Ultrasound Compatible RF Ablation Electrode Design for Catheter Based Guidance of RF Ablation - *In Vivo* Results with Thermal Strain Imaging

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***Abstract* — Currently the feedback guidance of intracardiac radiofrequency (RF) ablation is very limited, offering only a catheter electrode (not tissue) temperature estimation and a means to titrate RF power delivered to the tissue.**

Our "microlinear" (ML) forward imaging ultrasound catheter design, now at a true 9F (3mm) in size, has been optimized with several features to simultaneously permit a) high quality intracardiac steering and imaging, b) tracking of 3D position with electroanatomical mapping, c) RF ablation, and d) tissue thermal strain (TS) estimation for direct tissue temperature feedback.

Two types of ML catheters have been built and tested in 3 porcine animal models. The first type, in its third generation, is based on a PZT transducer array; the second type, in its second generation, is based on a cMUT array with custom integrated interface circuitry. Both types of devices are true 9F in size and performed well in imaging tests in recent *in vivo* studies. Both the ML-PZT and ML-cMUT arrays, as described previously, have a fine pitch (65 and 63 micron respectively) 24 element phased arrays operating at 14 MHz which project a B-mode plane directly out from the tip of the catheter. Intracardiac imaging performance was documented to show that the very small array aperture of the ML design (1.2mm by 1.58mm) permits good, high resolution imaging to depths as great as 4 cm. The ML-PZT catheter was equipped with a special low profile ablation tip which allowed simultaneous imaging and ablation at the distal end of the catheter. TS data were acquired during tissue ablation in the right atrium at three sites. The RF ablation TS data was processed off line.

***In vivo* use of this new technology has shown for the first time the very substantial potential for a single, low profile catheter to simultaneously image within the heart and perform intracardiac ablation therapy with tissue temperature guidance produced from incorporation of TS imaging. Work is underway to further assess the temperature estimation accuracy and to integrate the TS processing for real time displays.**

Keywords – catheter imaging; ultrasound; electrophysiology; intracardiac echo; ICE; cMUT ; thermal strain

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INTRODUCTION

Minimally invasive electrophysiology interventions to treat cardiac arrhythmias are increasing worldwide due to advances in technologies that enable more effective clinical procedures. Since intracardiac echo (ICE) imaging catheters for the guidance of interventional electrophysiology (EP) therapeutic procedures offer real time, direct observations and improved procedural guidance over that of fluoroscopy alone [1], their use is constantly increasing. Currently atrial fibrillation, the most common cardiac dysrhythmia, affects more than 2.2 million in the U.S. alone with at least 60,000 new cases each year [2]. The great need for integrated technologies to produce improved image guidance are certainly a driving force in EP therapeutics [3, 4].

Fluoroscopy is still the primary EP therapeutic guidance method as a means to direct catheter position and movement, however EP ablation procedures can take as long as 3 hours [5, 6], with long periods of radiation exposure. Recent developments in electroanatomical mapping have aided catheter positioning, but more procedural guidance is needed.

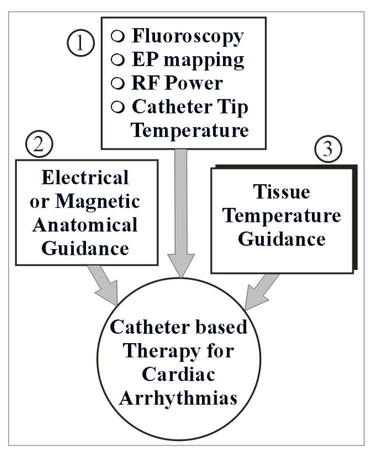

Figure 1. The guidance of catheter based ablation therapy for arrhhythmias. Fluoroscopy, ECG, RF ablation power, and simple catheter tip temperature (1) is the current standard for guidance. Recently, EM anatomical guidance (2) modalities have helped guide placement, but actual tissue temperature (3) would be most relevant in direct feedback to guide the actual ablation process.

A typical RF ablation procedure can involve a preliminary electroanatomical and ECG mapping of the heart, followed by catheter placement to a target site, ablation with RF power monitoring and catheter tip temperature monitoring, followed by more ECG mapping and possible attempts to re-induce fibrillation to test the effectiveness of the treatment. The catheter tip temperature (derived from a thermocouple embedded in the catheter tip) can vary from the actual tissue temperature and can present temperatures significantly higher or lower than the actual ablation tissue temperature. An approach which can provide actual tissue temperature can better guide the clinician in RF ablation (Figure 1).

The principal objective of this work is to describe for the first time a catheter based construction and method to obtain *in vivo* thermal strain echo data. This approach may yield the true tissue temperature during ablation to provide the much needed procedural feedback to avoid both under-treatment as well as excessive treatment of an ablation site in the patient's heart.

I. ULTRASOUND GUIDED ELECTROPHYSIOLOGY

A. *Microlinear ICE Catheters*

The efforts of our bioengineering research partnership have concentrated in the creation of several types of integrated imaging catheter designs specifically for use in electrophysiology therapy guidance. The smallest array device is known as the "microlinear" (ML) which currently exists as a 9F (3 mm) forward imaging catheter with bidirectional steering and at least two tip region electrodes, one for EP mapping and the other for distal tip ablation capability (Figure 2). The catheter and array general construction have been described before [7, 8] and have proven to be useful in imaging a specific intracardiac site when coupled with electroanatomical guidance.

The ML catheter metal ablation tip surrounding the periphery of the distal imaging array is intended allow radio-frequency ablation (RFA) while imaging simultaneously. This construction however has an inherent difficulty due to contradictory requirements: the best ablations are performed with a reasonably large contact footprint with a metal electrode, and the best means to guide the ablation is to view the ablation site at close proximity. Ideally one would "see through" a metal ablation tip. The method used to achieve this is described in the following section.

II. METHODS

A. *Two ML Catheter Designs: ML-PZT and ML-CMUT*

Two companion catheter designs have been made; both have imaged very well. The devices are true 9F in catheter profile, and both use a 24-element ultrasound array at the tip, but the arrays are built with entirely different materials and methods. The piezoceramic based array material design, the "ML-PZT" is designed with a 120 microns thick 2-2 composite with front side matching layers of the 25 micron thick polyimide flex circuit and a 10 micron thick parylene layer. The "ML-CMUT" array is 24 elements as well, with 10% less aperture area of that used by the ML-PZT. [9]

Figure 2. The microlinear (ML) general design format as a 9F (3 mm) catheter with a 24 element 14 MHz phased array at the tip. The steerability and multiple electrodes permit good endocardial positioning and operation with the electroanatomical mapping system used.

B. *Ultrasound Compatible RF Ablation Tip Design*

As thin metal layers are commonly used in transducer design stacks, it is reasonable to consider a sufficiently thin metal acting as a metal RF electrode which can permit the passage of high frequency ultrasound, even at 14 MHz. This electrode metal would need to be supported by a material which is strong enough to maintain its shape and retain the metalization layer, but also be transparent to ultrasound. A very thin gold layer has been applied to a machined TPX® (Mitsui Chemical, Japan) "cap" which can be mounted very easily to the distal tip of the ML catheter (Figure 3).

TABLE I. ACOUSTIC IMPEDANCE FOR THREE VARIETIES OF TPX

	MX002		MX004		RT18	
Freq.	**Vel.**	**Z**	**Vel.**	**Z**	**Vel.**	**Z**
MHz	*m/s*	*MRayls*	*m/s*	*MRayls*	*m/s*	*MRayls*
6	1927	1.59	1820	1.49	1720	1.41
8	2019	1.67	1980	1.62	1865	1.53
10	2080	1.72	2095	1.72	1965	1.61
12	2120	1.75	2175	1.78	2035	1.67
14	2150	1.78	2240	1.84	2085	1.71

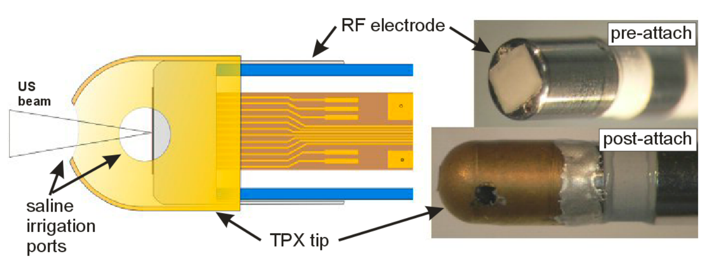

Figure 3. The position of the cMUT arrray mounted on the folded flex circuit is shown at the top with the unique through-wafer via to allow top trace communication with the flex pads. The lower right is a mock-up of the final assembly with metal tip enclosure.

The TPX tip cap is approximately 75 microns in thickness with a multiple metal layer structure sputtered on the cap exterior at thickness of approximately 1 micron. The metal layer resistivity was measured to be close to the theoretical value which provided ample current carrying capacity for use in preliminary bench experiments to ablate *ex vivo* tissue samples. Both the TPX and metal survived aggressive repeated bench ablations. Several varieties of TPX have been assessed for acoustic velocity near the 14 MHz operating frequency used by the ML catheters with measured densities of 826.5, 819.6, and 819.3 Kg/m^3 for MX002, MX004, and RT-18 respectively. The impedance data are given in Table I and plotted in Figure 4. Using typical values for cardiac tissue velocity and density, [10] and best acoustic impedance should be approximately 1.68 MRayls, which is shown as dots in Figure 4. RT-18 appears to be closest to this desired impedance in the principal frequency range of operation.

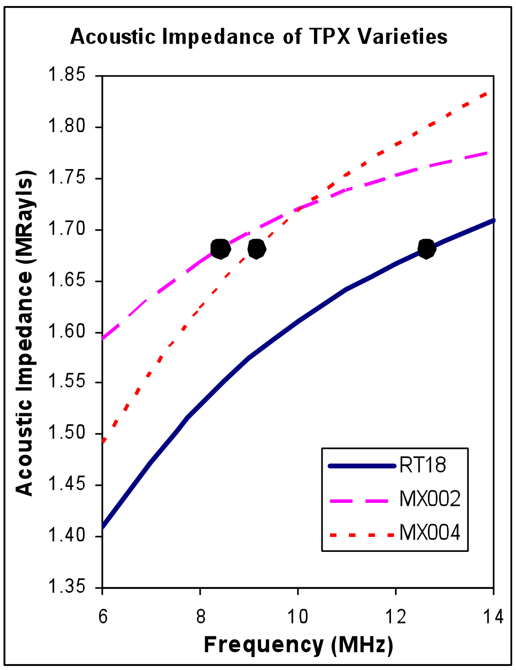

Figure 4. Acoustic impedance estimates from laboratory data. Both density and frequency dependent velocity characteristics were measured for these types of TPX. The densities measured are provided in the text.

C. Thermal Strain Methodology

Thermal strain imaging has been in development for some time by various groups [11, 12]. If the mechanical strain effects due to natural heart motion, etc. can be largely eliminated through appropriate signal processing methods, the small apparent tissue "strain" (~ 0.5% per degree C) due to the change in acoustic velocity with temperature change can be used for the extraction of tissue temperature status.

The TS processing used data sets of four continuous frames of RF echo data, taken at 11 F/sec (in color mode) using the Vivid-7 (GE Vingmed, Horten, Norway) imaging system. Reference frames were selected and 2-D cross-correlation was performed as well as 2-D speckle tracking to confirm echo registration. These four displacement sets were averaged to produce the measured axial displacement assessment. Finally in "fast time," the spatial derivatives of the displacements were computed to estimate temporal strains due to the sound speed changes from axial displacements using a simple 1-D difference filter along the axial direction for correlation windows separated by 0.9 mm.

Bench collected thermal strain data are shown in Figure 5, from which we could estimate both our TS sensitivity, but also the very interesting inflection point near 50 C. This inflection point can potentially be useful in the temperature feedback data set for the clinician. In addition, a FEA model (COMSOL Multiphysics, COMSOL, Inc., Burlington, MA) using electric fields and the bioheat equation was assembled to make an assessment regarding the expected depth of heating. This depth is quite shallow for peak temperatures; the simulation shows the maximum temperature during an ablation will exist at only about 0.5 mm from the tip in the myocardium (Figure 6).

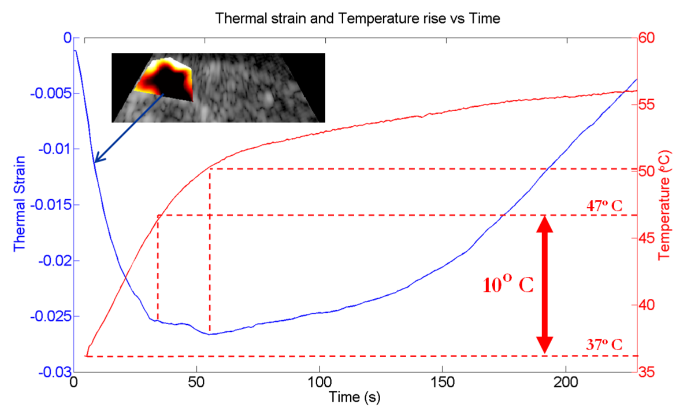

Figure 5. *In vitro* TS data which show an initial quasi-linear strain region as the termperature rises followed by a distinct inflection point near 50C.

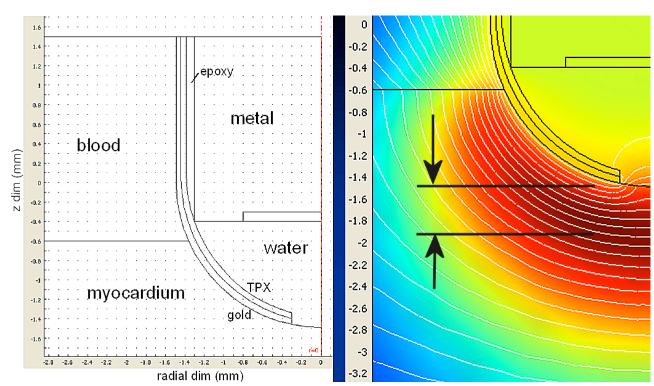

Figure 6. An axisymmetric FEM simulation showing the very shallow peak heating in tissue from an RF ablation tip, in this case with the TPX design.

III. Results

A. In Vivo Imaging of ML Catheters

The specially designed ML catheters were tested in five porcine models (35 – 45 kg) under general anesthesia and mechanical ventilation. Oxygen saturation and ECG were monitored continuously throughout the study. Access was obtained via femoral veins and arteries, as well as jugular veins. The Vivid-7 system was used as the imaging platform for the tests. Figure 7 shows clearly the excellent imaging performance with these very small aperture arrays, even with the presence of the TPX tip.

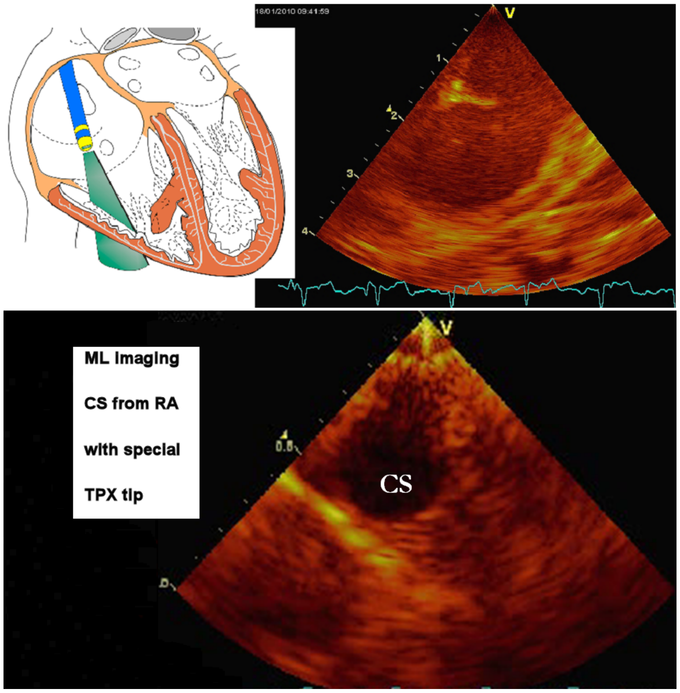

Figure 7. ML catheter imaging without (top) and with (bottom) the TPX tip for RF ablation. The top image view from the RA past the tricuspid valve shows very good resolution even at 4cm of penetration, while the lower image with the TPX tip shows the coronary sinus (CS) at about 0.35cm in depth with very good resolution in the near field and only minor TPX tip artifacts.

B. *In Vivo Thermal Strain During RF Ablation*

High quality b-mode imaging simultaneously with ablation in the pig heart with very little artifact or noise interference enabled successful echo acquisition for use in off-line TS processing. One result is provided in Figure 8.

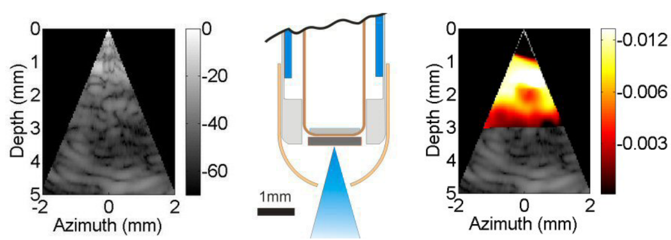

Figure 8. Thermal strain (TS) results from data collected simultaneously with the process of RF ablation. The far left panel shows an unprocessed b-mode frame, the middle is a graphic of the tip construction, and right is the TS off-line processing result overlaid on the b-mode image showing at least 1.2% peak strain magnitude. Note that the catheter in the heart chamber is very likely to have touched the endocardial wall at an oblique angle creating an interesting asymmetrical TS colorized pattern.

IV. Discussion

Although some difficulties with the acquisition of good quality ECG were encountered which would have improved the data processing, the TS echo data could be isolated from mechanically created tissue strains without major problems. In one experiment we used a thermocouple embedded in the TPX tip itself to acquire true tissue surface temperatures in an effort to validate the assumptions regarding the coefficient which relates the TS to actual temperatures. Work to extend this effort for *in vivo* validation is underway. Future designs of these catheters will make full use of the saline flushing of the TPX tip; the tips used thus far were simply preloaded with water before use in animal experiments.

V. Conclusions

For the first time, simultaneous ultrasound imaging and RF ablation with the same device has allowed the collection of high quality TS echo data. Future use of this technology may significantly benefit the clinician seeking to monitor closely the extent of ablation lesion formation during interventional treatment of cardiac arrhythmias.

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