Volumetric Intracardiac Imaging Using a Fully Integrated CMUT Ring Array: Recent Developments

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Abstract* — Atrial fibrillation, the most common type of cardiac arrhythmia, now affects more than 2.2 million adults in the US alone. Currently, electrophysiological interventions are performed under fluoroscopy guidance, a procedure that introduces harmful ionizing radiation without providing adequate soft-tissue resolution. Intracardiac echocardiography (ICE) provides real-time, high-resolution anatomical information, reduces fluoroscopy time, and enhances procedural success. We have previously developed a forward-looking, volumetric ICE catheter using a ring-shaped, 64-element capacitive micromachined ultrasonic transducer (CMUT) array with a 10MHz center frequency. The Ring array was flip-chip bonded to a flexible PCB along with 8 identical custom ASICs providing a total of 64 dedicated preamplifiers. The flex was then reshaped for integration with the catheter shaft. In the second-generation catheter, 72 micro-coaxial cables (reduced from 100) are terminated on a newly designed flex to provide the connection between the array electronics and the imaging system. The reduced number of cables enhances the catheter's steerability. Furthermore, the new flex allows grounding of the top CMUT electrode through proper level-shifting of the ASIC supplies without additional circuitry. This feature enables complete ground shielding of the catheter, which improves its noise susceptibility and is an important safety measure for its clinical use. Beyond real-time, forward-looking imaging capability, the Ring catheter provides a continuous central lumen, enabling convenient delivery of other devices such as HIFU transducers, RF ablation catheters, etc. Using a PC-based imaging platform from Verasonics and a commercial Vivid7 imaging system from GE, we have demonstrated the *in vivo*, volumetric, real-time imaging capability of the finalized Ring catheter in a pig heart.

Keywords – electrophysiology; ultrasound; capacitive micromachined ultrasonic transducer; CMUT; intracardiac echo; real-time; volumetric; forward-looking

I. INTRODUCTION

The most common type of cardiac arrhythmia, atrial fibrillation now affects over 2.2 million adults in the United States alone [1]. Currently, electrophysiological (EP) interventions are most commonly performed under fluoroscopy guidance. However, the ionizing radiation of fluoroscopy has proven dangerous for both patients and physicians alike. Furthermore, fluoroscopy guidance does not provide adequate soft tissue resolution. Real-time, high-resolution imaging can be provided by intracardiac echocardiography (ICE) [2]. In addition to enhanced procedural success, ICE also reduces harmful fluoroscopy exposure.

A 12F Ring catheter for real-time, forward-looking, volumetric intracardiac imaging has been developed for use in EP interventions [3-5]. A CMUT Ring array at the catheter tip provides real-time, forward-looking volumetric imaging. Furthermore, the catheter provides a central lumen through the device that may be used to deliver a variety of devices to the target area, including radio-frequency (RF) ablation catheter, laser ablation catheter, and optical fibers for photo-acoustic imaging. A short description of the components of the Ring catheter, several improvements to the first generation device, and characterization and imaging results are presented in this paper.

II. METHODS

A. CMUT Array Design

The CMUT Ring array consists of 64 transducer elements. The common dimensions of the fabricated device are listed in Table I.

TABLE I. CMUT RING ARRAY DESIGN PARAMETERS

Array Design Parameters	
Number of elements	64
Center frequency (MHz)	10
Element size (μm × μm)	80 × 100
Outer diameter (mm)	2.54
Inner diameter (mm)	1.63
Cell Design Parameters	
Membrane thickness (μm)	0.50
Gap height (μm)	0.10
Insulator layer thickness (μm)	0.18

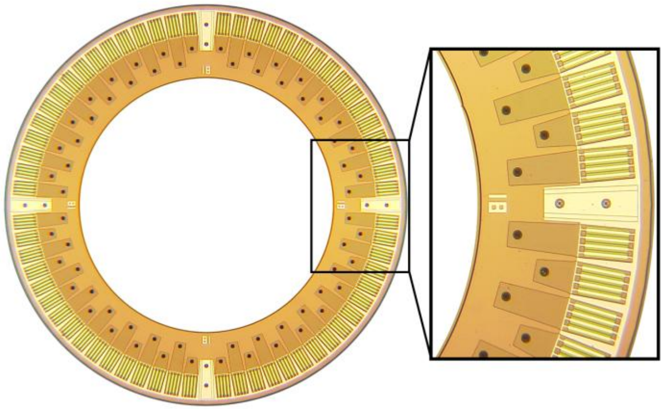


Figure 1. Optical image of a Ring array with rectangular elements.

The CMUTs were fabricated using a sacrificial layer process [4] with through-wafer vias that connect the flip-chip pads on the device's backside to the front-side electrodes. Fig. 1 shows an optical picture of an array with rectangular membranes with 18-μm width. Array singulation and inner hole fabrication were performed using a single step deep reactive ion etching process.

B. Custom-Designed Front-End Electronics

The capacitance of each element in the CMUT Ring array is approximately 1pF. A typical catheter cable, however, may be about two meters long with about 200pF capacitance. Therefore, direct connection of the elements to the imaging system using these long cables may result in poor SNR and lower image quality.

To improve image quality and to allow the CMUT elements to drive the signal cables, application specific ICs (ASICs) have been designed. These custom ASICs allow seamless integration of the CMUT Ring array with commercial imaging systems. The ASIC uses only a single cable for both transmit (Tx) and receive (Rx) phases of the imaging. This is accomplished by providing one path for Tx and another diode-protected path for Rx, which are connected at both ends. The Rx path provides a dedicated amplifier for each CMUT array element, improving signal quality. In the first generation Ring catheter, a transimpedance amplifier (TIA) was used to improve SNR [4]. Analysis of this amplifier proved that the feedback resistor was the largest contributor of noise in this design. In the second generation Ring catheter, the TIA is replaced with a charge amplifier. In the charge amplifier architecture, the main feedback element is a capacitor rather than a resistor, thereby reducing the noise generated by the amplifier and providing an overall improvement in SNR. Fig. 2 shows the second generation ASIC's noise figure compared to those of the direct connection (i.e., no ASIC) and the first generation ASIC.

Similar to the first generation, these ASICs measure about 1.2 mm × 1 mm (Fig. 3). Each ASIC has 8 channels; a total of 8 ASICs are used to address the Ring array's 64 elements.

C. Novel CMUT Biasing Scheme

In addition to an improved ASIC, the second generation Ring catheter has several other enhancements, including new features to increase its feasibility in a clinical setting. Among these features is a novel CMUT biasing scheme through the ASIC that allows the grounding of the CMUT top common electrode. This is accomplished by level shifting all the nodes of the ASIC by the desired CMUT DC bias and grounding the CMUT top common electrode (Fig. 4). This biasing scheme maintains the same voltage difference across all the ASIC components, similar to the conventional biasing scheme. This clinically significant feature is an important step forward for patient safety.

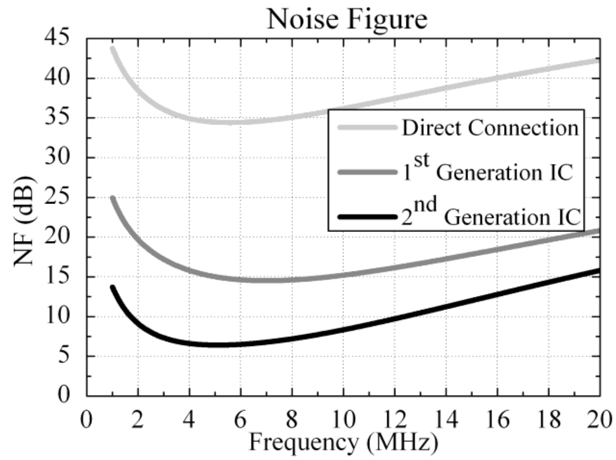
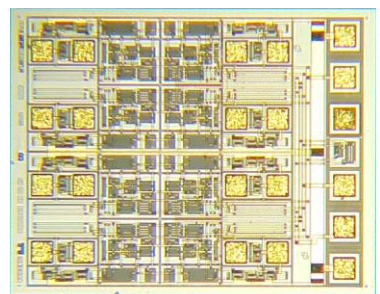


Figure 2. NF plots. The figure above shows the NF with the Ring array connected directly to the imaging system, with the first generation TIA ASIC, and finally the improved NF with the second generation charge amplifier-based ASIC.



- ± 2.5 V dual power supply
- Up to ±50 V bipolar TX pulse
- Power per channel: 4.35 mW
- Input referred noise current: 0.4 pA/√Hz
- Input referred noise voltage: 6.1 nV/√Hz

Figure 3. Die photograph.

In order to verify this biasing scheme idea, we made two integrated test Ring arrays. For each test assembly, we used eight first-generation ASICs and a Ring array wire-bonded in a pin-grid-array (PGA) package. For fair comparison, we selected two similar Ring arrays from the same wafer for both packages. An interface box was designed to provide voltage supplies to the packages and to provide connections to the imaging system. The first package was wire-bonded using the conventional biasing scheme. In the second package, the floating scheme was employed; the former CMUT bias pins were grounded and the former ground pins were arranged to receive the CMUT bias. We measured the pulse-echo response of a single array element for each package from the oil-air interface, approximately at the same distance (Fig. 5). For both these experiments, the CMUT DC bias was 80 V and a 1.5

cycle bipolar pulse with peak amplitude of 35 V was applied. As it is seen from Fig. 5, the two pulse-echo results match very well.

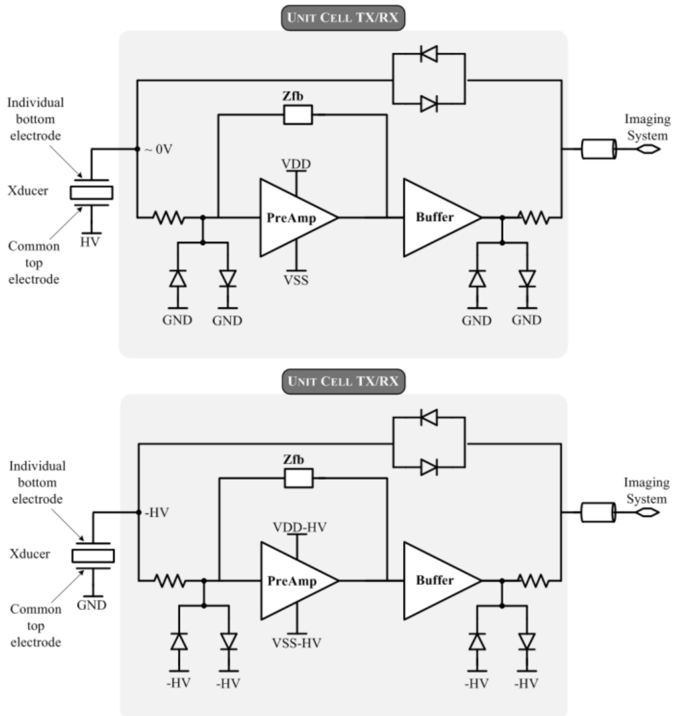


Figure 4. Top-level block diagram a single IC channel. The top diagram illustrates the conventional biasing scheme. The bottom diagram shows the level-shifted biases, allowing grounding of the CMUT top electrode.

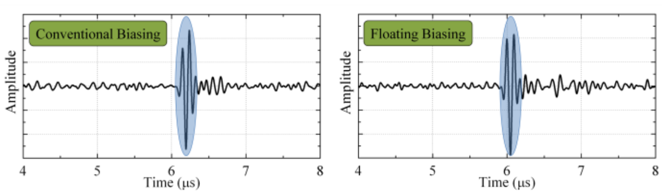


Figure 5. Pulse echo results using Ring array in bench-top test setups. The left figure was obtained from a Ring array using the conventional biasing architecture, and the right figure was obtained from a similar Ring array employing the floating biasing architecture. Comparing the echoes confirms that our floating biasing scheme works as expected.

D. Catheter Assembly

A new flexible PCB (flex) was designed and fabricated to provide connections between the Ring array, ASICs, and system cables (Fig. 6). Similar to the first-generation flex, this new design is composed of eight long, narrow legs that intersect at the center of the flex, where the Ring array is flip chip bonded. Additionally, one ASIC is flip chip bonded per leg. Each leg on the second-generation flex has an additional flap extension that, during assembly, is folded and soldered onto the neighboring leg. This new feature allows us to minimize the number of cables required to provide DC bias for all the ICs by shorting all the corresponding supply traces on the flex. Using this new flex, we reduced the number of cables from 100 to 72, improving the catheter's steerability and allowing access to more heart structures during testing.

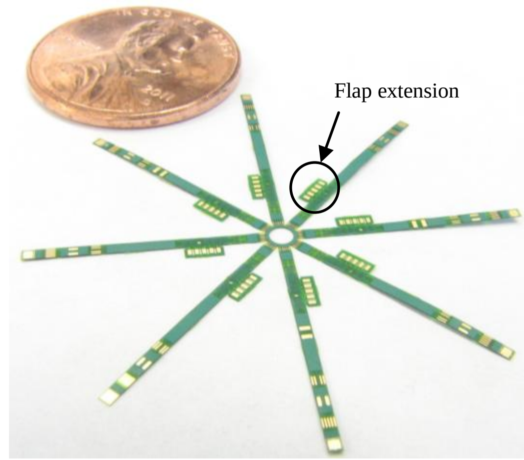


Figure 6. Second generation ring flex.

In the final catheter integration, the flex legs are folded under the Ring array, the cables are terminated on the flex legs, and the catheter shaft is attached.

A folded flex assembly before cabling and final catheter integration is shown in Fig. 7 along with the final integrated catheter. Fig. 7 also shows a Ring catheter with a 4F RF ablation catheter introduced through its inner lumen.

For further clinical convenience, the catheter's required power supplies have been consolidated in one enclosure whose outputs can be controlled and monitored by a PC (Fig. 8).

III. Imaging Results

We have acquired a Verasonics imaging system (Verasonics Inc., Redmond, WA) for PC-based real-time imaging. Using this system, we have developed several real-time image reconstruction schemes, including flash imaging (flat transmit, beamforming on receive), phased array imaging (beam steering and focusing), and full synthetic phased array imaging. Cross-sectional images of a metal spring acquired using synthetic phased array imaging are shown in Fig. 9. Norton's weightings and cosine apodization were applied for full-aperture resolution [6, 7].

A commercial imaging system (GE Vivid7, GE Healthcare, Wauwatosa, WI) has also been programmed for real-time classical phased array imaging. Fig. 10 shows *in vivo* images of the endocardial wall from a porcine heart acquired in real-time during a recent animal study.

IV. Conclusions

We have implemented several improvements in the second generation Ring CMUT ICE catheter for improved use in a clinical setting. These changes include grounding the top CMUT electrode for patient safety, improvements in the front-end electronics for better noise performance, as well as changes in the flex design to improve catheter steerability. Furthermore, we have demonstrated use of the Ring catheter in real-time, *in vivo* 3-D imaging of a pig heart.

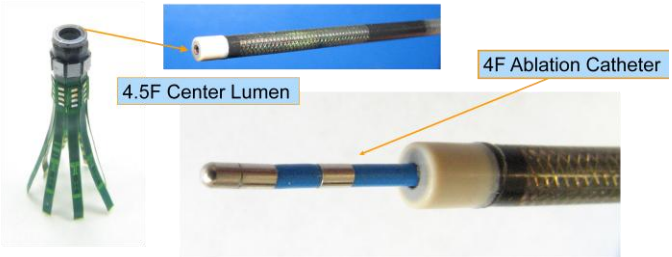


Figure 7. On the left is a completed ring assembly with bonded CMUT array and ASICs before catheter integration. The top image shows the final integrated catheter. On the bottom, a catheter with an ablation catheter is shown.

Figure 8. Power supply providing all necessary supplies to Ring catheter. Outputs can be monitored by a PC.

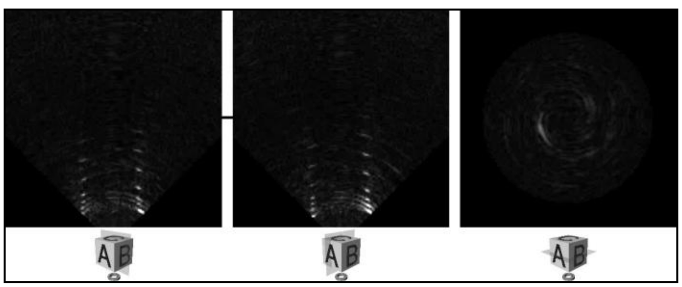


Figure 9. Off-line images reconstructed using synthetic phased array imaging method. Shown are images of a 4mm-diameter metal spring.

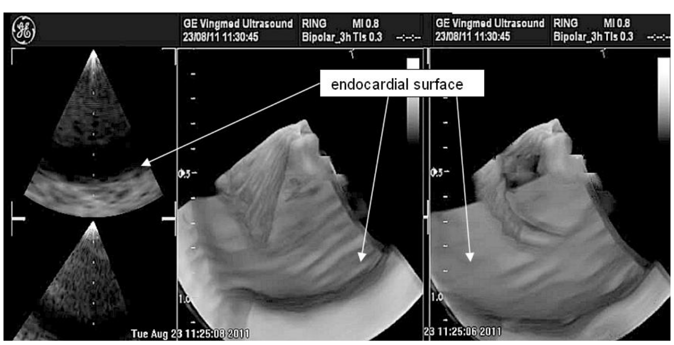


Figure 10. Real-time *in vivo* images of a pig heart taken with the Ring catheter show the endocardial surface.

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