10.1109/ULTSYM.2010.0196

Forward-Looking Intracardiac Imaging Catheters Using Fully Integrated CMUT Arrays

Amin Nikoozadeh[1], Ömer Oralkan[1], Mustafa Gencel[1], Jung Woo Choe[1], Douglas N. Stephens[2], Alan de la Rama[3], Peter Chen[3], Feng Lin[4], Aaron Dentinger[4], Douglas Wildes[4], Kai Thomenius[4], Kalyanam Shivkumar[5], Aman Mahajan[5], Chi Hyung Seo[6], Matthew O'Donnell[6], Uyen Truong[7], David J. Sahn[7] and Pierre T. Khuri-Yakub[1],

1 Stanford University, **2** University of California, Davis, **3** St. Jude Medical, **4** General Electric Corporate Research & Development, **5** University of California, Los Angeles, **6** University of Washington, **7** Oregon Health and Science University

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, which besides its harmful ionizing radiation does not provide adequate soft-tissue resolution. Intracardiac echocardiography (ICE) provides real-time anatomical information that has proven valuable in reducing the fluoroscopy time and enhancing procedural success. We developed two types of forward-looking ICE catheters using capacitive micromachined ultrasonic transducer (CMUT) technology: MicroLinear (ML) and ring catheters. The ML catheter enables real-time forward-looking 2-D imaging using a 24-element 1-D CMUT phased-array that is designed for a center frequency of 10 MHz. The ring catheter uses a 64-element ring CMUT array that is also designed for a center frequency of 10 MHz. However, this ring-shaped 2-D array enables real-time forward-looking volumetric imaging. In addition, this catheter provides a continuous central lumen that enables convenient delivery of other devices such as RF ablation catheter, EP diagnostic catheter, biopsy devices, etc. Both catheters are equipped with custom front-end IC's that are integrated with the CMUT arrays at the tip of the catheters. The integration of the IC's with the CMUT arrays was accomplished using custom flexible PCB's. We also developed several image reconstruction schemes for the ring catheter on a PC-based imaging platform from VeraSonics. We performed a variety of bench-top characterizations to validate the functionality and performance of our fully integrated CMUT arrays. Using both catheters, we demonstrated *in vivo* images of the heart in a porcine animal model. We have successfully prototyped the first CMUT-based ICE catheters and proven the capabilities of the CMUT technology for implementing high-frequency miniature transducer arrays with integrated electronics.**

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

e-mail contact: aminn@stanford.edu

I. Introduction

Atrial fibrillation is the most common type of cardiac rhythm disturbance that now affects over 2.2 million adults in the United States alone [1]. Catheter-based electrophysiological (EP) procedures have proven essential for improved diagnosis and treatment of cardiac arrhythmias. These interventions are commonly guided under fluoroscopy, which exposes both the patient and the physician to harmful ionizing radiation [2]. Additionally, fluoroscopy does not provide adequate anatomical information that is essential for accurate guidance of the catheters in the heart, even in the presence of contrast agents [3]. Hence, the use of echocardiography (ICE) catheters in EP interventions is gaining more attention. In addition to benefits in reducing the fluoroscopy time, ICE has proven useful in improving visualization and procedural success [4].

We developed two types of ICE catheters for forward-looking real-time imaging using fully integrated CMUT arrays. In this paper, we provide a short description of the components of these catheters and their method of integration. Also, we present some *in vivo* imaging results using a porcine animal model acquired with these catheters.

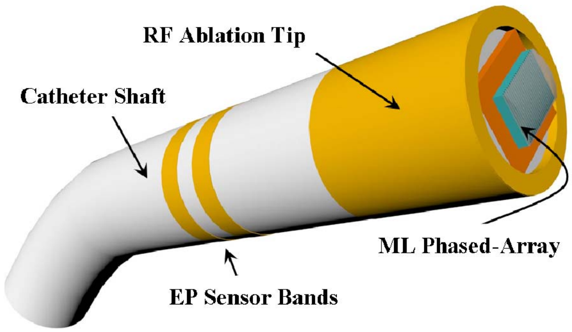
II. ICE Catheters

We developed two types of forward-looking ICE catheters using CMUT technology: ML and ring catheters. The ML catheter provides real-time forward-looking 2-D imaging [Fig. 1(a)]. It uses a 1-D CMUT phased-array integrated with custom front-end electronics at the tip of the catheter. The ring catheter enables real-time forward-looking volumetric imaging using a ring-shaped 2-D CMUT array [Fig. 1(b)]. Additionally, this catheter provides a continuous central lumen that enables convenient delivery of other devices such as RF ablation catheter, EP diagnostic catheter, biopsy devices, etc. The ring array is also closely integrated with custom front-end electronics at the catheter tip.

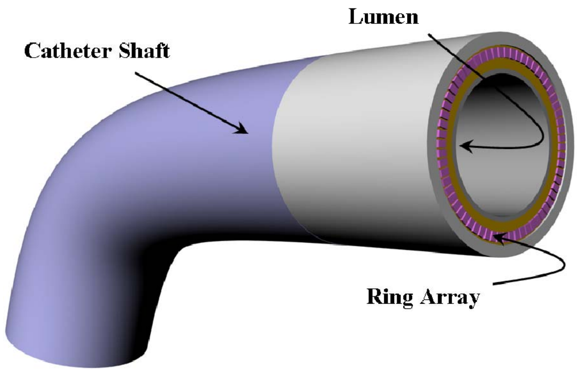
III. Methods

A. CMUT Arrays

The two CMUT array types used in these catheters were fabricated using the standard polysilicon sacrificial release process with through-wafer via interconnects [5]. Both arrays were designed for a center frequency of 10 MHz. The ML CMUT array is a 24-element 1-D phased array [Fig. 2(a)]. The ML die measures 1.7 mm × 1.3 mm and the array elements have a pitch of 63 µm. The CMUT ring array is a 64-element ring-shaped 2-D array with the array elements distributed along the periphery of the device [Fig. 2(b)]. Each array element

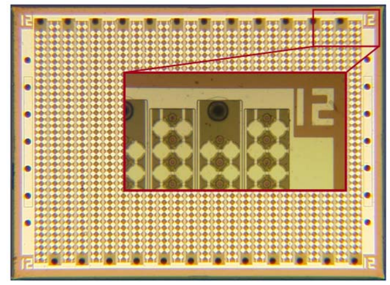


(a)

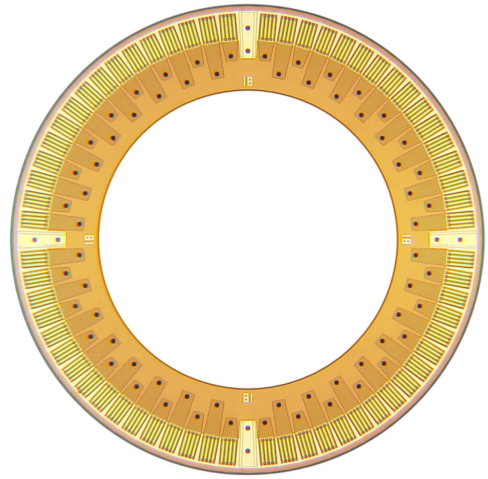


(b)

Figure 1. Conceptual drawing of the catheters. (a) ML Catheter. (b) Ring Catheter.



(a)



(b)

Figure 2. Optical picture of (a) CMUT ML array and (b) CMUT ring array.

measures 90 µm × 110 µm that correspond to an active capacitance of about 0.3 pF. The outer and inner diameter of the device measure 2.5 mm and 1.6 mm, respectively. The singulation of the arrays and also the fabrication of the ring array's inner hole were performed using a single step deep reactive ion etching process.

B. Custom-Designed Front-End Electronics

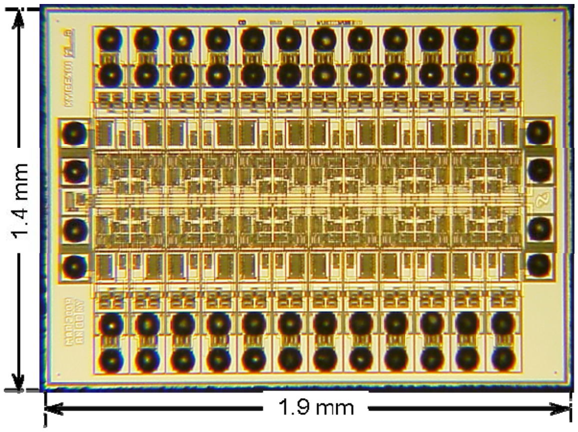
In a typical catheter assembly the micro-coaxial cable accounts for a capacitance of about 200 pF. Therefore, direct connection of small transducer elements with low capacitance to the imaging system suffers from low SNR. We designed custom front-end IC's for close integration with the CMUT arrays at the catheter tip to improve the SNR and the image quality. The chosen circuit architecture provides seamless integration with the imaging system requiring only a single cable per TX/RX channel [6]. The IC provides a dedicated low-noise amplifier for each element of the CMUT array. This circuit architecture was implemented in a 24-channel and 8-channel configuration for the ML array and the ring array, respectively (Fig. 3). For the ring array, eight IC's are used to address the 64 elements. Also the ring IC's were polished to a final thickness of 200 µm to enable tight packaging.

C. Catheter Assembly

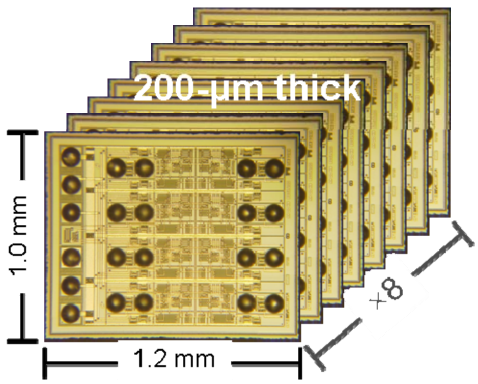
We designed custom flexible PCB's (flex) to integrate the CMUT arrays and the IC's.

For the ML catheter, the flex is a long strip that provides matching pads to the CMUT ML array and the ML IC in the center but on the opposite sides. 80-µm solder balls were deposited on the pads of both dies. The IC was first flip-chip bonded to the flex. After the solder reflow process, the CMUT was flip-chip bonded to the opposite side of the flex followed by another reflow process. The flex legs were then folded under the ML array. 48-AWG micro-coaxial cables were terminated on the cable pads at the end of the flex legs and the catheter was finalized in a 9F shaft. Figure 4(a) shows the 9F ML catheter at different stages of the assembly process.

The ring flex is composed of 8 long and narrow legs that intersect at the center of the flex. 80-µm and 60-µm solder balls were deposited on the pads of IC's and the CMUT ring array, respectively. The ring array and all the eight IC's were flip-chip bonded to the flex followed by a single reflow process. The flex legs were then folded under the ring array. Similar to the ML catheter, 48-AWG micro-coaxial cables were terminated onto the cable pads on the flex. A total of 100 cables were required to provide all the electrical connections to the IC's. Instead of a 9F catheter shaft, the first ring catheter was assembled in a 12F shaft to ease the integration with the large number of cables. Figure 4(b) shows the ring catheter at different stages of the assembly process. There are 244 solder interconnects involved in the integration of the ring array and the IC's. All these connections have to work for a fully functional catheter.

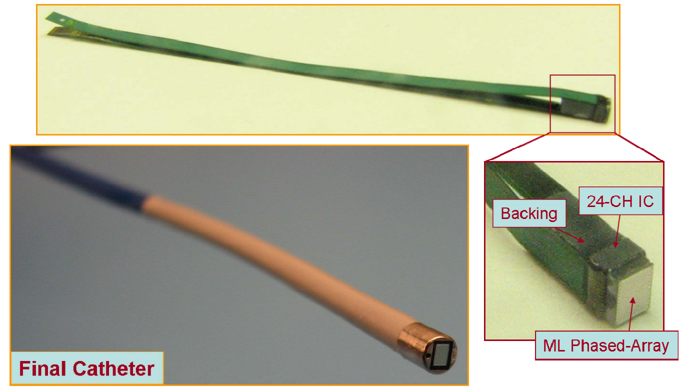


(a)

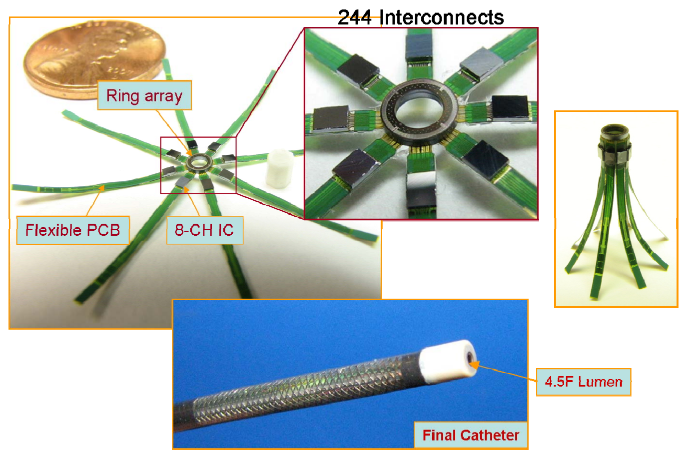


(b)

Figure 3. Custom front-end electronics. (a) 24-channel implementation for the ML array. (b) 8-channel implementation for the ring array. Eight IC's are used for a ring catheter.



(a)



(b)

Figure 4. Catheters in different stages of the assembly process. (a) ML catheter. (b) Ring catheter.

D. Real-Time Imaging

A commercial GE Vivid 7 imaging system (GE Healthcare, Wauwatosa, WI) and a PC-based imaging system (VeraSonics, Inc., Redmond, WA) were used in imaging experiments.

The Vivid 7 was programmed for conventional phased-array B-mode imaging. We programmed the VeraSonics platform specifically for imaging with the ring catheter. The image reconstruction is based on the full synthetic phased-array imaging. We also included Hadamard coding using all the 64 elements to improve the SNR [7]. Norton's weightings for full-aperture resolution [8] and cosine apodization are also implemented in our image reconstruction [9].

IV. Results

We characterized the imaging performance of the catheters using imaging phantoms and *in vivo* porcine animal models.

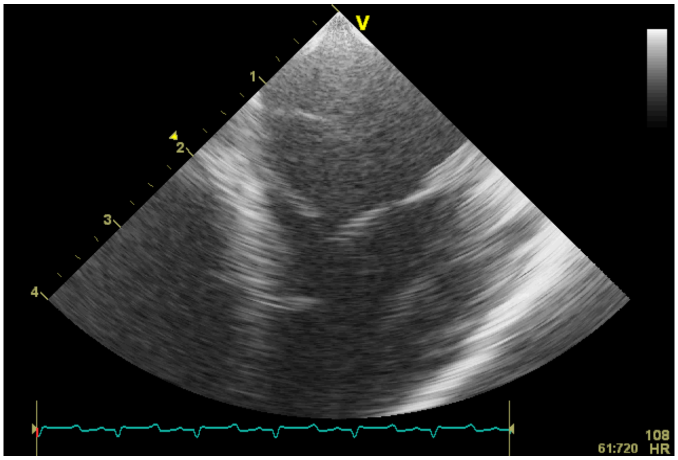
Figure 5 shows the *in vivo* imaging results with the ML catheter. The top image shows the tricuspid valve with the catheter placed in the right atrium. The bottom image shows an RF ablation catheter during ablation and its surrounding heart tissue. Both these images were acquired using the GE Vivid 7 imaging system.

Figure 6 shows two images acquired with the ring catheter that demonstrate its volumetric imaging capability. The top image is from a commercial gray-scale phantom (Model RMI 403GS LE gray scale phantom, Gammex, Inc., Middleton, WI) that clearly shows the three embedded nylon wires. This image was acquired using our VeraSonics imaging platform. The bottom *in vivo* image shows a guide-wire that was inserted into the heart through the inner lumen of the ring catheter. This image was acquired using the GE Vivid 7 imaging system.

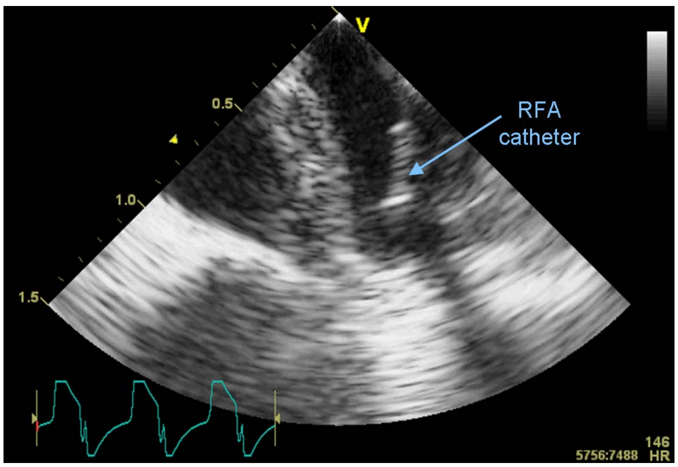
V. Conclusions

We have successfully prototyped the first CMUT-based ICE catheters for forward-looking real-time imaging. We also demonstrated *in vivo* imaging performance of both catheters in porcine animal models. These results demonstrate the capabilities of the CMUT technology for implementing high-frequency miniature transducer arrays fully integrated with front-end electronics.

We are currently continuing to work on improving our ring catheter for the next generation. We will try to reduce the number of cables for better catheter steerability and also reduce the size of the catheter to 9F.

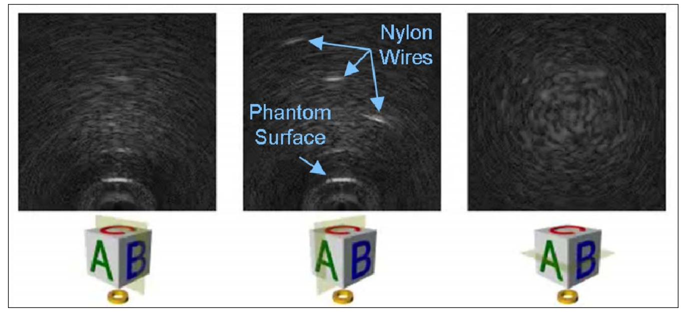


(a)

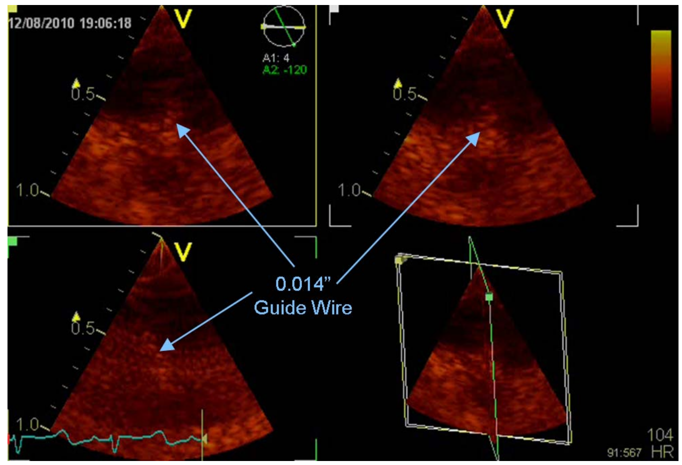


(b)

Figure 5. *In vivo* imaging performance of the ML catheter. Images were acquired using the GE Vivid 7 Imaging system. (a) View of tricuspid valve from right atrium. (b) Observation of an RF ablation catheter during abation and the sorrounding tissue.



(a)



(b)

Figure 6. Imaging performance of the ring catheter. (a) Image of a commercial gray-scale phantom (Model RMI 403GS LE gray scale phantom, Gammex, Inc.) showing three nylon wires. This image was acquired usign our VeraSonics platform. The right panel shows a C-mode image at 7.5 mm depth and the other two panels are perpendicular B-mode images. (b) *In vivo* image showing a 0.014" guide-wire inserted into the heart through the inner lumen. This image also shows the sorrounding heart tissue and it was acquired using the GE Vivid 7 Imaging system.

ACKNOWLEDGMENT

This work was funded by the National Institutes of Health under grant NHLBI 5R01HL067647, USA. We would like to 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. Solder bumping was provided by Pac Tech USA Inc. (Santa Clara, CA). We would like to thank Charlie Holtan (Precision Interconnects, Wilsonville, OR) for his valuable support on catheter cabling. We also thank VeraSonics for their programming support.

REFERENCES

[1] A. S. Go, E. M. Hylek, K. A. Phillips, et al., "Prevalence of diagnosed atrial fibrillation in adults: national implications for rhythm management andstroke prevention: the anticoagulation and risk factors in AF (ATRIA) study," *JAMA.*, vol. 285, pp. 2370–2375, 2001.

[2] J. W. Hirshfeld Jr., S. Balter, J. A. Brinker, et al., "ACC F/AHA/HRS /SCA I clinical competence statement on physician knowledge to optimize patient safety and image quality in fluoroscopically guided invasive cardiovascular procedures: A report of the American College of Cardiology Foundation/American Heart Association/American College of Physicians Task Force on Clinical Competence and Training," *J. Am. Coll. Cardiol.*, vol. 44, no. 11, pp. 2259–2282, 2004.

[3] M. C. Burke, M. J. D. Roberts, and B. P. Knight, "Integration of cardiac imaging and electrophysiology during catheter ablation procedures for atrial fibrillation," *J. Electrocardiol.*, vol. 39, no. 4, pp. S188–S192, 2006.

[4] M. Jongbloed, M. Schalij, K. Zeppenfeld, P. Oemrawsingh, E. van der Wall, J. Bax, "Clinical applications of intracardiac echocardiography in interventional procedures," *Heart*, vol. 91, pp. 981-990, 2005.

[5] A. S. Ergun, Y. Huang, X. Zhuang, O. Oralkan, G. G. Yaralioglu, and B. T. Khuri-Yakub, "Capacitive micromachined ultrasonic transducers: Fabrication technology," *IEEE Trans. Ultrason. Ferroelect., Freq. Contr.*, vol. 52, no. 12, pp. 2242–2258, 2005.

[6] A. Nikoozadeh, O. Oralkan, M. Gencel, et al, "Forward-looking volumetric intracardiac imaging using a fully integrated CMUT ring array," in *Proc. IEEE Ultrason. Symp.*, vol. 1, 2009, pp. 511-514.

[7] R. Y. Chiao, L. J. Thomas, and S. D. Silverstein, "Sparse array imaging with spatially-encoded transmits," in *Proc. IEEE Ultrason. Symp.*, vol. 2, pp. 1679–1682, Oct. 1997.

[8] S. J. Norton, "Annular array imaging with full-aperture resolution," *J. Acoust. Soc. Am.*, vol. 92, no. 6, pp. 3202–3206, Dec. 1992.

[9] D. T. Yeh, O. Oralkan, I. O. Wygant, M. O'Donnell, and B. T. Khuri-Yakub, "3-D ultrasound imaging using a forward-looking CMUT ring array for intravascular/intracardiac applications," *IEEE Trans. Ultrason., Ferroelect., Freq. Contr.*, vol.53, no.6, pp. 1202- 1211, June 2006.