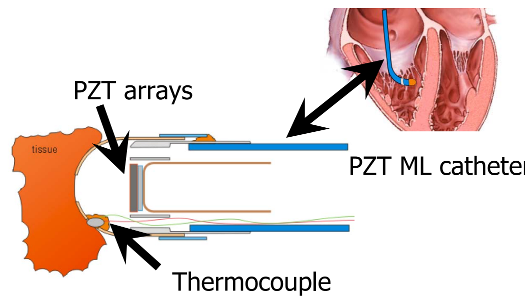

Figure 2. Approximate geometry of the PZT ML array for the in-vivo study.

III. RESULTS

B-mode images are overlayed with thermal strain images for the in-vivo animal study. Thermal strains at positions within the image are plotted against temperature rise. By plotting the slope of the thermal strain curve as a function of temperature, the sign change at around 50 °C is clearly observed. In particular, this method appears promising for the case where heating is sufficiently fast to minimize the effects of thermal diffusion (Figure 3). Photographs of the lesions confirm that RF ablation was successful (Figure 4).

The ML-CMUT ICE catheter provided high-resolution, real-time, wideband 2D images at an imaging frequency greater than 8 MHz, and is capable of both RFA, and electroanatomical mapping (EAM) guidance. The specially designed ultrasound compatible metalized plastic tip allowed simultaneously imaging during ablation, and direct acquisition of TSI data for tissue ablation temperatures. Post-processing analysis showed first order correlation between TSI and temperature, permitting early development of temperature-time relationships at specific myocardial ablation sites. Similar thermal strain curves as with ML-PZT ICE were generated (Figure 5).

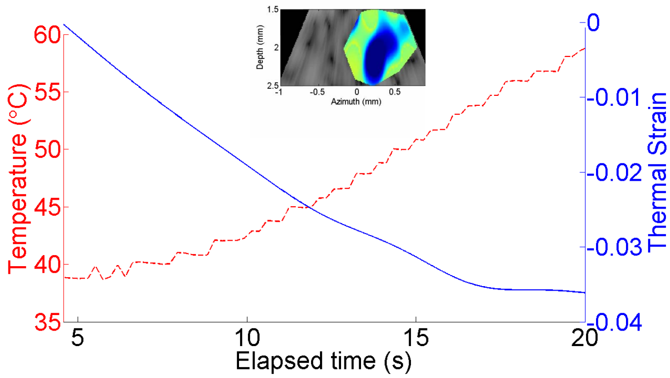

Figure 3. Thermal strain and temperature rise.

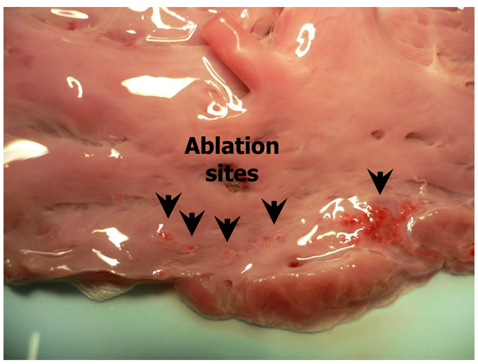

Figure 4. Lesions formed from RF ablation.

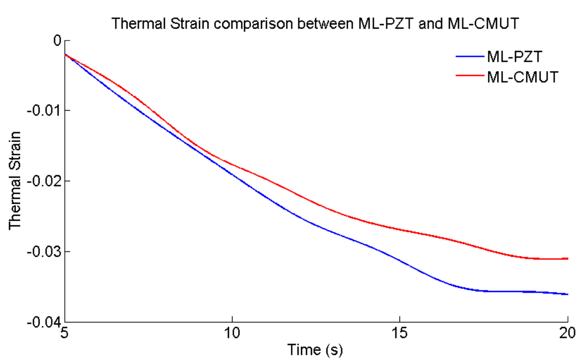

Figure 5. Thermal strain comparison between ML-PZT and ML-cMUT.

IV. POTENTIAL LIMITATIONS

A. Tissue motion

A major obstacle for in-vivo application of TSI is tissue motion, including respiratory and cardiac motion. Thermal strains are equivalent to their motion-induced mechanical counterparts and are typically much smaller. Using ECG signals to trigger array firing, cardiac periodicity can be fully utilized to minimize motion artifacts, allowing thermal strains to accumulate over multiple cardiac cycles if needed with little distortion (Figure 6).

B. Thermal diffusion

Thermal diffusion is not a significant issue for most applications of TSI in which the heat pulse is delivered over a 1-5 second interval. However, for cardiac ablation monitoring in which large temperature changes (typically 15-30 °C) can occur over a period of 10-60 seconds, thermal diffusion may be an issue. In particular, since the change in slope with time used to monitor therapeutic effectiveness, the change in temperature with time should be constant in the region of interest. This can only be assured if thermal diffusion is minimized.

To test whether diffusion would compromise the RF cardiac ablation protocol, a finite element model of thermal diffusion was developed for this application. Figure 7 shows that the experimental heating protocol operates in a region where thermal diffusion has not taken over. In particular, the pulse duration for the heating scheme used for this study is sufficiently short that we can assume instantaneous heating of the medium with minimal thermal diffusion. In a clinical environment, rapid heating is required to reduce the effects of thermal diffusion and motion.

C. Thermal-acoustic lens

Thermally-related changes in acoustic properties can distort the incoming acoustic wavefront, and potentially cause the acoustic focus to move and distort in an otherwise homogeneous media. The overall effect from short insonifications at high power (60-70 W) from sharply focused sources is found to be small [14]. The main factors in producing thermal-acoustic lensing are the amount of prefocal heating along the propagation path and the response of the medium along this path to heating. Higher f-number systems and long, inhomogeneous (i.e., mixed fat- and water-bearing tissues) propagation result in more acoustic lensing effects, For intracardiac ablation monitoring, very short propagation paths in homogeneous, water-bearing tissue will be used.

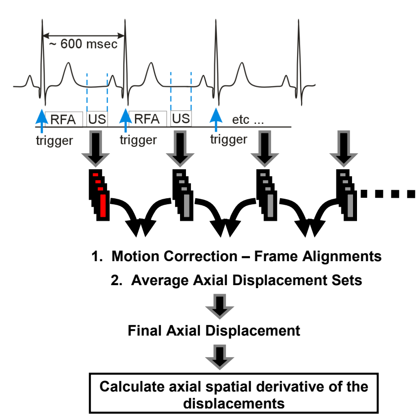

Figure 6.ECG triggered heating and acquisition scheme.

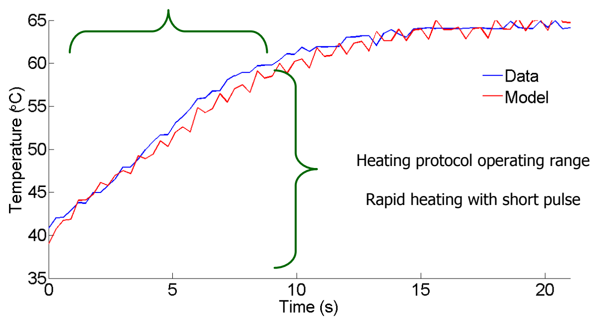

Figure 7. Temperature curve demonstrating minimal effect of thermal diffusion.

V. CONCLUSIONS

The potential of monitoring temperature during RF ablation using a slope change in the thermal strain curve has been demonstrated. For in-vivo experiments, thermal strain curves showed first a plateau and then slope change at around 50 °C. Because only three in vivo experiments have been completed to date, additional in vivo studies are needed to better evaluate the robustness of this technique for real clinical applications. Nonetheless, preliminary results look promising and suggest that thermal strain imaging may be a useful tool to guide RF ablations of the heart using intracardiac devices. Multifunctional forward-looking ML-CMUT ICE catheters, with simultaneous intracardiac guidance, ultrasound imaging, and RFA, may offer a new means to improve interventional ablation procedures.

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