Catheter Ultrasound Phased-Array Transducers for Thermal Ablation: A Feasibility Study

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The feasibility of catheter single-element ultrasound transducers for cardiac ablation has been shown previously. We describe the design and testing of catheter-sized linear phased arrays transducers for ultrasound ablation. One array has 86 PZT-4 elements operating at 8 MHz and 5 MHz. The overall array size is 14.9 mm by 3.1 mm (10 Fr). The other array has 50 PZT-5 elements operating at 4 MHz and is 17 mm by 3.1 mm (10 Fr). In order to produce the intensity needed to create lesions in heart tissue, we modified a real-time, 3D scanner to produce 100 V peak-to-peak, 256-cycle transmit pulses at a pulse repetition frequency of 14.1 kHz. This made it possible for the PZT-4 and PZT-5 transducers to produce $I_{SPTA}$ of 3.26 W/cm$^2$ and 142 W/cm$^2$, respectively. When driving the transducers at high duty factor, the transmit circuitry in the scanner was damaged. A mechanically-focused transducer with the same dimensions as the PZT-4 transducer was built. When transmitting continuously at 9 MHz, it produced an $I_{SPTA}$ of 29.3 W/cm$^2$. This created a lesion 5 mm across and 5 mm deep in beef tissue while raising the focal temperature 23°C. Ablation is within the capabilities of a catheter phased array transducer integrated into a diagnostic ultrasound scanner.

Key words: Catheter transducer; ultrasound ablation.

I. INTRODUCTION

Several researchers have shown the feasibility of using catheter-delivered ultrasound to ablate cardiac tissue for treatment of arrhythmias.\(^1\)\(^,\)\(^2\) This technology is being explored as a replacement for the current method of using intracardiac radiofrequency (rf) catheters to ablate the site of arrhythmia. For rf ablation, typically 50 W of power is delivered for up to 60 s per ablation site.\(^3\) Initial clinical studies using ultrasound ablation catheters have shown that 40 W of acoustic power applied for 30-120 s can create circumferential lesions in the pulmonary vein ostia in the left atrium.\(^4\) Experimental animal studies have also demonstrated the efficacy of using ultrasound ablation catheters transurethrally for treatment of the prostate. Here individual lesions are created by applying 20 W of acoustic power for 90 s.\(^5\)

We have previously described two generations of devices integrating real-time, three-dimensional ultrasound imaging and ultrasound ablation: a 12 Fr (outside diameter = 4.0 mm) side-viewing catheter with a 5 MHz imaging array adjacent to a 10 MHz ablation piston transducer and five integrated electrocardiogram electrodes\(^6\) (Fig. 1a) and a forward-viewing 14 Fr (outside diameter = 4.5 mm) catheter with a 5 MHz imaging array and a 10 MHz

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PZT-4 ablation annulus (outside diameter of 4.5 mm and inside diameter of 3.1 mm) placed around the imaging array (Fig. 1b).

These earlier devices produced spot lesions with diameters on the order of 4 mm after 60-120 s ablation.

The basic design includes a 112 element, 5 MHz imaging array for PZT-4 ablation annulus (outside diameter of 4.5 mm and inside diameter of 3.1 mm) placed around the imaging array (Fig. 1b). These earlier devices produced spot lesions with diameters on the order of 4 mm after 60-120 s ablation.

The treatment of arrhythmias in the atria frequently requires the creation of linear lesions in the myocardium 3 mm wide and up to 2 cm long using rf techniques. Therefore in a recent work, using computer simulations we examined designs for a side-looking, linear phased array catheter transducer to produce linear lesions by scanning a distance of 2 cm from the target tissue (Fig. 2). The basic design includes a 112 element, 5 MHz imaging array for...
real-time, three-dimensional imaging. This array is in the middle of two 43 element, 8 MHz linear phased arrays, which, in combination, transmit an ablation beam that can be focused and steered in the azimuth direction, i.e., along the length of the catheter, to create linear lesions. We estimated that such an array could produce a spatial-peak, temporal-average intensity ($I_{SPTA}$) of 25 W/cm$^2$ when focused through 2 cm of blood and 42 W/cm$^2$ when focused through water. Finite element analysis (FEA) further showed that in the latter case, the temperature rise in tissue at the focus (18.4°C after 120 s) is adequate for producing a lesion as determined using a thermal dose model.$^{12,13}$

In this paper, we describe our efforts to experimentally confirm our FEA findings in water by building a linear phased array transducer and connecting it to our Model 1 real-time, 3D ultrasound scanner (Volumetrics Medical Imaging, Durham, NC) for steering and focusing.$^{14,15}$ We describe building and testing two array designs, one operating at 8 MHz and one operating at 4 MHz. Additionally, we explain modifying the scanner to produce higher power and measuring acoustic output from the arrays while driven by the scanner. In Results, we report our findings from the two arrays and the modified scanner. In the Discussion section, we investigate some problems we experienced using the scanner, and report on a mechanically focused array. Finally, we conclude with some thoughts on possible future work.

II. METHODS

Scanner modification

The typical pulses used in diagnostic ultrasound imaging are 1-10 cycles long with a pulse repetition frequency (prf) around 1-15 kHz. Though the instantaneous intensity from these pulses may be high, due to their low duty factor the $I_{SPTA}$ produced in water is on the order of 1 W/cm$^2$. For example, the Model 1 scanner and a 5 MHz transthoracic 2-D phased array probe$^{16}$ produce an $I_{SPTA}$ of 782 mW/cm$^2$ when the scan depth is 10 cm (prf = 6.67 kHz) and the transmit pulse is 2 cycles long. This corresponds to a duty factor of less than 0.3%. As factory configured, the scanner’s maximum duty factor is only 6.4% at 5 MHz (32 cycle pulse with 10 kHz prf) but previous experience has shown that a duty factor of at least 50% is desirable for therapy. Therefore it was necessary to reconfigure the Model 1 scanner to produce pulses with a higher number of cycles and at a higher prf.

By changing the scanner’s software to decrease the minimum scan depth to 3 cm from 6 cm, we were able to increase the prf to 14.1 kHz. Increasing the number of cycles was more difficult, however, due to numerous safety checks built into both the scanner hardware and software. The user can vary the number of cycles per transmit pulse from 1 to 32, though the scanner limits the maximum to four when both the prf and transmit amplitude are high. This number is sent to a field programmable gate array (FPGA) controlling the transmit circuitry as a five bit number where it drives a series of five counters. Three counters (also controlled by the same five bit number) were added to the series, increasing the maximum number of cycles to 256. Then the safety checks were bypassed by using only the first two bits (i.e., one to four cycles per pulse) to control all eight counters and cover the new range of pulse lengths. The FPGA produces a pair of digital pulse trains, one as input for a positive-going amplifier and the other for a negative-going amplifier. Combined, these amplifiers produce the sinusoidal transmit pulse.

The Model 1 scanner is capable of transmitting at frequencies from 1.25 to 10 MHz. Our linear phased array design is in the upper end of this range, so we first measured the peak-to-peak transmit voltage across a 12kΩ resistor from a single channel across the range
of frequency. The scanner is incapable of transmitting at any selected frequency. Instead, because its master clock runs at 40 MHz and the transmit pulses must be an integer number of those cycles, the available frequencies are, for example, 5 MHz (8 clock cycles), 6.7 MHz (6 clock cycles) and 8 MHz (5 clock cycles). Additionally, the transmit voltage peaks at 2.9 MHz, and is 2 dB down at 4 MHz and nearly 10 dB down at 8 MHz.

**Phased arrays**

The total size of the 8 MHz linear phased array proposed in the previous paper is 3.1 mm in the elevation dimension by 14.9 mm in azimuth. To build an inexpensive prototype array, PZT-4 (840, APC International, Mackeyville, PA) with a 10 MHz nominal parallel resonant frequency (230 μm thick) was bonded to copper-plated polyimide with silver epoxy. The array and copper layers were then diced on a 150 μm (0.8λ at 8 MHz) pitch, resulting in copper traces electrically connected to the underside of each transducer element, but isolated from each other. Liquid crystal polymer (LCP) sputtered with 0.25 μm gold on one side was bonded to the top of all elements as a common ground layer. Rather than attempt to build the array into a catheter, this prototype was instead bonded to an aluminum substrate with a 5 mm deep groove milled into it. The array was positioned so that the transducer elements were over this groove, providing air backing to increase transmit efficiency. The layer thicknesses were used in KLM model simulations (PiezoCAD, Sonic Concepts, Woodinville, WA) of the transmit impulse response spectrum. To complete the transducer, the copper traces were wired to interface with the Model 1 scanner transducer handle.

Because of the low transmit voltages at high frequencies, a second prototype designed to operate at 4 MHz was also built. This second array used PZT-5H (TRS 610HD, TRS Technologies, State College, PA) with a nominal parallel resonant frequency of 5 MHz (360 μm thick) and was diced on a 300 μm (0.8λ at 4.0 MHz) pitch. Instead of aluminum, it was built on a polymer substrate with a 5 mm deep groove to provide air backing.

**Transducer characterization**

The transmit impulse response from several elements on both transducers was measured. A pulser/receiver (5073PR, Panametrics, Waltham, MA) excited individual elements. The signal was received on a calibrated PVDF membrane hydrophone (Model 804, Sonic Technologies, Hatboro, PA) positioned approximately 1 cm away and was saved with an oscilloscope (744A, Tektronix, Wilsonville, OR). A discrete Fourier transform was performed on the transmit impulse response to obtain the transmit spectrum for comparison to KLM simulation.

The I_{SPTA} from the two arrays was measured using the procedures outlined by the Center for Devices and Radiological Health of the Food and Drug Administration. The transducers were positioned in a water tank with the hydrophone at the focus. The scanner transmitted one line focused at 2 cm on-axis. With the prf set to the minimum 2.5 kHz, the transmit frequency was swept to find the maximum received pulse amplitude. At the maximum frequency, the number of cycles per pulse was increased from one cycle to higher values and the intensity was measured at each setting.

Finally, the transmit beam profiles of the transducer arrays at a 2 cm focus were measured in both azimuth and elevation by recording the peak-to-peak voltage as the hydrophone was swept in front of the arrays at steps of 0.1 mm. Additionally, the azimuth beam profiles were measured when the 4 MHz PZT-5H array was steered off-axis to angles of ±26.6°. (The distance between these two foci is 17.9 mm to simulate the production of a linear lesion by phased array scanning.) These results were compared to beam profiles simulated using the Field II program.
III. RESULTS

After bonding and dicing, the 8 MHz PZT-4 array had 86 working elements (Fig. 3) and the 4 MHz PZT-5H array had 50 working elements (Fig. 4) with the first five on one end shorted together. These yields were sustained through later fabrication steps. The transmit impulse response spectrum from the 8 MHz PZT-4 array showed two peaks (Fig. 5), one at 7.6 MHz with a –6 dB bandwidth of 6.5% and a smaller peak at 5.2 MHz with a –6 dB bandwidth of 12.8%. The KLM simulation shows reasonable agreement with three peaks; one at 4.6 MHz with 7.6%–6 dB bandwidth, one at 7.1 MHz with 5.6%–6 dB bandwidth and one at 11.2 MHz with 4.4%–6 dB bandwidth. The high and low frequency peaks originate in the backing layers of the transducer.

A typical transmit impulse response from the 4 MHz PZT-5H array transducer shows a peak at 4.4 MHz with 35.6%–6 dB bandwidth (Fig. 6). The KLM simulation of the element has two peaks, but also shows reasonable agreement with one at 4.7 MHz with 16.0%–6 dB bandwidth and one at 8.3 MHz with 10.8%–6 dB bandwidth.

By decreasing the minimum scan depth to 3 cm, the maximum prf was increased to 14.1 kHz. With the new maximum pulse length of 256 cycles, the maximum duty factor is 45.1% at 8.0 MHz and 90.2% at 4 MHz. This pulse has significant droop, however, because of sag in the power supply high voltage provided to the transmit amplifiers. Further, this sag is due to insufficiently large capacitors in the scanner’s high-voltage AC-to-DC converters. The last cycle of a 5 MHz 256-cycle pulse is approximately half of the amplitude of the first cycle.

The Model 1 scanner was used to drive the transducers at the minimum prf of 2.5 kHz as the transmit frequency was changed. The 8 MHz PZT-4 transducer produced a maximum peak-to-peak output voltage at 5 MHz and a local maximum at 8 MHz. The 4 MHz PZT-5H transducer’s maximum was at 4 MHz. We next attempted to measure the intensity with increasingly long pulse lengths. Unfortunately, even at the minimum prf longer pulses damaged the transmit circuitry in the scanner making some channels inoperable. Therefore,
FIG. 5 The impulse response spectrum from a typical element on the PZT-4 transducer shows a peak at 7.6 MHz. The –6 dB bandwidth is 6.5%. There is also a smaller peak at 5.2 MHz with a –6 dB bandwidth of 12.8%. The KLM simulation shows three peaks; one at 4.6 MHz with 7.6% –6 dB bandwidth, one at 7.1 MHz with 5.6% –6 dB bandwidth, and one at 11.2 MHz with 4.4% –6 dB bandwidth.

FIG. 6 The impulse response spectrum from a typical element on the PZT-5H transducer shows a peak at 4.4 MHz. The –6 dB bandwidth is 35.6%. The KLM simulation of the element shows a center frequency of 4.7 MHz and a –6dB bandwidth of 16.0%.
accurate $I_{spta}$ data with all transducer channels transmitting could only be collected at a maximum of four cycles after replacing the damaged transmitters. These values were extrapolated to the maximum settings possible on the scanner first by scaling $I_{spta}$ to 14.1 kHz instead of 2.5 kHz, and then by multiplying by 64 (to scale to 256 cycles) and dividing by 2 (because of the voltage droop). These results indicate that if the transmit circuitry had not failed, the scanner could achieve 3.26 W/cm$^2$ at 5 MHz with the PZT-4 transducer and 142 W/cm$^2$ at 4 MHz with the PZT-5H transducer (Table 1).

The focal on-axis beam plots from the 4 MHz PZT-5H transducer were measured in both elevation and azimuth and compared to simulated results (Figs. 7a, b). Because of its low intensity, no beam plots were measured from the 8 MHz PZT-4 transducer. The $-6$ dB beamwidth of the PZT-5H transducer is 0.74 mm in azimuth (compared to 0.63 mm simulated) and 3.4 mm in elevation (compared to 3.5 mm simulated). Azimuthal side lobes are 12 dB down at 1.0 mm and 11 dB down at $-1.1$ mm. This compares favorably to simulated side lobes $-8.5$ dB down at $\pm 0.8$ mm. The beam was then steered off-axis at angles of $\pm 26.6^\circ$ and the focal beam plot was measured and compared to simulation (Fig. 8). The $-6$ dB beamwidth when steered at a positive angle is 0.73 mm in azimuth (compared to 0.57 mm simulated). In the other direction, the measured $-6$ dB beamwidth is 0.76 mm, compared to a simulated value of 0.56 mm. Additionally, when steered off-axis the amplitude of the transmit pulses are 0.3 dB less than when on-axis. Contours of $-6$ dB beam widths for all three foci are plotted on the same axes in figure 9 (elevation beam width is assumed the same for all three foci) to illustrate a linear lesion produced by phased array scanning. The dimensions are 3.4 mm wide by 19 mm long which is good agreement with Olgin et al.\textsuperscript{9}

### IV. DISCUSSION

The ability of the transducers to produce adequate intensity for ablation was severely limited by the Model 1 scanner. The PZT-4 transducer was designed to operate at 8 MHz, but because of the air and other backing layers it also transmitted sound at 5 MHz. Due to the roll-off in transmit voltage over 3.5 MHz, this transducer actually produced higher intensity at the lower frequency. The 4 MHz PZT-5H transducer operated closer to the transmit peak of the scanner and its own resonant frequency and thus was able to produce much higher intensity. The measured and extrapolated intensity results were encouraging, and seemed to indicate that this transducer could produce enough intensity to produce a lesion in heart tissue, given a more robust scanner.

In order to test this hypothesis, a third transducer was built similar to the 8 MHz PZT-4 transducer. In the new transducer, the copper layer was only partly diced so that all of the elements are electrically connected on both top and bottom. Rather than bonding the

<table>
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<th>Transducer</th>
<th>Frequency MHz</th>
<th>Measured $I_{spta}$ W/cm$^2$</th>
<th>Extrapolated $I_{spta}$ W/cm$^2$</th>
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<td>PZT-5</td>
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FIG. 7 Measured beamplots (dots) are compared to beamplots simulated in Field II (solid) for the 4 MHz PZT-5H array steered on-axis. Azimuth (a) and elevation (b) plots are shown.

FIG. 8 The measured beamplots (dots) are compared to beamplots simulated in Field II (solid) for the 4 MHz PZT-5H array steered off-axis. The top plot (a) is of the beam steered to an angle of 26.6°. The bottom plot (b) is of the beam steered to an angle of –26.6°.
polyimide to an aluminum substrate with a groove, the transducer was bonded to the inside of an aluminum half-cylinder with a radius of 20 mm (Figs. 10a, b). As a result, all of the 86 transducer elements are mechanically focused 20 mm from the transducer face.

The mechanically-focused transducer was driven by a signal source (8165A, Hewlett-Packard, Palo Alto, CA) and amplifier (525 LA, ENI, Rochester, NY) at 9.0 MHz and the \( I_{SPM} \) was measured at a prf of 3.12 kHz and a range of cycles per pulse. The intensity is 5.1 W/cm\(^2\) at 500 cycles (Fig. 11). No intensity measurements were made during continuous wave operation to safeguard the hydrophone. When extrapolated to continuous wave operation, the intensity from the transducer is 29.3 W/cm\(^2\). Next, a thermocouple was embedded 2 mm deep in 8 mm thick beef tissue. The transducer was positioned so that the mechanical focus was just in the tissue and was driven continuously for 120 s. The thermocouple measured the temperature in the tissue every 15 s and the results compared favorably with our earlier FEA results (Fig. 12). This ablation procedure produced a lesion 3 mm across and 5 mm deep in 8 mm thick beef tissue. Figure 13 shows a photograph of a cross-section of the lesion with a dashed line denoting its extent.

Converting a diagnostic scanner to a combined ablation/imaging system places large demands on all components of the system. A successful phased-array ablation system must be highly efficient and be able to handle high average power transmission, rather than just high peak power as in a diagnostic system. There are numerous ways that the transducer efficiency might be increased. This would reduce the power drawn from the Model 1 scanner, possibly allowing it to be used without damage. For example, electrical matching could re-

**FIG. 9** The 4MHz PZT-5H transducer was steered on-axis and at ±26.6° off-axis. The –6 dB beam widths at each foci are shown indicating that it is possible to create a linear lesion 3.4 mm wide and 19 mm long by scanning the ablation beam within the dashed lines.

**Fig. 10** The radius of curvature of the mechanically focused transducer is 20 mm. The aperture is otherwise as shown in figure 3, except 5 mm thick aluminum replaces the air.
The mechanically-focused array produced a maximum $I_{SPTA}$ of 5.11 W/cm$^2$ at a prf of 3.12 kHz (solid markers). When extrapolated to 17.9 kHz, i.e., continuous wave operation at 500 cycles (dashed lines, empty markers), the mechanically-focused array produced a maximum $I_{SPTA}$ of 29.3 W/cm$^2$.

![Graph showing the relationship between cycles and $I_{SPTA}$](image)

**Fig. 11** The temperature at the focus of the mechanically-focused transducer (empty circles) rose 23°C in two minutes as measured by a thermocouple embedded in bovine tissue. These results compare favorably to those found using FEA in the previous paper cited in the text (solid line).

![Graph showing temperature change over time](image)

**Fig. 12** The temperature at the focus of the mechanically-focused transducer (empty circles) rose 23°C in two minutes as measured by a thermocouple embedded in bovine tissue. These results compare favorably to those found using FEA in the previous paper cited in the text (solid line).
duce the current drawn by the transducer elements and low-loss matching layers could better couple acoustic energy into the tissue. While the scanner was able to produce the needed transmit voltage on individual transducer elements, when the entire transducer was driven with long pulses at high prf the transmit circuitry was damaged. Additionally, the scanner was incapable of producing high frequency transmit pulses with large peak-to-peak voltage. Even within these limitations, however, the 4 MHz PZT-5H transducer was able to produce an intensity of 786 mW/cm$^2$ with a duty factor of 0.25%. As shown by the mechanically-focused transducer, an $I_{SPTA}$ of 29.3 W/cm$^2$ will produce a lesion. If the value measured from the 4 MHz PZT-5H transducer is extrapolated to a 256-cycle pulse (i.e., multiply by 64 and divide by 2), a prf of 2.9 kHz (duty factor of 19%) will transmit at that intensity. We have also shown an ability to steer the 4 MHz PZT-5H transducer off-axis without a substantial decrease in intensity or increase in beam width. Thus, the creation of a linear lesion 19 mm long by 3.4 mm wide is achievable.

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