Forward-Looking Intracardiac Ultrasound Imaging Using a 1-D CMUT Array Integrated With Custom Front-End Electronics

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***Abstract*—Minimally invasive catheter-based electrophysiological (EP) interventions are becoming a standard procedure in diagnosis and treatment of cardiac arrhythmias. As a result of technological advances that enable small feature sizes and a high level of integration, nonfluoroscopic intracardiac echocardiography (ICE) imaging catheters are attracting increasing attention. ICE catheters improve EP procedural guidance while reducing the undesirable use of fluoroscopy, which is currently the common catheter guidance method. Phased-array ICE catheters have been in use for several years now, although only for side-looking imaging. We are developing a forward-looking ICE catheter for improved visualization. In this effort, we fabricate a 24-element, fine-pitch 1-D array of capacitive micromachined ultrasonic transducers (CMUT), with a total footprint of 1.73 mm × 1.27 mm. We also design a custom integrated circuit (IC) composed of 24 identical blocks of transmit/receive circuitry, measuring 2.1 mm × 2.1 mm. The transmit circuitry is capable of delivering 25-V unipolar pulses, and the receive circuitry includes a transimpedance preamplifier followed by an output buffer. The CMUT array and the custom IC are designed to be mounted at the tip of a 10-Fr catheter for high-frame-rate forward-looking intracardiac imaging. Through-wafer vias incorporated in the CMUT array provide access to individual array elements from the back side of the array. We successfully flip-chip bond a CMUT array to the custom IC with 100% yield. We coat the device with a layer of polydimethylsiloxane (PDMS) to electrically isolate the device for imaging in water and tissue. The pulse-echo in water from a total plane reflector has a center frequency of 9.2 MHz with a 96% fractional bandwidth. Finally, we demonstrate the imaging capability of the integrated device on commercial phantoms and on a beating *ex vivo* rabbit heart (Langendorff model) using a commercial ultrasound imaging system.**

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[1] A unit of measure equal to one-third millimeter used in measuring the outside diameter of a tubular instrument.

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I. Introduction

Atrial fibrillation (AF), the most common sustained cardiac rhythm disturbance [1], now affects approximately 2.2 million adults in the United States alone [2], and this number is projected to increase to more than 5.6 million by 2050 [2]. Electrophysiology (EP) has proven valuable in providing information that is essential for effective diagnosis and treatment of cardiac arrhythmias. During an EP study, an electrophysiologist may provoke arrhythmia events and collect data about the flow of electricity in the cardiac muscle and generate an electrical mapping of the heart. These data help physicians to accurately locate the specific areas of the heart tissue that give rise to abnormal electrical impulses that cause the arrhythmia. As a result a proper treatment, which may include ablating the malfunctioning tissue, can be applied. EP tests are usually performed with multiple catheters equipped with EP electrodes. RF ablation, the most common method of ablation therapy, is also performed using catheters.

The most common method of catheter positioning and movement during therapeutical EP interventions is fluoroscopy. The radiation exposure involved with this guidance method is undesirable and hazardous for both the patient and the practitioner [3]. Various randomized clinical studies show that an exposure time of tens of minutes is not uncommon in interventional EP therapeutic procedures [4]–[6]. Besides its hazardous nature, fluoroscopy provides poor soft-tissue resolution; even with the use of contrast agents it does not provide adequate anatomical information for accurate catheter placement inside the heart [7]. Hence, the use of intracardiac echocardiography (ICE) for guiding EP interventions is gaining more attention.

In addition to benefits in reducing radiation exposure, ICE improves visualization in real time and enhances procedural guidance compared with fluoroscopy alone [8], [9]. The use of ICE not only reduces the risk of complications but also enhances the procedural success rate. ICE has also proven valuable in direct monitoring of acute procedure-related complications. For example, ICE can be used to monitor potential risks associated with ablation at the site of the pulmonary veins (PV), such as PV stenosis,

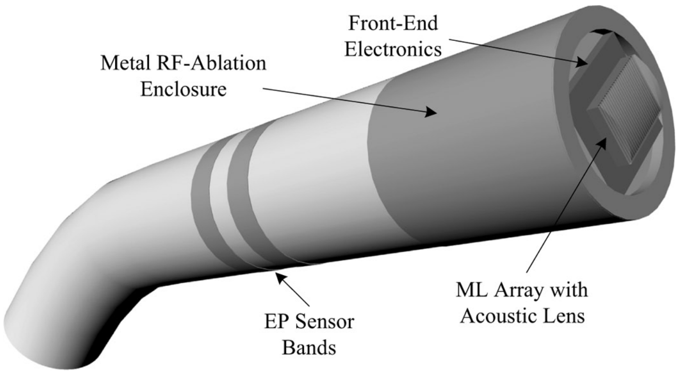


Fig. 1. Conceptual drawing of the proposed multifunctional EP-ICE catheter. This catheter is capable of forward-looking imaging and is equipped with EP and RF ablation capabilities. The custom front-end IC and the CMUT ML array are closely integrated at the tip.

thromboembolic complications, and perforation with pericardial tamponade [8], [10].

Phased-array ICE catheters have been available for several years now. A 10-Fr[1] phased-array imaging catheter has been used in several animal and clinical studies [11]–[13] since 2000 and in 2005 an 8-Fr version of the device (AcuNav, Siemens Medical Solutions USA, Inc., Mountain View, CA) was introduced. In these catheters, a piezoelectric transducer array is mounted on the side of the catheter for side-looking imaging. Limited available space and stringent packaging requirements challenge efforts to mount the transducer array at the tip of the catheter for forward-looking imaging, which is expected to enhance visualization in EP therapeutic interventions.

The existing piezoelectric transducer fabrication technology relies on meticulous and labor-intensive steps such as hand lapping, polishing, and high-precision dicing. The capacitive micromachined ultrasonic transducer (CMUT) technology, however, takes advantage of mature silicon integrated circuit (IC) fabrication techniques, which make it possible to fabricate CMUTs of different shapes and sizes on a single wafer (i.e., 1-D array, 2-D array, ring array). The ease of fabrication also extends to CMUT devices for high-frequency applications such as intravascular ultrasound imaging (IVUS), where a fine-pitch array of small elements is required. Compared with piezoelectric transducers, CMUTs offer wider bandwidth for improved resolution. Another advantage of this technology is its seamless tight integration with supporting electronic circuitry that can be achieved either monolithically [14]–[16] or through flip-chip bonding [17].

We are developing a multifunctional EP-ICE catheter that is not only capable of forward imaging but is also equipped with both EP and RF ablation capabilities (Fig. 1). This design utilizes a 1-D CMUT "MicroLinear" (ML) array mounted at the tip of the catheter for high-resolution, high-frame-rate, forward-looking imaging. To improve image quality, a custom-designed IC is closely integrated with the CMUT array. The catheter also incorporates several EP sensor bands near the distal tip and a metal tip enclosure for RF ablation. In this paper, we report on the characterization of the CMUT ML array integrated with the custom front-end electronics and also the imaging results of the assembly using a commercial ultrasound imaging system.

TABLE I. Design Parameters of the CMUT ML Array.

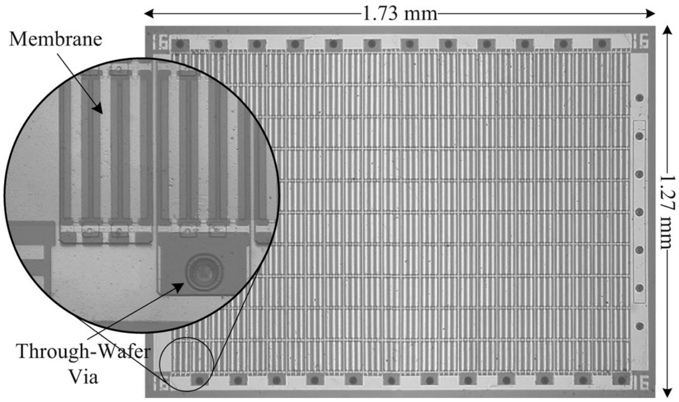
Array Design Parameters	
Number of elements in the array	24
Element pitch (µm)	63
Length of the element in elevation (µm)	1037
Width of the element in azimuth (µm)	51
Center frequency (MHz)	10
Cell Design Parameters	
Membrane thickness (µm)	0.50
Gap height (µm)	0.15
Insulating layer thickness (µm)	0.18

II. Design and Implementation

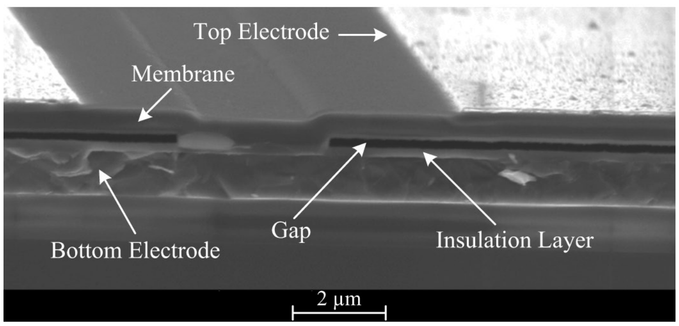
A. CMUT Array

The ML array is a 24-element, fine-pitch 1-D transducer array that was fabricated using CMUT technology. Some of the key design specifications of the fabricated arrays are summarized in Table I. The ML array is intended to operate around the center frequency of 10 MHz for high-resolution real-time intracardiac imaging. We chose the element pitch of 63 µm primarily based on the $\lambda/2$ spacing requirement to prevent grating lobes. Accordingly, we decided on a 24-element 1-D array smaller than 1.8 mm $\times$ 1.3 mm so that it could fit at the tip of a 10-Fr catheter. For the cell-level design of the CMUT array we used the linear CMUT equivalent circuit model [18], for which some of the parameters were derived using the analytical calculation of the membrane displacement [19].

We fabricated the CMUT ML array using the standard polysilicon sacrificial layer process with through-wafer via interconnects [20]. In this process, 400-µm-thick highly resistive ($\rho > 10{,}000$ Ω-cm) silicon wafers are used. The CMUT membranes are made of low-stress LPCVD silicon nitride. A layer of doped polysilicon in the through-wafer via creates the conductive path between the front and back sides of the wafer. A low-parasitic-capacitance isolation is provided between the interconnect and the highly resistive substrate through a metal-insulator-semiconductor (MIS) structure [21]. Through-wafer vias connect the common reference electrode and the individual signal electrodes of the array elements on the front side to the flip-chip bond pads on the back side. Flip chip bonding provides tight integration of the CMUT array with supporting electronic circuitry. Instead of the conventional wafer-saw dicing method, we used deep reactive ion etching (DRIE) to singulate the arrays. DRIE provides tight control over the device boundaries and is particularly advantageous for other array geometries such as the ring array [22]. The total footprint of the ML array measures 1.73 mm $\times$ 1.27 mm.

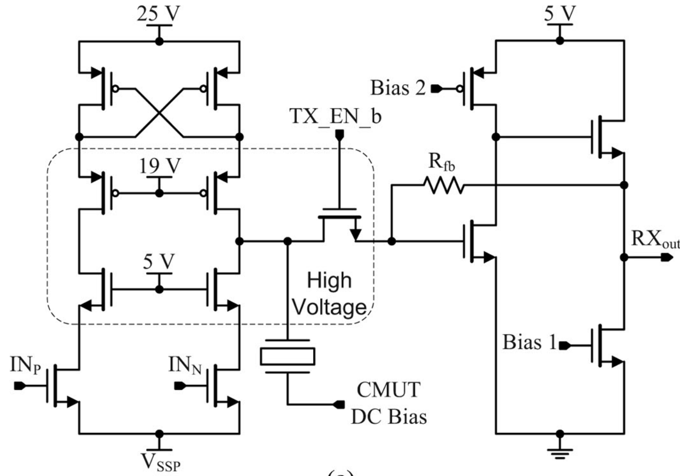


(a)

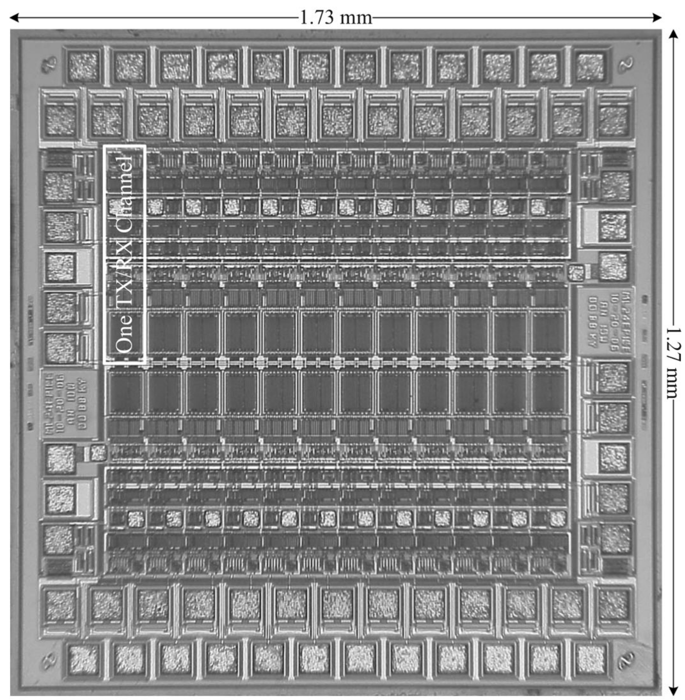


(b)

Fig. 2. (a) Photograph of the front side of a CMUT ML array composed of rectangular membranes. Through-wafer vias for bottom electrodes of the elements alternate between the top and the bottom of the array for larger separation. The magnified view of the bottom left corner shows a through-wafer via and several CMUT cells. (b) SEM picture of the cross section of the array with various parts identified on the image.



(a)



(b)

Fig. 3. (a) Transistor-level schematic of the main components of a single TX/RX channel. Shown in this schematic is the pulser, protection switch, and the preamplifier (Biasing, output buffer, and digital circuitry are not shown). The enclosed region depicts the high-voltage part of the circuit. (b) Photograph of the front-end electronics. The white rectangle highlights one TX/RX channel.

We included several different cavity shapes (circular, rectangular, tent) and sizes on a single wafer to allow for extensive testing. For the experiments summarized in this paper, we used a device composed of rectangular membranes with a width of 16 μm [Fig. 2(a)]. A scanning electron microscope (SEM) image of the cross section of this device is shown in Fig. 2(b).

B. Custom-Designed Front-End Electronics

The CMUT ML array is designed to be mounted at the tip of a catheter. Each element of the array has a capacitance of approximately 2 pF, which is quite small compared with typical catheter cable capacitance as high as 300 pF [23]. Because direct connection of the transducer elements to the imaging system through catheter cables will severely degrade the signal and in turn the image quality, we therefore designed an IC comprising the front-end transmit and receive electronics of an imaging system to be integrated closely with the ML array at the tip of the catheter.

The custom-designed IC has a dedicated transmitter (TX) and receiver (RX) circuit for each element of the ML array. Each of the 24 channels of the IC consists of a pulser, a transimpedance amplifier, an output buffer, a protection switch, and some digital circuitry [Fig. 3(a)]. A 5-V unipolar pulse is required to trigger the pulser. The pulser converts that input into a unipolar pulse with an amplitude as high as 25 V. The width of the output pulse is controlled by the input pulse supplied to the IC. During the transmit cycle, the protection switch is turned off to isolate the amplifier from the pulser and protect the low-voltage circuitry against high-voltage pulses at the output of the pulser. During the receive cycle, the protection switch is closed, the output of the pulser is high impedance, and the transimpedance amplifier senses the current flow through the CMUT element.

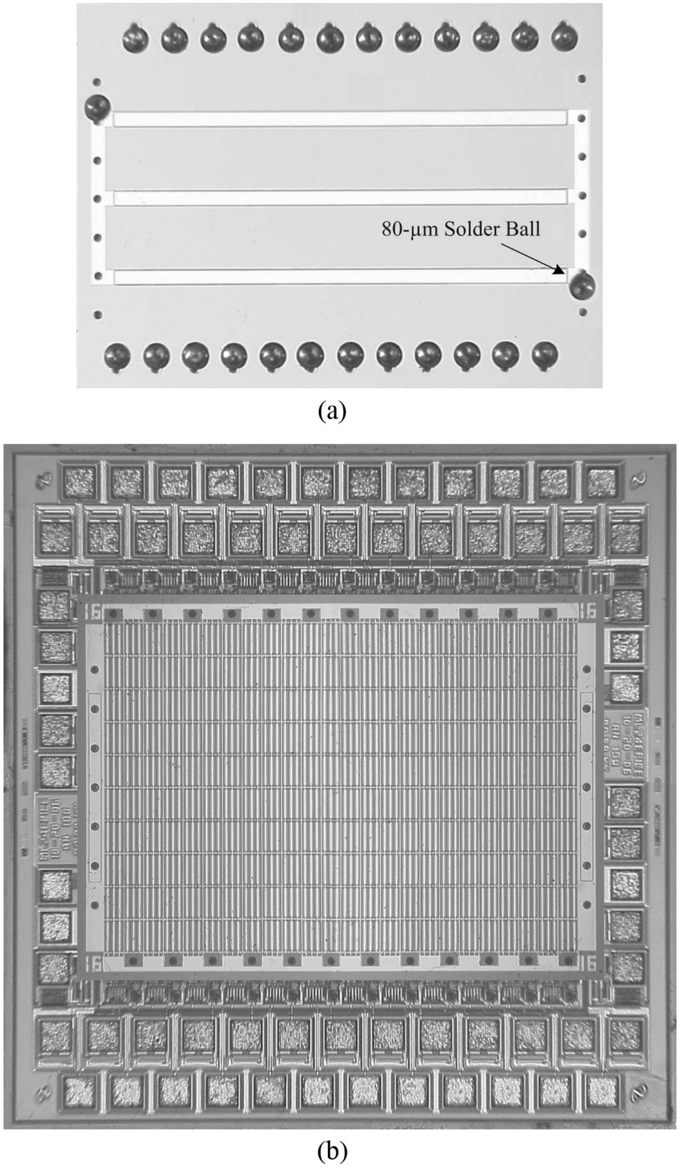


Fig. 4. (a) Back side of a CMUT ML array with solder bumps. The flip-chip pad pitch (center-to-center distance between adjacent solder balls) on the top and bottom rows is 126 μm. (b) A CMUT ML array flip-chip bonded to the front-end electronics.

The described IC is based on the circuit topology used earlier for a 2-D CMUT array [17]. For this work, we modified the design parameters to achieve higher frequency of operation and removed the amplifier enable and selection circuitry. In addition, we made a slight modification to the pulser circuit so that rather than connecting its V_{SS} [denoted as V_{SSP} in Fig. 3(a)] node to ground we can externally set the voltage at this node equal to the amplifier's input dc bias. Without this change, because the amplifiers in this IC are always active, the voltage on the CMUT would jump between the amplifier's input dc bias voltage and the ground when the protection switch opens or closes. This jump would cause the CMUT to generate a small unwanted ultrasound wave.

The IC was designed for a high-voltage process with 2 metal layers and a minimum feature size of 1.5 μm (National Semiconductor, Santa Clara, CA) and occupies an area of 2.1 mm × 2.1 mm [Fig. 3(b)]. The transistors used are standard CMOS devices except for the middle 4 transistors in the pulser and the transistor used as the protection switch, which are high-voltage CMOS devices.

C. Integration of CMUT ML Array with Custom Front-End IC

The CMUT array and the IC were designed with matching pad layouts for flip-chip bonding. During the fabrication of the CMUT arrays, a metal stack of 15/15/300-nm Ti/Pt/Au was evaporated over the aluminum pads as the under-bump metallization (UBM) layer required for flip-chip bonding. A solder jetting process (Pac Tech USA, Santa Clara, CA) was used to deposit 80-μm-diameter eutectic Sn-Pb solder balls on the pads [Fig. 4(a)]. On the IC side, an electroless plating process (Pac Tech USA, Santa Clara, CA) was used to grow a 5-μm/50-nm Ni/Au stack as the UBM layer [24].

We flip-chip bonded an ML array to the IC by first aligning the 2 dies using an aligner bonder (Model M8, Research Devices, Inc., Piscataway, NJ) and then reflowing the solder bumps in an in-house, miniature inert oven [Fig. 4(b)]. After the reflow process, we filled the gap between the ML array and the IC with a nonconductive underfill encapsulant material (Hysol FP4549SI, Henkel Corporation, Irvine, CA). This process relieves the thermomechanical stresses on the solder interconnections and also enhances the mechanical strength of the assembly.

After the flip-chip bonding, the IC pads on the perimeter were wire-bonded to a pin-grid-array (PGA) ceramic package for testing. Bond wires were then buried under UV-cured epoxy (Norland Optical Adhesive 61, Norland Products, Inc., Cranbury, NJ) for protection and easier handling. After initial testing of the ML array in air, we conformally coated the device with a 180-μm-thick layer of polydimethylsiloxane (PDMS) to provide electrical isolation for experiments in water and also imaging. This PDMS layer could also be cast as an acoustic lens for elevation focusing to improve the image quality.

D. Test and Imaging Methods

To characterize the performance of the array, we used a PC-based data-acquisition system capable of acquiring pulse-echo data from all transmit and receive combinations. Using this system, we measured each element's resonant frequency in air and pulse-echo frequency response in immersion. With a calibrated hydrophone we measured the output pressure of the array elements as a function of dc bias.

For imaging experiments, we used a commercial portable imaging system (Vivid *i*, GE Healthcare, Wauwatosa, WI). We designed an interface electronics box (I-BOX) that allows proper communication between the imaging system and our custom IC. With both the TX inputs and the RX outputs individually accessible for maximum flex-

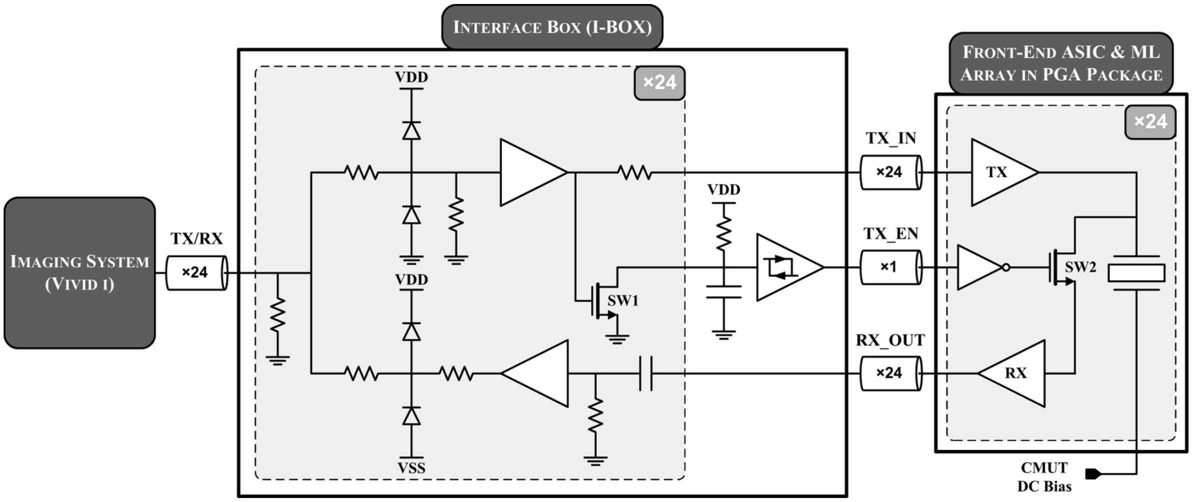


Fig. 5. Block diagram of the imaging setup. The gray shaded regions depict one TX/RX channel. The whole system is composed of 24 replicas of this unit cell.

ibility, the IC can be used with general-purpose platforms. In addition to the 5-V input trigger pulses for the built-in pulsers, our IC requires a control signal (TX_EN), which is a 5-V pulse that is high during the whole transmit cycle and low in the receive mode. A commercial imaging system in its standard mode of operation does not output these signals and communicates with each transducer element over a single line. Therefore we designed the I-BOX to generate the trigger pulses and the control signal for the IC from the transmit pulses provided by the system. The I-BOX also splits each shared transmit and receive line of the system into 2 paths suitable for the IC.

A block diagram of the imaging setup, with the main components of the I-BOX, is shown in Fig. 5. Using diode limiters in the I-BOX, the output pulses (usually bipolar and high amplitude) from the imaging system are converted to 5-V unipolar trigger pulses. The I-BOX generates the TX_EN signal by a simple analog "OR" implementation of all the 24 pulses using 24 switches, a resistor, a capacitor, and an inverting Schmitt trigger. The purpose of the RC network before the Schmitt trigger is to ensure that the TX_EN remains high during the whole transmit cycle.

The fully integrated CMUT ML array prototype in the PGA package was used to image point and contrast resolution test phantoms. To further demonstrate the imaging capability of the device, the same assembly was used to image the left atrial appendage of an isolated Langendorff-perfused rabbit heart.

III. Results

A. Array Characterization

We first measured the resonant frequency of each element of the CMUT ML array in air before coating it with the PDMS passivation layer. We excited each element of the array with a 24-V, 30-ns pulse (supplied by the IC). We analyzed the resulting electrical signal at the output of each receiving amplifier and determined the center frequency of the oscillation, which corresponds to the short-circuit resonant frequency of the CMUT. We measured a mean resonant frequency of 17.9 MHz with a standard deviation of 67 kHz (0.37% of the mean) when the array was biased at negative 20 V (Fig. 6). This characterization showed that every element of the array was working, 100% yield; it also confirmed that the IC was fully functional.

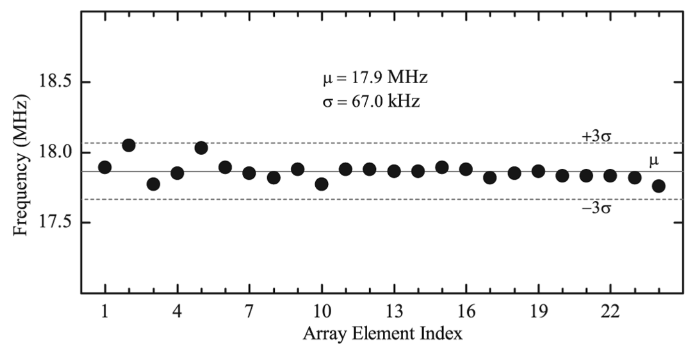


Fig. 6. Resonant frequency in air measured across the 24-element ML array. In this experiment, the unipolar transmit pulse amplitude was 24 V and the ML array was biased at negative 20 V.

After coating the array with PDMS we measured the acoustic output pressure as a function of dc bias using a calibrated hydrophone (Model HNV-0400, Onda Corporation, Sunnyvale, CA). A unipolar 24-V, 30-ns pulse (provided by the IC) was applied to an element of the CMUT array. We measured the pressure at a distance of 5 mm from the array immersed in water. Then we corrected for one-way attenuation and diffraction losses [25] to convert the measured pressure at the distance to the average pressure generated at the face of the array (Fig. 7).

We also tested the pulse-echo performance of the ML array in water using the water-air interface at 4.7 mm as a total plane reflector [Fig. 8(a)]. The frequency spectrum

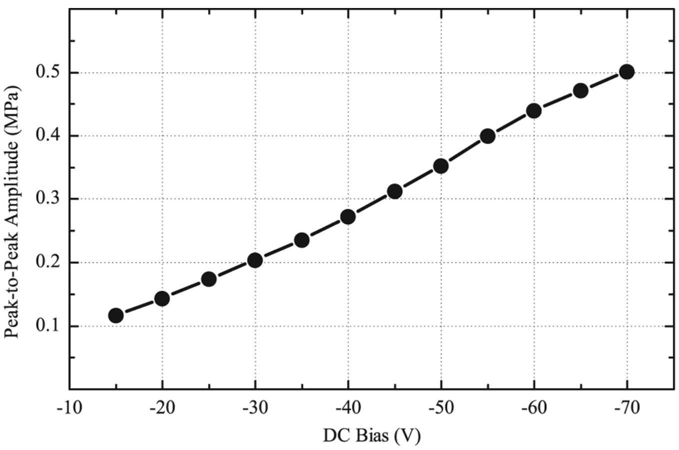


Fig. 7. Acoustic peak-to-peak pressure at the face of the ML array as a function of dc bias. Pressure was measured using a calibrated hydrophone at 5-mm distance from the array immersed in water and was then corrected for attenuation and diffraction losses, which were calculated to be 23.6 dB at a frequency of 11.7 MHz. In this experiment, the unipolar transmit pulse amplitude was 24 V.

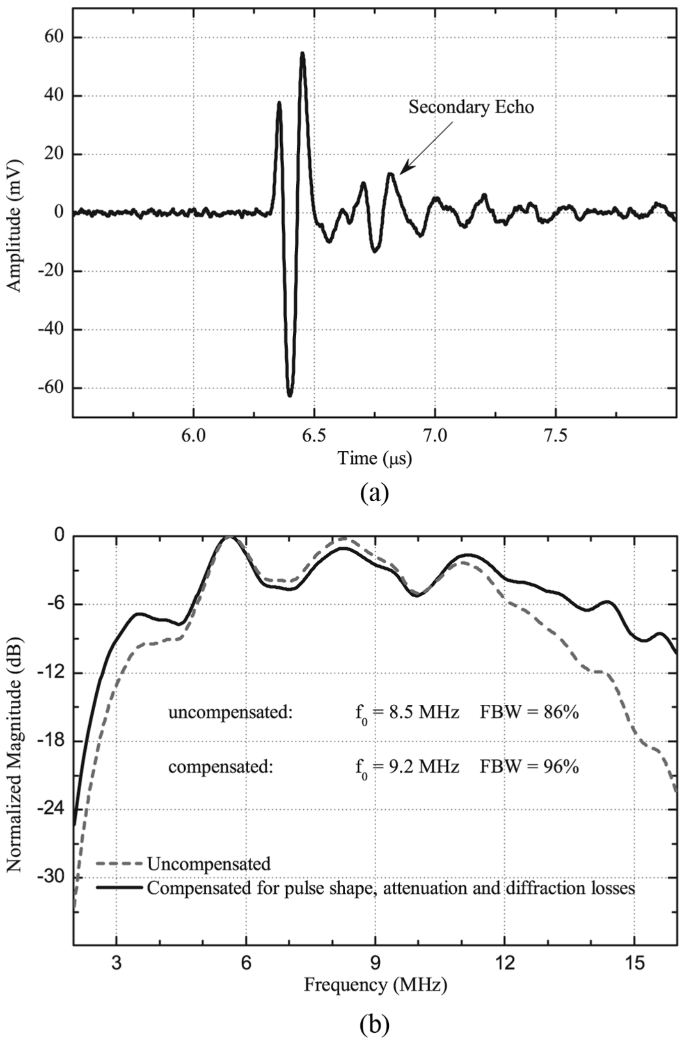


Fig. 8. (a) The pulse-echo signal in water reflected from the water-air interface at about 4.7 mm. The secondary echo in the received signal is the reflection from PDMS-water interface due to the impedance mismatch between PDMS and water. (b) Corresponding frequency spectrum. The solid line shows the compensated frequency spectrum, in which we have corrected for pulse shape, and attenuation and diffraction losses. In this experiment, the unipolar transmit pulse amplitude was 24 V and the ML array was biased at negative 30 V.

was centered around 9.2 MHz with a −6-dB fractional bandwidth of 96% [Fig. 8(b)]. We observed a secondary echo in the received signal, which is due to an undesired reflection from the interface of the PDMS passivation layer and water. This echo reveals an acoustic impedance mismatch between PDMS and water, which can be avoided by using a passivation layer material that is acoustically matched to the imaging medium.

B. Imaging Tests

The imaging performance of the same ML array prototype used in the characterization was tested with commercial phantoms and an *ex vivo* rabbit heart. A commercial portable imaging system (Vivid *i*) was used for these experiments. The software was modified to reconstruct phased-array images using a 24-element 1-D aperture with an element pitch of 63 μm. For all the following imaging results, the ML array was biased at negative 60 V and the transmit pulse amplitude was 24 V.

We imaged two commercial phantoms. The first was a standard point resolution test phantom (Model RMI 404GS LE gray scale phantom, Gammex, Inc., Middleton, WI). The axial target resolution group that we imaged had a minimum separation of 0.25 mm, which was resolved in the image [Fig. 9(a)]. The second was a contrast resolution test phantom using rubber-based soft-tissue mimicking material (ATS Laboratories, Inc., Bridgeport, CT) [Fig. 9(b)].

We also tested the imaging performance of the same assembly on an isolated Langendorff-perfused rabbit heart. The beating isolated heart was suspended sideways in a water bath. Moving cardiac structures were visualized in this experiment. Since the left atrial appendage extended out from the body of the left atrium when the Langendorff heart was tipped on its side, we were able to move it into the field of imaging of the ML array. In addition to visualizing normal dynamic contraction of the atrial appendage [Fig. 9(c) and (d)](see the first supplementary video), we were also able to detect fine rapid fibrillation movements of the left atrial appendage when the heart went into atrial fibrillation toward the end of the experiment (see the second supplementary video). The presented video clips were acquired at a frame rate of approximately 60 fps. Thus we believe we have demonstrated both high spatial and high temporal resolution for CMUT ML array imaging.

IV. Conclusion

We successfully tested a CMUT ML array fully integrated with custom-designed front-end electronics. We

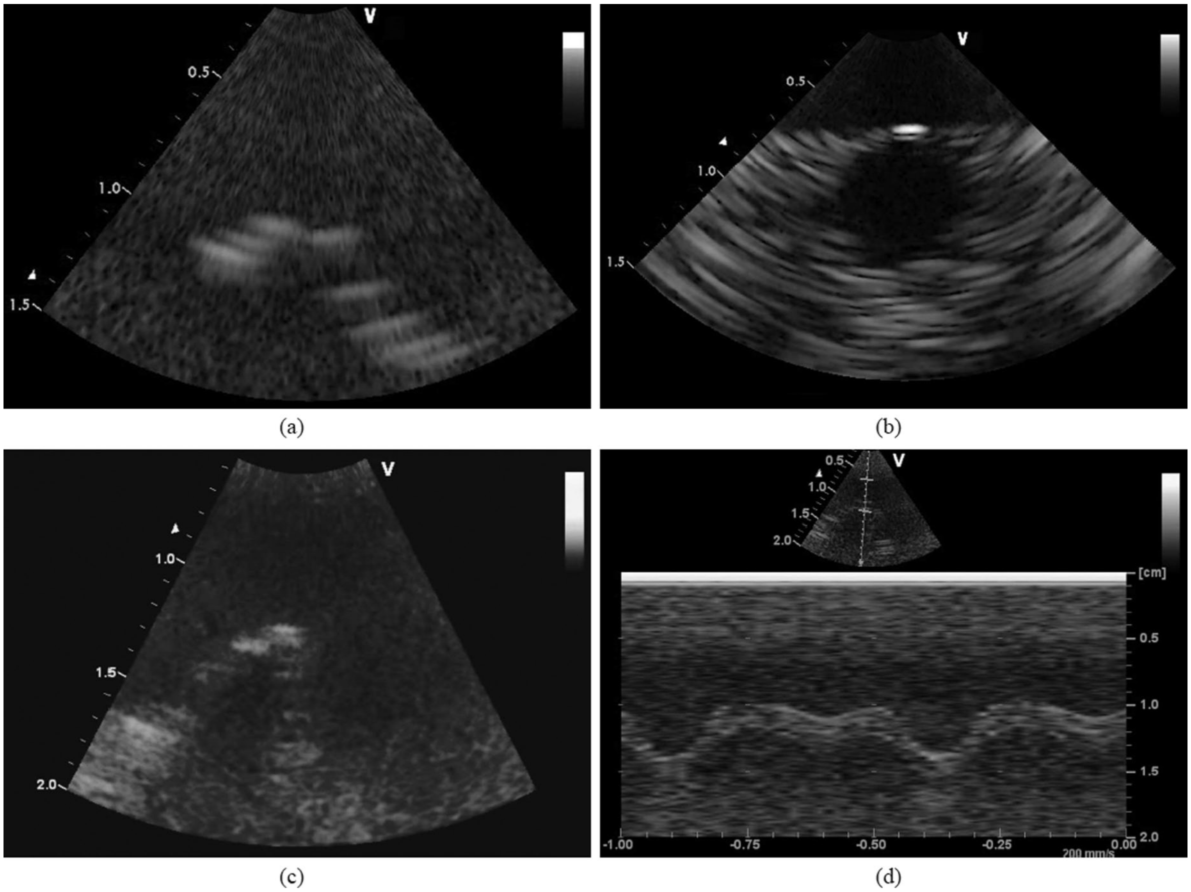


Fig. 9. Images with the CMUT ML array assembly in the PGA package using a portable commercial ultrasound system (Vivid-*i,* General Electric). (a) An image of a point resolution test phantom (Model RMI 404GS LE gray scale phantom, Gammex, Inc., Middleton, WI). (b) An image of a contrast resolution test phantom (Rubber-based soft-tissue mimicking material, ATS Laboratories, Inc., Bridgeport, CT). (c) An image of the left atrial appendage of an isolated Langendorff-perfused rabbit heart. (d) An M-mode image through the left atrial appendage of the same isolated Langendorff-perfused rabbit heart. The downward deflection shows the atrial contraction.

demonstrated the imaging capability of the prototype with commercial phantoms as well as a beating *ex vivo* rabbit heart (Langendorff model). These results show that we can manufacture a small high-frequency ultrasound transducer array with 100% yield. With the same CMUT technology, we can make arrays with even higher frequencies and with other array geometries desired for catheter-based intracardiac and intravascular applications. The fabrication of similar transducer arrays with traditional piezoelectric transducer technology would be challenging. Additionally, these results show that we can tightly integrate the transducer array with an integrated circuit, which is particularly important for catheter-based applications, where the long cable connecting the catheter tip to a separate system of electronics adds significant parasitic capacitance.

We are currently working on the integration of the CMUT ML array and the custom IC at the tip of a catheter. This catheter will also be equipped with several EP sensor bands near its distal tip and a metal ablation tip enclosure. This single multifunctional catheter will therefore be capable of imaging, EP characterization, and RF ablation.

Acknowledgments

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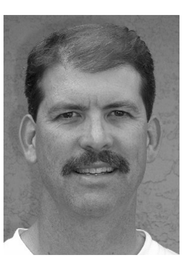

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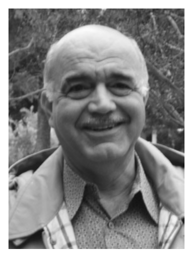

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