Integrated Catheter for 3-D Intracardiac Echocardiography and Ultrasound Ablation

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Abstract—A catheter device with integrated ultrasound imaging array and ultrasound ablation transducer is introduced. This device has been designed for use in interventional cardiac procedures in which the cardiac anatomy is first imaged using real-time three-dimensional (3-D) ultrasound, then ablated to treat arrhythmias. The imaging array includes 112 elements operating at 5.4 MHz arranged in a 2-D matrix. Individual elements have a bandwidth of 21% and an insertion loss of 80 dB. The array has an azimuth resolution of 12° and an elevation resolution of 8.7°. The ablation transducer is a concentric piezoelectric transducer PZT-4 ring (outside diameter (O.D.), 4.5 mm, inside diameter (I.D.), 3.1 mm) operating at 10 MHz that surrounds the imaging array. It can produce a spatial-peak, temporal-average intensity up to 16 W/cm². The entire device fits into a 9 Fr lumen with a 14 Fr tip to accommodate the ablation ring. With this device we have imaged, in real-time 3-D, a variety of targets including wire phantoms, fixed sheep hearts, and fresh bovine tissue. The ablation ring has been used to heat tissue-mimicking rubber 14°C, as well as create lesions in fresh bovine tissue.

I. INTRODUCTION

Atrial fibrillation (AF) is the most common cardiac arrhythmia. This disease affects up to 2 million Americans with 160,000 new cases every year, and it is associated with both increased morbidity and mortality [1]–[3]. Radiofrequency (RF) catheter ablation is the most widely used treatment for AF. It seeks to block conduction of arrhythmic electrophysiological waves from the sites of AF initiation and maintenance (usually in or near the pulmonary veins) to other parts of the atria by creating transmural lesions in the left atrial wall [4]. A catheter with multiple electrodes 4–8 mm in length is positioned in contact with the left atrium. An RF generator produces up to 50 W of power at 300–1000 kHz, which travels from the electrodes through the body and into a dispersive ground pad on the patient’s skin [5]. Resistance in the interface between the catheter tip and the heart tissue causes heating; keeping the electrode tip at 50–65°C for 30–60 seconds creates lesions [5]–[7]. Catheter placement within the heart usually is performed under fluoroscopic guidance. Long procedure times associated with RF catheter ablation increase the risks associated with long-term exposure from ionizing radiation to the patient as well as medical personnel. Additionally, RF ablation is associated with stenosis of the pulmonary vein.

In an attempt to reduce fluoroscopy exposure, researchers have used intracardiac echocardiography (ICE) to visualize heart anatomy during RF catheter ablation procedures. A 9 Fr, 9-MHz, rotating single-element catheter (EP Technologies, Boston Scientific Corp., San Jose, CA) produces a radial scan useful for imaging a cross section of the pulmonary veins [7]. (The outside diameter of a lumen is measured in French, or Fr, 1 Fr ≈ 0.33 mm). After the ablation is performed, ultrasound is used to monitor for stenosis of the vessel. A 10 Fr, 5.5–10 MHz, phased array ultrasound catheter (Acuson Corp., Mountain View, CA) also has been used to guide RF ablation [8]. In this case the ultrasound catheter is kept in the right atrium where it can image both atria and the RF catheter. Both of these commercial devices are limited to planar B-scan images.

In real-time, 3-D (RT3D) imaging, a 2-D array transducer is used to steer and focus the ultrasound beam over a pyramidal volume [9], [10]. The Model 1 commercial ultrasound system (Volumetrics Medical Imaging, Durham, NC) can acquire this pyramidal volume and display up to five simultaneous image planes from within this volume, as well as RT3D rendered images. Clinical and animal evaluations have shown potential advantages over conventional 2-D scanners for measurement of cardiac function in terms of ventricular volumes [11], peak left ventricular flow velocities [12], and perfusion [13]. In intracardiac RT3D imaging, the 2-D array is built into a catheter that then is guided into the heart. Several RT3D catheters have been described by our laboratory; a 5 MHz, 12 Fr side-viewing device [14], [15], a 7 MHz, 9 Fr side-viewing device [16]; and most recently, 5 MHz, 14 and 22 Fr forward-viewing devices with integrated working lumens [17]. These catheters have visualized heart anatomy, including pulmonary vein ostia, and been used to guide a number of surgical procedures in vivo in sheep, including RF ablation.

Catheter-delivered ultrasound also has been investigated for use in performing the actual ablations necessary to treat AF. The amount of energy transferred from the acoustic wave to the tissue is directly proportional to both the intensity of the wave and the absorption coefficient of the tissue [18]. Thus, if the ultrasound ablation transducer transmits into a medium with low absorption (e.g., water, blood), unlike RF ablation the catheter tip need not be in direct contact with the myocardium. Zimmer et al. [19] created transmural lesions in canine cardiac tissue using transducers producing spatial-average,
temporal-average intensities ($I_{SATA}$) of 5–15 W/cm² for 60 seconds. A commercial ablation transducer (Atrionix, Inc., Sunnyvale, CA) was reported to have created circumferential lesions in human pulmonary vein ostia after a 2-minute ablation procedure [20]. These researchers also have reported a lack of pulmonary vein stenosis after ultrasound ablation. In animal studies, Azegami et al. [21] used ICE to assess pulmonary vein size before and after ultrasound ablation. The maximum power applied to the ablation transducer was 40 W for 30–240 seconds. Most recently, Meininger et al. [22] reported successful circumferential lesion creation outside canine pulmonary veins using a circular transducer (Transurgical, Setauket, NY) emitting 40 W acoustic power for 30-120 seconds.

This paper describes a combined catheter capable of both RT3D ICE and ultrasound ablation [Fig. 1(a)]. Such a device could greatly simplify cardiac procedures in which the heart anatomy must first be imaged then ablated, such as to treat AF. A clinical device must image both the cardiac chambers and pulmonary vein ostia and create transmural lesions at targeted locations. Previously, we described a combined 12 Fr, side-viewing catheter with a 5 MHz imaging array, adjacent to a 10 MHz ablation element, and five integrated electrocardiogram (ECG) electrodes [Fig. 1(b)] [23]. This device imaged wire phantoms and ex vivo bovine tissue. The ablation element produced a spatial-peak, temporal-average intensity ($I_{SPTA}$) of 30 W/cm². At this intensity, a 56-mm³ transmural lesion was created in the 7-mm thick bovine tissue. Because of the ablation element’s placement adjacent to the imaging array, direct visualization of ablation sites was difficult. Herein, we describe our efforts to improve on this device by increasing imaging resolution and designing the ablation beam and imaging volume to be coincident. In Section II we describe design and fabrication of a 14 Fr, forward-viewing catheter with a 5-MHz array for RT3D ICE and a 10-MHz ring transducer that fits around the imaging array [Fig. 1(c)]. In Section III, imaging of wire phantoms and an ex vivo sheep heart and ablation studies on phantom materials and ex vivo bovine tissue are described. In Section IV, our results are analyzed and future work is described.

II. Methods

A. Transducer Design and Fabrication

The imaging part of our combined transducer is based on a proven design [17]. As shown in Fig. 1(c), the imaging array (no shading) has 112 elements on a 150-µm pitch arranged in a 10 by 14 matrix. Each element operates at 5 MHz. In an earlier paper [24], the two-way acoustic beam from this array was simulated using Field II software (available for download at http://www.es.oersted.dtu.dk/staff/jaj/field) and found to have a −6 dB width of 12° in azimuth and 8.7° in elevation (Fig. 2). This transducer was built with methods
Fig. 2. Simulated imaging array beamplots in the elevation direction, left, and azimuth direction.

Fig. 3. Simulated ablation ring beamplot.

Fig. 4. Face of completed integrated imaging and ablation transducer.

described previously [25] using PZT-5H on a multilayer flexible interconnect circuit (MicroConnex, Snoqualmie, WA) backed by low impedance polymer ($Z = 3.8$ MRaysl, $\alpha = 1.1$ dB/mm/MHz). Sixteen ribbon cables with 14 conductors per ribbon [seven signal channels alternated with grounded conductors (Microflat, W. L. Gore & Associates, Pleinfeld, Germany)] were fed through a 9 Fr catheter lumen to electrically connect the solder pads on the flex circuit to the system cable of our 3-D scanner.

The size of the ablation transducer [light gray in Fig. 1(c)] was constrained by the design of the imaging array. A ring of grounded elements (dark gray) surrounds the imaging array, thus the minimum I.D. of the ablation transducer is 3 mm; our ring has a 3.1-mm I.D. The O.D. was chosen to be 4.5 mm, both to keep the overall diameter of the device small (14 Fr) and to ensure an electrical impedance well matched to our driving hardware. The transmitted acoustic beam of the ablation transducer was simulated using Field II software and found to have a $-6$ dB width of 2.0$^\circ$ and a $-20$ dB width of 22$^\circ$ (Fig. 3). A 10-MHz, PZT-4 ring (VP-A40, Boston Piezo-Optics, Inc., Bellingham, MA) was centered on the imaging array and epoxied to the flex circuit. The PZT-4 was chosen for the ablation transducer because its higher Curie temperature and lower dielectric losses make it more suitable for high-power applications in comparison to PZT-5H. Additionally, PZT-4 has a higher mechanical Q and fewer mechanical losses than PZT-5H. The ring was mounted on the imaging transducer so approximately half of it was backed by the multilayer, flexible interconnect circuit and backing epoxy with the remainder air backed. A miniature coaxial cable was run through the catheter lumen and soldered to the ring; the proximal end was terminated to a British Naval Connector (BNC) connector. Heat-shrink tubing approximately 1 cm long was used to transition from the smaller catheter lumen to the ablation ring and complete the device (Fig. 4). No matching layers were used for either the imaging array or the ablation transducer in this prototype device.
B. Transducer Characterization

The impulse response of the imaging array was measured by transmitting from one element with a Model 9073PR pulser/receiver (Panametrics, Waltham, MA) and receiving the reflection from an aluminum block with a nearby element. The power spectrum was measured using a Panametrics Model 5605A stepless gate and a Model 3588A spectrum analyzer (Hewlett-Packard, Palo Alto, CA). The 50 Ω insertion loss of individual elements operating in both transmit and receive was measured by sending a pulse and receiving the echo from an aluminum block 5 mm in front of the transducer. The imaging resolution of the system/array was measured by using the 3-D scanner to image a 400-μm diameter sapphire sphere embedded in an acoustically transparent gel pad 4.7 cm from the transducer. The brightness of the reflection from the sphere was captured in a C scan parallel to the transducer face. A cross section of this image, which approximates the system beam plot of the array, was compared to a Field II simulation of the array in which dead elements, element bandwidth, and distance between transducer and target were taken into account. The parallel processing performed by the 3-D scanner widens the beam in comparison to the simulation beam [9], [10]. This effect was not included in the simulation.

The electrical impedance of the ablation ring transducer was measured with a Hewlett-Packard 4194A impedance analyzer. In subsequent experiments, the ablation transducer was excited by a signal source (Hewlett-Packard 8165A) producing small-amplitude (<0.5 V), high-frequency bursts with arbitrary cycle length and pulse repetition frequency (PRF). These bursts were amplified by an RF power amplifier with 50 dB of gain (Model 525 LA, ENI, Rochester, NY). Between the amplifier and the transducer, a power meter (Model NRT, Rohde & Schwartz, Munich, Germany) measured the power available from the amplifier (forward power) as well as the power reflected from the imperfectly matched transducer (reverse power). The width of the ablation beam was measured by scanning a Model 804 calibrated membrane PVDF hydrophone (0.6-mm spot diameter, Sonic Technologies, Hatboro, PA) in a plane parallel to the transducer face and recording the voltages as measured with a Model 744A digitizing oscilloscope (Tektronix, Wilsonville, OR). After finding the peak voltage at a range of 2 cm, the magnitude of the voltage along four radii was measured and averaged. The same setup was used to find the $I_{\text{STA}}$ produced by the ablation transducer according to the procedures outlined by the Center for Devices and Radiological Health of the FDA [26]. Intensity was measured first as a function of frequency in order to find the optimum center frequency of the device at which the least amount of power is reflected from the transducer. Then intensity was measured as a function of the number of cycles in the excitation burst. The PRF was 10.3 kHz for all of the above experiments.

C. Measurements

Our device was used to image the AIUM 100-mm wire phantom with the Volumetrics scanner displaying both 65° and 90° pyramidal fields of view. Next, the ability of the device to visualize heart anatomy was tested by imaging a fixed sheep heart with a 90° field of view.

The ability of the ablation transducer to create lesions was first tested in a tissue phantom material (polyvinyl alcohol cryogel and graphite [27]) with an attenuation coefficient of approximately 0.5 dB/cm/MHz. Five type T thermocouples (0.127-mm diameter wire, 5TC-TT-T-36-36, Omega Engineering, Stamford, CT) were embedded in the 2-cm thick, tissue-mimicking rubber as shown in Fig. 5. The ablation transducer was suspended in water so that it was above the phantom. A digital multimeter/data acquisition system (Model 2700 with 7708 multiplexing module, Keithley Instruments, Cleveland, OH) under the control of a laptop computer running LabVIEW software (National Instruments, Austin, TX) was used to collect temperature data from all five thermocouples once the signal source had been enabled. After a selected amount of time passed, the thermocouples stopped measuring and the temperature data was passed from the multimeter to the computer for display. For these experiments, the signal source was set to produce 500 cycle bursts with an amplitude of 0.2 V and a frequency of 10 MHz with a PRF of 10.2 kHz. The total duty cycle of the excitation pulse was 51% and the transducer was powered for 60 seconds. The ablation transducer was first positioned so that it was nearly touching the phantom, then a second procedure was run with it positioned 5 mm above the rubber.

The ability of the ablation transducer to produce lesions in ex vivo beef muscle was tested. A hole 12 mm in diameter was bored in a piece of beef 12–13-mm thick to approximate an ostium in the wall of the myocardium. For these first experiments, we approximated a degassed system by using deionized water and massaging the tissue to remove air bubbles. The catheter was suspended above the beef and the Volumetrics scanner was used to image the model. Then, the device was lowered to the surface...
of the beef, and the ablation transducer was used to create a lesion near the lumen. The signal source was set to produce 300 cycle bursts with an amplitude of 0.2 V and a frequency of 10 MHz with a PRF of 17.6 kHz. The total duty cycle of the excitation pulse was 53%, and the ablation lasted for 2 minutes. In total, three lesions were created. The catheter was raised to its original position, and the model was again imaged.

III. Results

A. Transducer Characterization

The typical impulse response of an imaging array element is shown in Fig. 6(a). Fig. 6(b) shows the corresponding power spectrum. The elements had a center frequency of 5.4 MHz and a −6 dB bandwidth of 21%. Without accounting for diffraction losses, the average of 50 Ω insertion loss measurements of six pairs of elements was 80 dB. The azimuth and elevation beam profiles at a depth of 4.7 cm were measured using the C scan image of the sapphire bead and compared to beam profiles simulated with Field II (Fig. 7). In the azimuth direction, a −6 dB width of 1.1 mm was measured compared to 0.83 mm for the simulated beam. In the elevation direction, a −6 dB width of 8.7 mm was measured as compared to a predicted width of 5.8 mm.

The ablation ring transducer had an impedance of 89 Ω at the parallel resonance (10.1 MHz) of the thickness mode. This was a good match to the 50 Ω output impedance of the power amplifier, so no electrical matching was used. The resonance at 2.55 MHz is caused by vibration in the width of the ring. In Fig. 8, the measured and simulated beam profiles of the ablation ring at a distance of 2 cm are compared. The measured beam had a −6 dB width of 1.1 mm compared to 0.83 mm for the simulated beam. The optimum center frequency of the ablation transducer was 10.0 MHz. At this frequency the amount of power reflected from the transducer varied from 14% at low duty cycle (1%, or 10 cycles per burst) to only 6.8% at high duty cycle (52%, or 500 cycles per burst). The low reflected power may indicate an even better match to 50 Ω during high-power operation. The maximum ISPTA measured in this study was 16.1 W/cm² at 500 cycles per burst. At that intensity, the amplifier provided 5.9 W to the transducer according to the power meter. In Fig. 9, both ISPTA and forward power are plotted as a function of burst length. Forward power increases linearly with burst length, as expected, but ISPTA is linear only up to 100 cycles per burst.

B. Tissue Phantoms

Fig. 10 shows images of the AIUM wire phantom taken with the catheter 2-D array. Fig. 10(a) shows a schematic of the phantom with the separation of the wires. Fig. 10(b)
Fig. 8. Comparison of experimental and simulated ablation beam profiles.

Fig. 9. Ispta and the electrical power available to the transducer are shown as a function of the number of cycles per burst.

shows an axial view of the wires. In Fig. 10(c) a lateral view in the elevation direction is shown. The two wires 1 mm apart are not resolved in this view. Fig. 10(d) shows a RT3D rendered view of the wires. In Fig. 11, images of the fixed sheep heart are shown. The catheter was positioned in the right ventricle (RV) of the heart and was able to clearly image the RV, the left ventricle (LV) and the septum separating the two chambers of the heart.

With the ablation transducer just above the tissue-mimicking rubber, it was able to raise the temperature of the tissue-mimicking rubber by 14°C as shown in Fig. 12(a). The numbering of the traces refers to the numbering of the thermocouples in Fig. 5. Fig. 12(a) shows that thermocouple 3, directly under the ablation transducer, reached a steady-state temperature change of 14°C in 45 seconds. Thermocouples 2 and 4 reached a temperature change of approximately 7°C, and thermocouples 1 and 5 only recorded a temperature rise of a few degrees. Fig. 12(b) shows the temperature rise achieved when the ablation transducer was positioned 5 mm above the absorbing rubber. In this case, thermocouple 3 was heated only 8°C, thermocouples 2 and 4 were heated 3°C, and thermocouples 1 and 5 were heated only a few degrees each. For both of these experiments, the amplifier was providing 5.4 W of forward power with 5% of that reflected.

In Fig. 13, the results of our combined imaging and ablation experiment are shown. Figs. 13(a) and (b) are a B-scan and C-scan, respectively, of the hole in the beef. Fig. 13(c) shows the results of one of the ablation experiments. The three lesions had an average depth of 1.3 mm (standard deviation = 0.6 mm), an average diameter on the surface of 4.1 mm (standard deviation = 0.9 mm), and an average volume of 15.8 mm³ (standard deviation = 1.4 mm³). No images were viewable during the ablation procedure due to interference from the ablation signal, and the postablation images looked no different from those in Figs. 13(a) and (b). During the ablation procedure, the amplifier provided 5.8 W of forward power with 14% reflected.

IV. Discussion

We have developed a prototype catheter with integrated RT3D ICE and ultrasound ablation that may be useful in interventional cardiac procedures in which the cardiac anatomy is first imaged then ablated to treat arrhythmias. We have presented images made by this device of a wire phantom, a fixed sheep heart, and fresh bovine tissue. The imaging array has resolution sufficient for the visualization of important cardiac anatomy, such as the cardiac chambers and septum. The ablation transducer has heated tissue-mimicking rubber by 14°C. We have shown that this heating is adequate for creating lesions in bovine muscle.

The current prototype design leaves room for improvements in many areas. Imaging array resolution and sensitivity can be improved by increasing imaging frequency [16] and by using matching layers, respectively. In order to more directly monitor the ablation procedure, an ECG electrode and thermocouple could be introduced in the face of the transducer. The electrode would monitor for the cessation of arrhythmia that should accompany cell death, and the thermocouple would monitor temperature at the transducer face. Research has shown that temperatures on the tissue surface in excess of 60°C enhance the success of ultrasound ablation [28]. This thermocouple also would be used to ensure that the temperature at the transducer surface never exceeds 100°C, the point at which the blood boils. A lower operating temperature also extends the life of the piezoelectric material in the ablation ring transducer. Furthermore, in an attempt to simplify the construction of this prototype catheter, we have not used any acoustic matching layers or electrical impedance tuning of the ablation ring, which could increase the acoustic output of the device.
V. SUMMARY

One main limitation of the device is its size. The 9 Fr lumen is small enough for clinical use. By placing the ablation transducer around the imaging array, we have ensured that the ablation site is in the device’s field of view, but we have made the tip too large (14 Fr) for routine use in the clinic. One possible solution to the problem of device size would be a single 2-D array for both imaging and ablation. In imaging mode, the new array could be slightly larger than the array presented here, improving imaging resolution. Higher ablation $I_{SPTA}$ also would be possible because of the increased surface area devoted to ablation and focusing of the ablation beam. An additional advantage is that the ablation beam could be steered in 2-D to create lesions of nearly any size or shape. Of course, such a device would use the same piezoelectric material for both imaging and ablation. If conventional PZT ceramics (like PZT-5H and PZT-4 presented here) were used either imaging or array performance will be compromised.

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Fig. 12. Temperature rise versus temperature in the five thermocouples shown in Fig. 5 and with the ablation transducer (a) nearly touching the absorbing rubber, and (b) 5 mm above the absorbing rubber.

Fig. 13. (a) Image of beef tissue with 12-mm diameter hole. (b) C-scan of hole in beef tissue. The arrows in (a) indicate the plane of this C-scan. (c) Photograph of lesion to the left of the hole.

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