Forward Looking Intracardiac Imaging Catheters for Electrophysiology

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Abstract — **Minimally invasive electrophysiology interventions to treat cardiac arrhythmias are increasing worldwide due to advances in technologies that enable more effective clinical procedures. A forward imaging ultrasound catheter design has been developed and tested to advance the methods of integration of intracardiac imaging and electrophysiology sensing.**

The first catheters built have been constructed with a 9F (3mm) shaft and a large (15F) tip to support experimental wire ports adjacent to a 24 element phased array operating at 14MHz. The final tip design construction size will be 9F and possess an integrated metal electrode at the catheter distal end.

Two forward looking array designs have been developed in parallel to produce two contrasting fine pitch (65 microns) 24 element phased array construction approaches. The first array has been assembled with a standard 2-2 composite PZT technology with the flex circuit mounted on the front facing side, and the second design is a cMUT version with a flip-chip bonded silicon die bonded to a backside flex circuit. The cMUT design requires a special interface to assure a safe element biasing scheme while enhancing the array's linearity and sensitivity.

The first PZT array prototypes, built without explicit matching layers, have been characterized and agree with FEA and KLM analyses in operation at 14MHz. Matching layer variations have been used on the front layer flex circuit to optimize the sensitivity and bandwidth of the PZT arrays while minimizing the thermal boundary layer. Specially designed assembly approaches addressed the challenging forward looking array configurations that utilize interconnection flex circuits with bend radii at 250 microns.

Animal studies have been performed utilizing beam forming adaptations for the forward looking imaging catheter operation on a Vingmed Vivid-7 system. The first piezoceramic array devices were used successfully to image the myocardium of the right atrium of a pig while simultaneous tissue ablation was performed.

Keywords – forward looking; electrophysiology; intracardiac echo; electroanatomical mapping; guidance; ultrasound; capacitive micromachined ultrasonic transducers; cMUT

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INTRODUCTION

The use of intracardiac echo (ICE) imaging catheters for the guidance of interventional electrophysiology (EP) therapeutic procedures is becoming more common because of its features offering real time, direct observations and improved procedural guidance over that of fluoroscopy alone [1]. The opportunity for applications of improved image guidance are certainly apparent in EP therapeutics. Atrial fibrillation itself, the most common cardiac dysrhythmia, now affects more than 2.2 million in the U.S. alone with 60,000 new cases each year [2].

Current standard EP therapeutic guidance methods include fluoroscopy as the primary means to direct catheter position and movement, however EP ablation procedures can take as long as 3 hours [3, 4], with long periods of radiation exposure. Methods are needed to improve clinical outcomes and reduce these undesirably long fluoroscopic exposures. Average exposure times of 22 minutes [5] for isthmus ablation procedures to correct atrial flutter in the readily accessible right atrium are not uncommon, and the average fluoroscopy time during cardiac resynchronization device implantation procedures can be 35 minutes or longer [6]. Extensive fluoroscopic exposures are hazardous for the patient and practitioner alike.

The technology and use of intracardiac echocardiography has progressed from the early days of the first experimental intracardiac probe built of 16 piezoceramic elements circumferentially arranged on a catheter tip [7]. Excellent work has been done in the development of volumetric scanning imaging arrays on catheters for use in EP [8], however our approach seeks to concentrate on multifunctional catheters that unite highly compatible technologies to advance EP guidance.

We are now entering a "virtual anatomy" realm in EP therapeutic guidance where advanced integration of non-fluoroscopic imaging modalities are emerging [9,10]. Using such imaging modalities as electroanatomical (EA) mapping of the cardiac anatomy can produce a significant reduction in fluoroscopic exposure [3, 11-13]. We believe that EA mapping capability can be integrated into novel intracardiac imaging catheters to add yet another dimension to the image guidance equation for EP. Although there are several non-fluoroscopic guidance devices currently available [10], the NavX (St. Jude Medical) system has the very desirable ability to track in 3D any EP catheter with standard plug connections, making it ideal for use with our family of EP-ICE catheters. This feature makes the integration of 3-D spatial location and ICE imaging on a single catheter a very straight forward proposition.

I. Ultrasound Guided Electrophysiology

A. *A Family of Integrated ICE Catheters*

Our efforts have concentrated in the creation of several types of integrated imaging catheter designs specifically for use in electrophysiology therapy guidance. The first of three devices, the “HockeyStick” (HS), has been described [14] as a 9F side-looking 64 element, phased array catheter operating at 7 to 12 MHz which has at least 2 EP sensor bands to allow electrical mapping within the heart chambers. The second device we have in development is a 9F forward-looking 64 cMUT element ring array catheter operating at 10MHz that ultimately will allow the central catheter lumen to be used as a conduit for any of many small wire, fiber, or electroded therapy devices to be used simultaneously with forward-looking imaging. The ring array has been used with synthetic aperture imaging techniques in laboratory testing [15-18] to demonstrate its usefulness. Work to incorporate this ring design into a catheter is in progress. Parts of the early EP-ICE integration assemblies are shown in Figure 1.

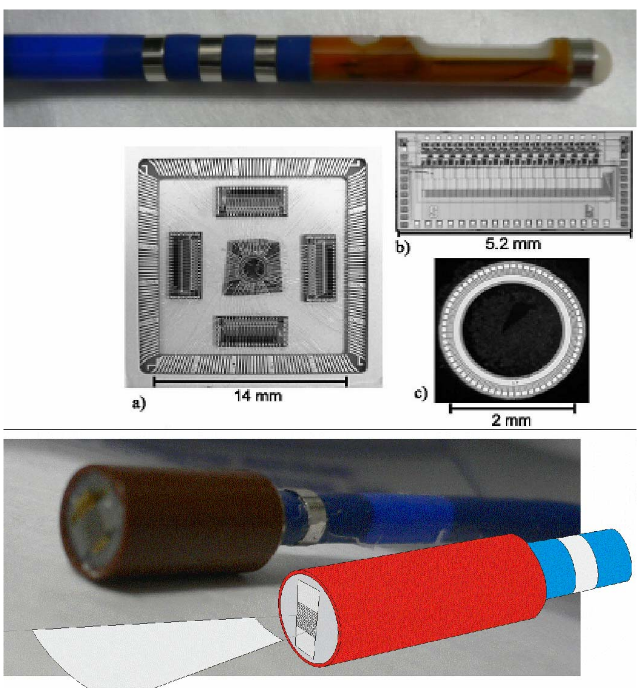

Figure 1. Prototype assemblies of the three members of the EP-ICE catheter family in development. The distal end of the HS catheter is shown at the top of the figure. The middle panel shows a) the laboratory test assembly of the “ring array” surrounded by wire-bonded Tx-Rx interface circuitry, b) the close-up of the array interface electronics and c) the 64 element cMUT ring itself with individual connection pads on the periphery. A 15F early prototype assembly of the MicroLinear catheter is shown at the bottom.

A third member of the EP-ICE family of integrated devices is the “MicroLinear” (ML) catheter. This is an EP capable catheter with an array mounted at the tip for high definition, high frame rate, forward looking imaging. The final design configuration for the ML catheter will include a metal ablation tip surrounding the distal array allowing both radio-frequency ablation (RFA) and imaging simultaneously. The early assembly, testing and imaging results of the MicroLinear catheter are the principal subject of this paper.

II. Methods

A. *Catheter Design*

The ML catheter uses the same bi-directional steering shaft design and system connector interface arrangement as the HS catheter previously described [14] for the HS catheter. The ML shaft incorporates either one or two EP electrode sensor bands near its distal end and the final design calls for a metal ablation tip enclosure to house the distal tip forward-looking ultrasound array.

B. *Array Design*

The forward-looking ML catheter is quite different from the HS catheter at the distal tip. Since the array design is rectangular flat-end facing in format, the flex circuit on which the array is mounted must be folded to fit within the distal tip housing. We have utilized two very different types of array designs, one is piezoceramic based, the other is silicon MEMS based. Both array types are designed with the same element dimensions as shown in Table I. The one key difference though in construction is that the piezoceramic array is mounted on the “inside” of the flex circuit bend, and the MEMS array is mounted on the “outside” bend.

TABLE I. PZT and MEMS Acoustic Array General Parameters

Design Parameter	**Acoustic Array Design Type**	
	Piezoceramic	*MEMS Silicon*
Configuration	2-2 composite PZT	cMUT Disk, or Rectangle
Position on flex circuit	inside	outside
Array elements	24	24
Center Frequency (MHz)	14	14
Array pitch (mm)	0.065	0.065
Element Elevation (mm)	1.2	1.2

The piezoceramic array is designed as a 2-2 composite structure using L155N ceramic (TFT Corp., Tokyo, Japan). The piezoceramic array design includes a simple stack structure where the 2-2 PZT composite itself is 120 microns thick with 15 micron epoxy filled kerfs. The front-side materials are simply a 25 micron thick polyimide flex with 4.5 micron metal traces that make a compression bonded contact with the 2-2 composite structure, and a parylene layer at 10 microns thickness to serve as a insulating outer layer that prevents the flex circuit outside (ground shield) metal from touching biological tissue. The backing is a cast-on electrically conductive reference electrode side which is 1 millimeter thick E-solder 3022 (Von Roll Isola, New Haven, CT). Both FEA (PZFlex, Weidlinger Associates, Inc., Mountain View, Ca.) and KLM simulation tools were used to assess the piezoceramic design performance.

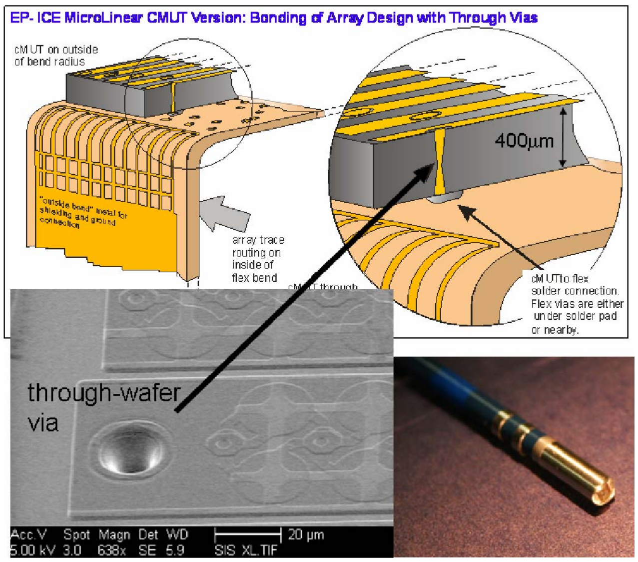

Figure 2. The position of the cMUT arrray mounted on the folded flex circuit is shown at the top with the unique through-wafer via to allow top trace communication with the flex pads. The lower right is a mock-up of the final assembly with metal tip enclosure.

The MEMS array is constructed of 24 elements using a capacitive micromachined ultrasonic transducer (cMUT) structure with a 0.5 micron silicon nitride membrane. Various cMUT array designs have been fabricated with membrane configurational shapes including both round disk and rectangular sub-elements collectively making each of the 50 by 1200 micron elements on a particular array design. The cMUT uses "through-wafer" vias to allow the signal and reference electrodes on the array side to communicate to the backside flip-chip solder pads of the device as depicted in Fig. 2 above. These backside pads use 80 micron SnPb solder bumps to make contact to the 25 micron thick flex circuit. The cMUT is under filled with epoxy following flip-chip bonding.

Both the piezoceramic and MEMS assemblies were assembled by folding the flex circuit into its final orientation with special tooling fixtures, and coax cabling attachment completes the sub-assembly for final catheter integration.

C. *Imaging Methods*

The prototype piezoceramic MicroLinear catheter assemblies were used in an *in vivo* porcine heart model in several experiments to determine the imaging capability, steering, and ablation guidance while imaging as a 14MHz phased array device. The Vivid-7 (Vingmed, Horten, Norway) system was used as the imaging platform for the tests.

III. Results

A. *Bench Testing of the ML Array Designs*

The initial piezoceramic ML catheter arrays showed only modest fractional bandwidth (FBW) performance at 24%, however with improved assembly techniques the 2nd generation devices have shown FBW performance in the 50% range and have agreed well with simulations, as shown in Fig. 3. First generation MEMS devices, designed for assembly into ML catheters, have been lab tested for their pulse echo performance in oil. Initial test results are shown in Fig.4 where the device was operated in membrane collapse mode.

B. *Imaging Tests In Vivo*

The initial array prototypes of the piezoceramic version were assembled into large tipped (15F, 5mm) ML catheters and were tested in two adult Yorkshire pigs. Excellent 14MHz phased array imaging was observed on the Vivid-7 system with direct observation of RFA procedures during actual ablation without noise appearing in the image, Fig. 5.

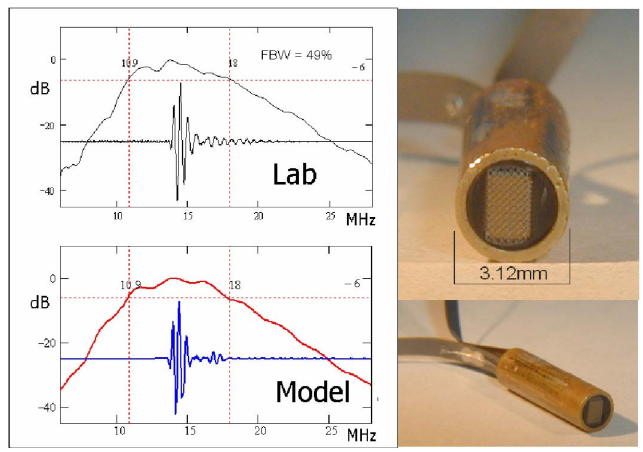

Figure 3. The measured and KLM model performance of the 2nd generation forward-looking PZT array, mounted on the inside of the flex circuit bend.

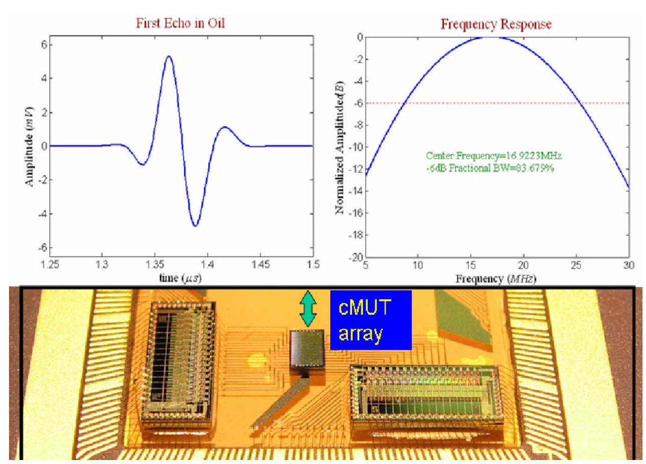

Figure 4. The pulse echo and spectral response from the 24 element cMUT array emersed in oil at a 1mm depth. A 60VDC bias and 24V pulses were used with a transimpedance amplifier configuration.

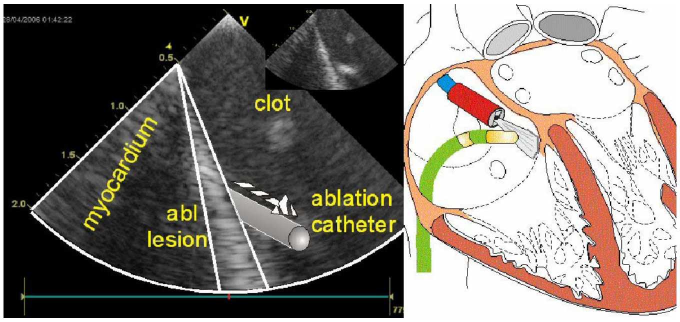

Figure 5. A 15F early PZT array prototype ML catheter imaging an ablation catheter during a RFA procedure in the right atrium of a live porcine model using the Vingmed Vivid-7 imaging system. Both the ablation catheter and the lesion (in outlined region) are clearly visible.

IV. Discussion

Our first experiences with the 15F large tipped piezoceramic ML catheters were very successful even with 25% fractional array bandwidth performance. The 2nd generation piezoceramic ML catheters will be smaller, more steerable, and will have much better FBW for imaging. The cMUT array devices will be assembled into finished ML catheters and tested in the very near future. It is expected that a receive-only buffer circuit will be needed near the cMUT array elements to avoid the cable loading effect during echo reception. The cMUT devices will require some special consideration for biasing; this will be accomplished by modifying the system interface connector assembly to allow introduction of a large (e.g. 60VDC) bias signal to gain optimal array performance.

V. Conclusions

EP-ICE imaging catheters have been developed in both side-looking and forward-looking configurations, with improvements in both concurrently underway. With as few as 24 array elements, and in addition with only 24% FBW, the forward looking phased array sector imaging exceeded our expectations and appears to be a viable imaging tool. Careful electrical shielding design has allowed noise free ultrasonic imaging of radio-frequency ablations *in vivo* which encourages us to proceed with our ablation tipped forward-looking catheter design approach.

The ultimate goal of fluoroscopy radiation reduction and improved EP therapeutic guidance though may be better realized following our next generation improvements combined with a demonstration of ICE imaging integrated with real time 3D electroanatomical navigation within the chambers of the heart.

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