Intracardiac Forward-Looking Ultrasound Imaging Catheters Using Capacitive Micromachined Ultrasonic Transducers

A. Nikoozadeh, I.O. Wygant, D.-S. Lin, Ö. Oralkan, K. Thomenius, A. Dentinger, D. Wildes, G. Akopyan, K. Shivkumar, A. Mahajan, D.N. Stephens, M. O'Donnell, D. Sahn, and P.T. Khuri-Yakub

Abstract Atrial fibrillation is the most common sustained arrhythmia that now affects approximately 2.2 million adults in the United States alone. Minimally invasive catheter-based electrophysiological interventions have revolutionized the management of cardiac arrhythmias. We are developing forward-viewing ultrasound imaging catheters based on two types of transducer arrays using the capacitive micromachined ultrasonic transducer technology: A 10-MHz, 24-element MicroLinear (ML) array with a footprint of 1.7 mm $\times$ 1.3 mm, and a 10-MHz, 64-element annular ring array with an outside diameter of 2.6 mm and inner diameter of 1.6 mm. Both arrays are integrated with custom-designed front-end electronic circuitry to overcome the performance degradation associated with long cables in the catheter. The ML and ring arrays provide real-time 2-D and 3-D images, respectively, in front of the catheter tip. Using the ML array, we demonstrated ex-vivo images of the left atrial appendage in an isolated Langendorff-perfused rabbit heart model and in-vivo images of heart through the open chest in a porcine animal model. We used the ring array to demonstrate 3-D images of coronary stents and an anatomic cast of a left atrial model.

Keywords Intracardiac imaging · Intracardiac echocardiography · Ultrasound imaging · Forward looking · Cardiac electrophysiology · Capacitive micromachined ultrasonic transducer (CMUT) · Catheter

1 Introduction

Atrial fibrillation is the most common type of cardiac dysrhythmia that now affects approximately 2.2 million adults in the United States alone [1]. Minimally-invasive catheter-based electrophysiological (EP) interventions provide valuable information about the electrical behavior of the cardiac muscle that yields to better diagnosis and treatment of arrhythmias. Catheter-based radio-frequency (RF) ablation, which is the most common ablation therapy, is often used to destroy a small amount of

A. Nikoozadeh (✉)
Stanford University, Stanford, CA, USA
e-mail: aminn@stanford.edu

M.P. André et al. (eds.), *Acoustical Imaging*, Acoustical Imaging 30,
DOI 10.1007/978-90-481-3255-3_24,

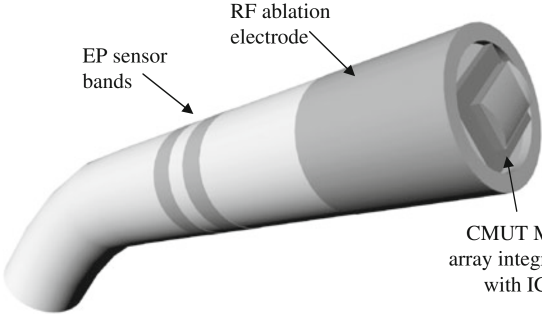

Fig. 1 Conceptual drawing of the multifunctional EP-ICE ML catheter. This catheter is capable of forward-looking imaging and is equipped with EP sensor bands and RF ablation electrode

the malfunctioning tissue that causes the arrhythmia. Multiple catheters are used for electrophysiology assessment and ablation.

Currently, fluoroscopy is the standard method for navigating catheters throughout these procedures. This guidance method exposes both the patient and the practitioner to hazardous ionizing radiation that could take tens of minutes. Also the poor soft-tissue resolution of fluoroscopy, even with the use of contrast agents, does not provide adequate anatomical information for precise catheter positioning in the heart [2].

We are developing forward-looking intracardiac ultrasound imaging catheters for real-time guidance and monitoring of EP interventions. These are multi-function catheters that are integrated with EP electrodes and ablation devices (Fig. 1). These catheters not only simplify interventions in the heart and improve the procedural success but also reduce the undesirable use of fluoroscopy.

2 Methods

2.1 CMUT Arrays

We are developing forward-viewing ultrasound imaging catheters based on two types of transducer arrays using the capacitive micromachined ultrasonic transducer (CMUT) technology: MicroLinear (ML) array and ring array. Both these transducers are designed for a center frequency of 10 MHz. For the design of the CMUT arrays we used the linear CMUT equivalent circuit model [3]. Some of the parameters required for this circuit were derived using the analytical calculation of the membrane displacement [4]. Table 1 summarizes the design parameters of these transducer arrays.

The ML array is a 1-D transducer array composed of 24 elements with an element pitch of 63 μm (Fig. 2). The device measures about 1.3 mm × 1.7 mm. This device provides real-time 2-D images in front of the catheter tip. The ring array is composed of 64 elements that are approximately 100 μm × 100 μm in size (Fig. 3). The outer diameter of the device is about 2.6 mm and the inner diameter measures

Table 1 Design parameters of the CMUT arrays

CMUT ML array		CMUT ring array	
Center frequency	10 MHz	Center frequency	10 MHz
Number of elements	24	Number of elements	64
Element pitch	63 μm	Element size	100 μm × 100 μm
Device size	1.3 mm × 1.7 mm	Outer/inner diameter	2.6 mm/1.6 mm

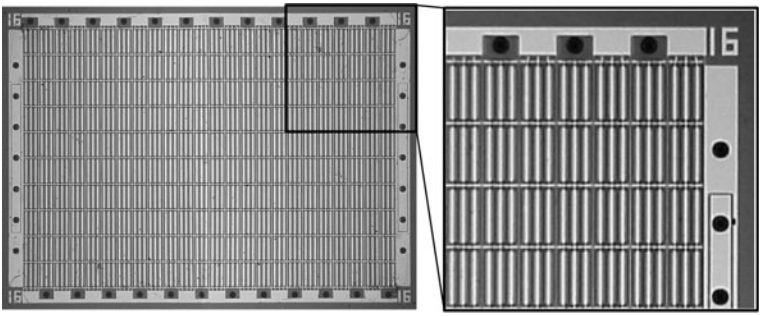

Fig. 2 Photograph of the front side of a CMUT ML array

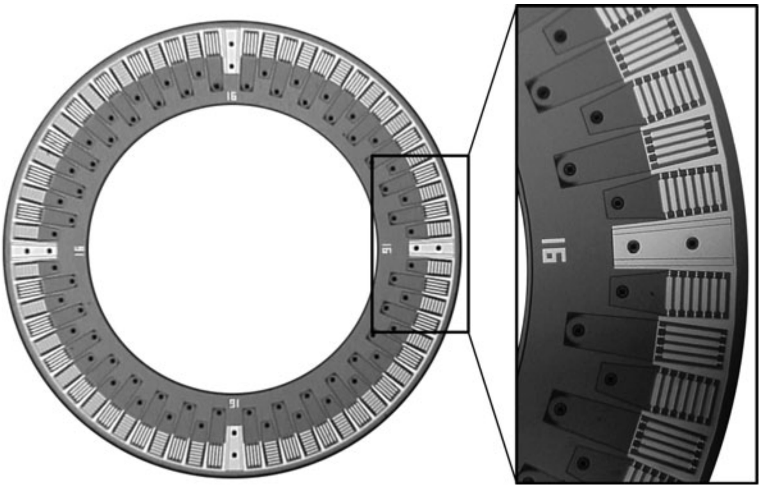

Fig. 3 Photograph of the front side of a CMUT ring array

about 1.6 mm in diameter. This device is capable of providing real-time volumetric images in front of the catheter tip. Also the central lumen available in the ring array geometry enables a variety of other applications such as high intensity focused ultrasound, photoacoustic imaging, laser and RF ablation, etc.

The CMUT arrays were fabricated using the standard polysilicon sacrificial layer process with through-wafer via interconnects [5]. The silicon nitride membrane is

0.5-μm thick, the thickness of the bottom electrode insulation layer is 180 nm, and the vacuum gap height measures 150 nm. The through-wafer via interconnects provide electrical connection to individual array elements from backside pads. These pads facilitate the tight integration with the front-end supporting electronics through flip-chip bonding.

2.2 Custom-Designed Front-End Electronics

Catheter cables usually account for a capacitance of approximately 100 pF/m. Each element of the CMUT array has a capacitance of about 1–2 pF. Therefore direct connection of the transducer elements to the imaging system will result in performance degradation. A closely integrated front-end electronics with the transducer array enhances the SNR and hence the image quality.

We designed a custom front-end electronics composed of 24 transmit/receive channels. Each channel is composed of a pulser, a switch, a transimpedance amplifier and a buffer (Fig. 4a, b). The pulser can provide up to 25-V unipolar pulses. The switch is used to isolate the low-voltage amplifier from the pulser during the transmit cycle. The transimpedance amplifier provides low impedance for the transducer while providing a better noise performance than a simple resistive load termination. This integrated circuit (IC) has matching pads with the CMUT ML array for flip-chip bonding.

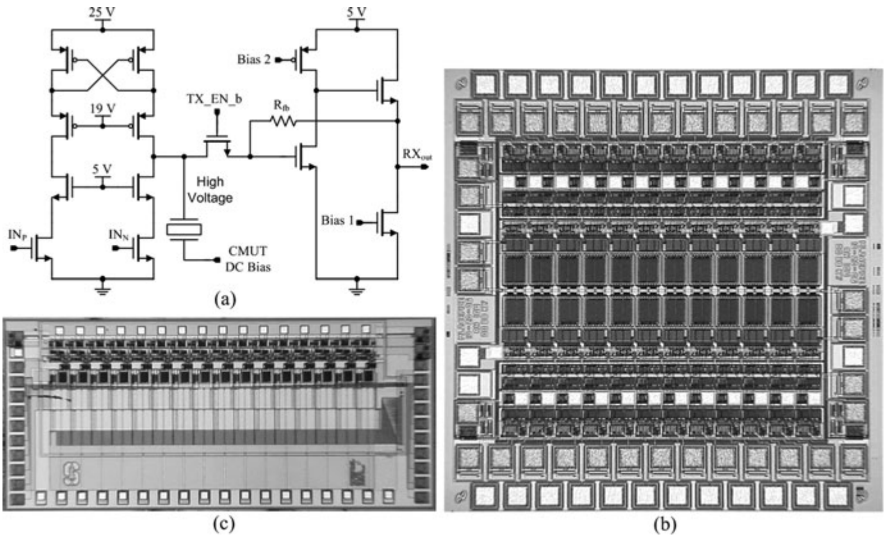

Fig. 4 (**a**) Schematic of the main components of one channel of the custom front-end IC, (**b**) 24-channel design for ML array, (**c**) 16-channel preliminary design for ring array

A 16-channel version of the same circuit topology was used for an early assessment of the ring array imaging capability (Fig. 4c). Four IC's were wire-bonded to the 64-element ring array in a ceramic package.

3 Imaging Results

3.1 ML Array

For preliminary experiments, we flip-chip bonded an ML array to the 24-channel custom IC and then wire-bonded the IC pads to a ceramic package. A commercial imaging system was used for imaging experiments. Additional electronic circuitry was designed to interface the imaging system to the custom IC.

The assembly was used to image standard phantoms and an *ex vivo* rabbit heart. Figure 5a shows an image of a contrast resolution test phantom (rubber-based soft tissue-mimicking material, ATS Laboratories, Inc., Bridgeport, CT). Figure 5b shows an image of a standard point resolution test phantom (Model RMI 404GS LE gray scale phantom, Gammex, Inc., Middleton, WI). Figure 5c shows one frame of the real-time image of the left atrial appendage of an isolated Langendorff-perfused rabbit heart.

3.2 Ring Array

For preliminary experiments, we wire-bonded a ring array to four 16-channel custom IC's in a ceramic package. A PC-based data acquisition system was used to collect the data. Volumetric images were reconstructed offline with the full 64×64 set of data using synthetic phased-array image reconstruction method. Norton's weightings [6] and cosine apodization [7] were applied to obtain the full-disk resolution and to suppress the side-lobes, respectively.

Figure 6a, b show cross-sectional and 3-D rendered images of an undeployed stent and an anatomical cast of atrial model, respectively.

4 Conclusion

We demonstrated real-time ultrasound imaging with a 1-D forward-looking CMUT array. We also confirmed the volumetric imaging capability of a forward-looking CMUT ring array. These results show that using the CMUT technology we can make high-frequency, miniature transducer arrays with different geometries that are readily integrated with electronics to guide catheter-based intracardiac and intravascular interventions.

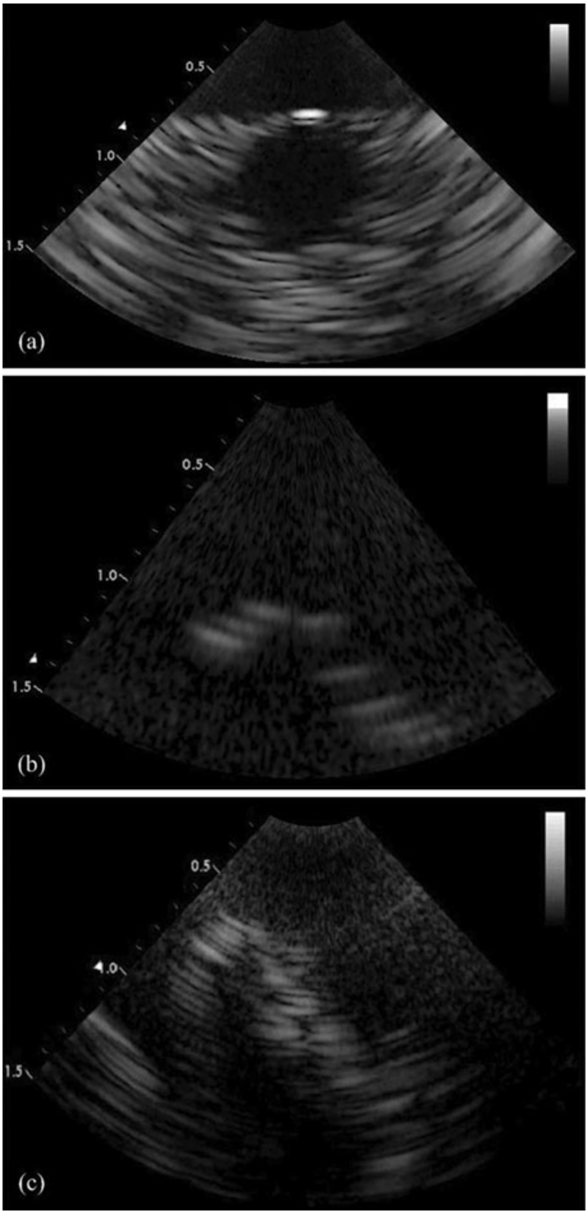

Fig. 5 Images with the CMUT ML array assembly in the PGA package. (**a**) An image of a contrast resolution test phantom. (**b**) An image of a point resolution test phantom. (**c**) An image of the left atrial appendage of an isolated Langendorff-perfused rabbit heart

We are currently working on the full integration of the arrays and the custom front-end IC's within the catheter for forward-looking imaging. We are also working on a second generation front-end electronics that would allow for direct connection to the commercial imaging systems to take full advantage of their capabilities.

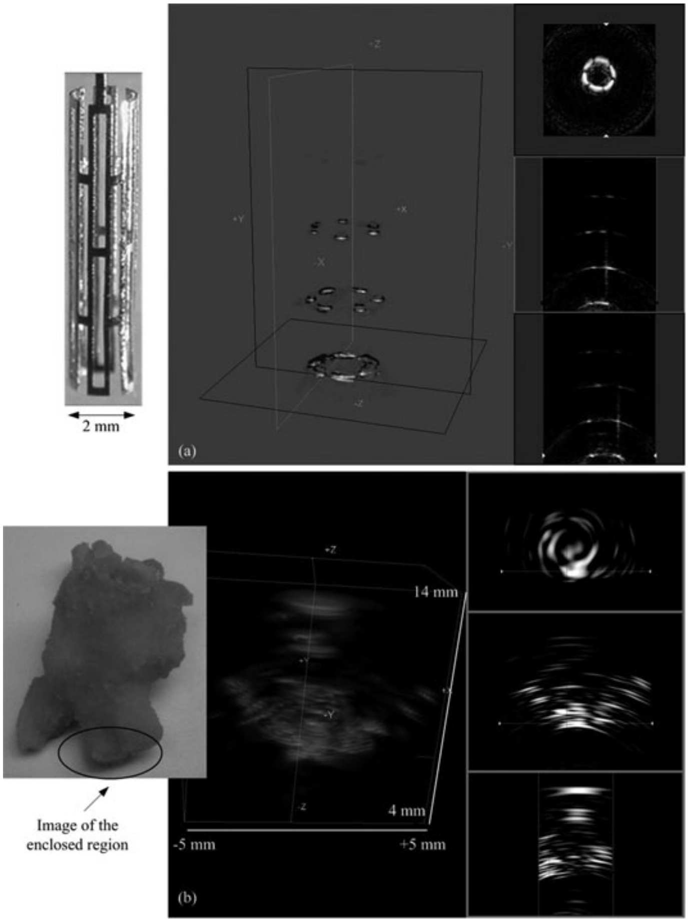

Fig. 6 Images of (**a**) an undeployed stent, and (**b**) an anatomic cast of left atrial model

Acknowledgments This work was supported by the National Institutes of Health under grant HL67647, USA. We thank National Semiconductor (Santa Clara, CA) for their valuable support in the design and fabrication of the IC. CMUT fabrication was done at the Stanford Nanofabrication Facility (Stanford, CA), which is a member of National Nanotechnology Infrastructure Network. Pac Tech USA, Inc. (Santa Clara, CA) provided electrodeless Ni/Au UBM plating and solder bumping.

References

1. Go, A.S., Hylek, E.M., Phillips, K.A., et al.: Prevalence of diagnosed atrial fibrillation in adults: National implications for rhythm management and stroke prevention: The anticoagulation and risk factors in atrial fibrillation (ATRIA) study. JAMA **285**(18), 2370–2375 (2001)

2. Burke, M.C., Roberts, M.J.D, Knight, B.P.: Integration of cardiac imaging and electrophysiology during catheter ablation procedures for atrial fibrillation. J. Electrocardiol. **39**(4), S188–S192 (2006)
3. Lohfink, A., Eccardt, P.-C.: Linear and nonlinear equivalent circuit modeling of CMUTs. IEEE Trans. Ultrason. Ferroelect. Freq. Contr. **52**(12), 2163–2172 (2005)
4. Nikoozadeh, A., Bayram, B., Yaralioglu, G.G., et al.: Analytical calculation of collapse voltage of CMUT membrane [capacitive micromachined ultrasonic transducers]. Proceedings of the IEEE Ultrasonics Symposium, vol. 1, 256–259 (2004)
5. Ergun, A.S., Huang, Y., Zhuang, X., et al.: Capacitive micromachined ultrasonic transducers: Fabrication technology. IEEE Trans. Ultrason. Ferroelect. Freq. Contr. **52**(12), 2242–2258 (2005)
6. Stephen, J.N.: Annular array imaging with full-aperture resolution. J. Acoust. Soc. Am. **92**(6), 3202–3206 (1992)
7. Brunke, S.S., Lockwood, G.R.: Broad-bandwidth radiation patterns of sparse two-dimensional vernier arrays. IEEE Trans. Ultrason. Ferroelect. Freq. Contr. **44**(5), 1101–1109 (1997)