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Multifunctional Catheters Combining Intracardiac Ultrasound Imaging and Electrophysiology Sensing

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Abstract

A family of 3 multifunctional intracardiac imaging and electrophysiology (EP) mapping catheters has been in development to help guide diagnostic and therapeutic intracardiac EP procedures. The catheter tip on the first device includes a 7.5 MHz, 64-element, side-looking phased array for high resolution sector scanning. The second device is a forward-looking catheter with a 24-element 14 MHz phased array. Both of these catheters operate on a commercial imaging system with standard software. Multiple EP mapping sensors were mounted as ring electrodes near the arrays for electrocardiographic synchronization of ultrasound images and used for unique integration with EP mapping technologies. To help establish the catheters' ability for integration with EP interventional procedures, tests were performed in vivo in a porcine animal model to demonstrate both useful intracardiac echocardiographic (ICE) visualization and simultaneous 3-D positional information using integrated electroanatomical mapping techniques. The catheters also performed well in high frame rate imaging, color flow imaging, and strain rate imaging of atrial and ventricular structures. The companion paper of this work discusses the catheter design of the side-looking catheter with special attention to acoustic lens design. The third device in development is a 10 MHz forward-looking ring array that is to be mounted at the distal tip of a 9F catheter to permit use of the available catheter lumen for adjunctive therapy tools.

I. Introduction

Intracardiac echocardiography (ICE) imaging catheters are increasingly being used to guide interventional electrophysiology (EP) therapeutic procedures because they offer real-time, direct observations and improved procedural guidance over that of fluoroscopy alone [1]. Improved interventional image guidance can certainly lead to improved clinical outcomes. Recent reports have shown procedural improvements for atrial fibrillation using ICE integrated with other available imaging modalities [2], [3]. We have taken this integration approach by building and testing a multifunctional catheter capable of both EP sensing and ICE imaging functions.

A. Arrhythmias and Interventional Procedures in Electrophysiology

Atrial fibrillation (AF), the most common cardiac dysrhythmia, now affects more than 2.2 million adults in the United States alone and was the discharge diagnosis for 465,000 hospitalizations in 2003 [4]. Because cardiac dysrhythmia is more prevalent in ages beyond 60 years, the yearly rate of increase in the patient population with AF is expected to peak by 2030 due to the growing population of aging baby boomers, resulting in an expected 5.6 million U.S. patients by 2050 [5].

Nonpharmacologic therapies using catheter-based procedures are becoming more common to treat both left and right side superventricular arrhythmias. Many successful catheter-based interventional procedures to treat superventricular arrhythmias have evolved from invasive surgical techniques developed in the 1980s. In the late 1990s, there was a transition to radiofrequency ablation catheter-based approaches for many superventricular arrhythmias [6].

Both atrial chambers can be accessed and treated by minimally invasive catheter-based EP therapies. Catheters are usually inserted into the patient's femoral vein to access the low-pressure right side of the heart. They are typically guided by fluoroscopic means via the inferior vena cava to the right atrium, allowing immediate access to the right atrioventricular (AV) sulcus, the coronary sinus, and sites on the right atrial walls including the atrial septum. By first using EP diagnostic catheters to map heart wall electrical pathways, the interventionalist can then use therapeutic radiofrequency ablation (RFA) catheters to ablate along specific endocardial paths to isolate aberrant electrical conduction paths disturbing normal sinus rhythm. Left atrial procedures to correct AF are more difficult than right side procedures. Common access to the left atrium is achieved by first crossing the thin atrial septal wall and locating the pulmonary vein ostia, typical targets for ablation therapy to correct AF arrhythmias. Currently there are many therapeutic approaches to ablate undesirable endocardial conduction pathways, including catheter devices producing electrical RF energy, high-intensity focused ultrasound energy, laser energy, and even catheters designed to use cryogenic energy absorption techniques [7]–[9].

B. Conventional Interventional EP Guidance and Early ICE Development

ICE catheter designs have existed for some time [10], [11], although multi-site use was not seen until the late 1980s and early 1990s when catheters with wire-driven rotating piezoelectric transducers were used clinically [12]– [15]. These early mechanical ICE catheters [16] were typically large (e.g., 10F), were not directly steerable (needed a steerable sheath), had limited tissue penetration due to a small circular aperture effecting transmitted power and depth of focus, a slow frame rate (30 Hz), and were incapable of high-quality Doppler or tissue velocity imaging (TVI).

A technological progenitor 10F phased-array device has been used in key studies since 2000 [17]–[19], and in 2005, an 8F version (AcuNav, Siemens Medical Solutions USA, Inc., Malvern, PA) of the device was approved for human use.

C. Opportunities for Interventional Guidance of EP Therapies

To treat atrial fibrillation, ICE can provide important guidance not only identifying key anatomic structures, but also in direct ablation guidance and avoidance of therapeutic procedure complications such as microemboli production during ablation and thrombus formation on sheaths and catheters [2], [20]. Other complications ICE can help identify include esophageal imaging to avoid atrial-esophageal fistulas [21], [22], and phrenic nerve damage in ablations of the right atrium (RA), right superior pulmonary vein (RSPV), or the superior vena cava (SVC) [7].

Considerable work has been done in a wide range of imaging modalities to produce guidance superior to that of fluoroscopy and endocardial potential mapping alone [2], [3]. In addition to transesophogeal echocardiography (TEE) and ICE, there are efforts to add other modalities such as multidetector computed tomography (MDCT), magnetic resonance angiography (MRA), and electroanatomical mapping to the guidance tool set for EP.

With the use of MRA-imaging techniques in EP cases, observations have been made regarding the oblong shape of the PV ostia, and as many as 38% of patients observed had unusual anatomical features that may have contributed to their condition. MRA may be useful in post ablation follow-up to screen for PV stenoses [23]. Recent studies have been performed with a canine model to evaluate an image integration system for catheter ablation with 3-D computed tomography (CT) images in real time to explore anatomy-function interconnection theories in AF [24]. Similar integration studies with a multislice CT (MSCT) imaging system and an image integration platform have been reported on human patients in Europe [25].

A novel method for endocardial electroanatomical mapping based on magnetic field-sensing technology (CARTO, Biosense Webster, Diamond Bar, CA) was reported in the mid-1990s and remains a popular way to combine 3-D spatial position information with the EP mapping data of endocardial surface potentials [26], [27]. Additional studies using this technology have been conducted [28] showing efficacy as well as the very real potential for reducing fluoroscopy radiation exposure [29].

To better use electroanatomic visual display features describing a fairly coarse volume-space of a cardiac electrical road-map, a more advanced integrated guidance tool has been developed to combine very precise noninvasive imaging data from preacquired CT or MR images (CartoMerge, Biosense Webster), with reports from several groups [24], [30]. A new catheter is now offered to integrate ICE and CARTO, the SoundStar (Biosense Webster, Diamond Bar, CA).

Alternative engineering methods have been introduced recently to provide a volumetric cardiovascular image using catheter-based impedance tomography or “electroanatomical mapping” (LocaLisa, Medtronic, Minneapolis, MN, and Ensite NavX, St. Jude Medical, St. Paul, MN). Both of these methods employ the use of low-frequency electric field gradients, rather than an explicit magnetic field tracking as with the CARTO method. The electric field gradients are detected with simple catheter-based electrodes providing spatial data to calculate an instantaneous back-projected electrode position in 3-D space. Numerous electrodes on many catheters can be tracked in position with reproducible electrode localization to within 1 mm spatial accuracy [31]. An early version of this type of electroanatomical mapping has been shown to provide premapped EP data for post-processing integration with rotational ICE with particular value for anatomically based arrhythmia ablations [32].

Ultrasound itself has acted as a spatial referencing method using a triangulation approach to establish a 3-D position in body tissue (RPM, Boston Scientific, Natick, MA). Validation studies have reported some success [33]. The growing importance of non-fluoro mapping

tools has prompted a recent study comparing some of the more promising mapping systems [34] with particular acknowledgment of the attributes pertaining to the NavX mapping technique by the author conducting the comparison study.

D. Fluoroscopic Exposure: Therapeutic Complications and Reduction Need

Significant radiation exposure reduction is a strong motivator in the development of real-time functional guidance methods to improve clinical outcomes and reduce undesirably long fluoroscopic exposures. Since fluoroscopy remains the current standard for EP therapeutic guidance to direct catheter position and movement, the consequence for patients is long periods of radiation exposure during ablation procedures taking as long as 3 h [35]. Average exposure times of 20 min [36] and 22 min [37] for isthmus ablation procedures to correct atrial flutter in the readily accessible right atrium are not uncommon. EP ablation therapy in the LA can expose patients to more than 21 [38] to 50 [39] min of fluoroscopic radiation. An average fluoroscopy exposure time during cardiac resynchronization device implantation procedures can be 35 min or longer [40]. Extensive fluoroscopic exposures can be hazardous to the patient and practitioner alike, especially if the particular fluoroscopy equipment is substandard in minimizing radiation exposure levels.

Although fluoroscopic techniques have been available for years, the first known necrotic injury from radiation did not appear in the medical literature until 1996 [41]. As late as December 2004, the authoritative committee from the American College of Cardiology Foundation, American Heart Association, and the American College of Physicians Task Force on Clinical Competence and Training recommended no firm quantifiable limits on tolerable exposure levels. Recently, in June 2005, the FDA [42] has recommended relatively modest upper limits on fluoroscopic exposure, although there are more restrictive maximums for both patient and operator mandated in the United Kingdom since 2000 [43].

Although it is convenient to quantify exposure casually in minutes of exposure, the accepted quantification unit of absorbed dose is the gray (Gy), which for diagnostic radiology is also equal to an equivalent dose, the sievert (Sv). The common total exposure metric is taken as the gray per unit time, times an area of exposure, times the time used, usually stated in dose-area-product (DAP) units of centigray centimeter squared, or cGy-cm^2. A patient undergoing an AF ablation procedure, for example, may experience a DAP exposure of 2590 cGy-cm^2 [36], and if one assumes a 10 cm square exposure, the total dose is then 0.26 Gy (or 0.26 Sv). For reference, a typical equivalent annual dose of radiation from natural sources is 2.5 mSv; for patients undergoing fluoroscopic exposure of a small region of the body, transient erythema (skin redness) can occur at 2 Sv, permanent skin epilation at 7 Sv, and late onset dermal necrosis at levels above 10 to 12 Sv [41]. For whole body exposure, the Center for Disease Control [44] has determined that the lethal dose for 50% of a population within 60 d of exposure is 2.5 to 5 Gy (i.e., 2.5 to 5 Sv for a fluoroscopic exposure).

The potential for significant radiation exposures is a true concern if there happens to be a case combining a high-exposure fluoroscope with a lengthy procedure in a young patient. An example is given [41] of an atrophic indurated plaque forming two years later on the skin of a 17 year old following an EP ablation procedure that used approximately 100 min of

fluoroscopy; the corresponding dose to skin was estimated to be 10 gray. One study [45] conducted as a survey of diagnostic fluoroscopy machines from various hospitals in the Netherlands showed that there were substantial variations in exposure rates, with the highest exposure rate at 15 times that of the least. With the highest-dose fluoroscopic device, a patient could receive 1 Sv in as little as 7 min of exposure. Thus a lengthy, but not uncommon, 50-min procedural exposure with this level of radiation could produce an alarming total equivalent dose of more than 7 Sv to a region of the chest.

There have been only a few studies focused specifically on fluoroscopic radiation exposures to patients during EP procedures; attention to patient exposure rates and measurement accuracy is still in development. One recent study [46] stated that patients undergoing RF ablation procedures for paroxysmal AF with long duration exposures that averaged 57 min produced an effective dose of (only) 0.0011 Sv on average. Improvements in radiation exposimetry in a clinical setting are apparently still in development because another author [47] strongly questions this dubious result.

Serious efforts to diminish unnecessary radiation exposure have been conducted by groups integrating various mapping tools to display electrical data collected along with anatomical 3-D location. The CARTO system has been employed by investigators [35], [37], [39], [48], all showing significantly decreased radiation exposure. Additionally, the LocaLisa system was used [49], [50] with 35% and 50% reduction in fluoroscopic radiation exposure, and the NavX system [35], [36], [38], [51], provided marked reductions that offer compelling rationale for the utility of these guidance systems.

Guiding interventional EP therapies is clearly challenging. Among the issues are: 1) adequate endocardial electrical mapping, 2) identification of appropriate landmarks and recognition of individual variants in anatomy, 3) specific site guidance of ablation devices, and 4) the determination of therapeutic success while the heart is in motion, and importantly, while radiation exposure is held to a minimum.

We are now entering a “virtual anatomy” realm in EP therapeutic guidance where advanced integration of non-fluoroscopic imaging modalities is emerging[52], [34]. Using imaging modalities such as electroanatomical mapping of the cardiac anatomy, a significant reduction in fluoroscopic exposure can be achieved [35], [31], [36], [38]. We believe that electroanatomical mapping can be integrated into novel intracardiac imaging catheters to add yet another dimension to EP image guidance. Although there are several nonfluoroscopic guidance devices currently available [47], the NavX system has the very desirable ability to track in 3-D any EP catheter with standard plug connections, making it ideal to 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 straightforward proposition.

II. Methods

A. A Family of Integrated ICE Catheters

Our Bioengineering Research Partnership has targeted several integrated imaging catheter designs specifically for electrophysiology therapy guidance. The first of 3 devices, the

"HockeyStick" (HS) [53], is a 9Fr (3 mm) combination EP mapping and ICE catheter designed to be easily deployed with standard introducer sheaths, possess dual direction steering capability, and incorporate fully integrated EP mapping electrodes near the imaging tip. A 64-element array was chosen in the first design to operate at a center frequency in the range of 7 to 12 MHz with a fractional bandwidth of 50% or greater. The design of this catheter is discussed in more detail in the companion paper [54]. The HockeyStick catheter is depicted in Fig. 1 as it has been used in the right side of the pig heart.

The second member of the EP-ICE family is the "MicroLinear" (ML) catheter. The most recent design is a 9Fr EP capable catheter with a 24-element, 14 MHz phased array mounted at the tip for high definition, high-frame rate, forward-looking imaging. A preferred 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. Prototypes of the MicroLinear forward-looking catheter are shown in Fig. 2 and Fig. 3 with our latest design version shown in the latter.

The third device is a 9Fr forward-looking 64 capacitive micromachined ultrasonic transducer (cMUT) element ring array catheter operating at 10 MHz 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 that can be used simultaneously with forward-looking imaging. The ring array has been used with synthetic aperture imaging techniques in laboratory testing [55]–[57] to demonstrate its usefulness. Work to incorporate this ring design into a catheter is in progress.

B. Animal Studies

Several animal studies using juvenile Yorkshire pigs have been performed to examine the capabilities of the combination catheters. All animal experiments conformed to accepted standards for the use of laboratory animals and were performed under an institutionally approved protocol at Oregon Health and Science University. Tests were proposed to evaluate prototype catheter performance in the areas of mechanical steering and mapping sensor use, imaging compatibility with active RF ablation, visualization and guidance of ablation catheters, observation of ablation lesion size and bubble formation, general compatibility with the imaging system platform (Vingmed Vivid 7, GE Healthcare, Horten, Norway), and performance in color flow and strain rate imaging modes.

The multifunctional catheters were introduced in the jugular or femoral vein to advance the catheter to the RA from either the superior vena cava (SVC) or inferior vena cava (IVC), respectively. While in the RA, the HockeyStick catheters can be used to image the left atrium (LA) and the pulmonary veins (PV) of the LA, or the larger left ventricular (LV) or right ventricular (RV) chambers.

A special electrical connection interface unit for the catheters was used to allow the easy bedside connection of the multifunctional catheters to the imaging system. A separate proximal catheter connector was directly connected to an electrical EP sensor signal-processing system near the bedside.

The imaging system beamforming setup parameter files were adjusted to allow for a reasonably straightforward adaptation for the use of the imaging catheters on a standard imaging platform without the need for custom software. The ease of operational adaptation permitted as well the use of advanced imaging modes such as strain rate imaging (SRI) at high frame rates. Tissue motion tracking of arrhythmias can be interpreted using SRI data derived from tissue velocity imaging (TVI). Experimental designs were proposed to track multiple spatial velocity gradients at specific heart wall sites by displaying in real time their high fidelity tissue motion (in strain rate as units of $time^{-1}$) to aid in the assessment of sinus rhythm abnormalities.

A NavX electroanatomical mapping system with multiple lead inputs and full 3-D software mapping tools were used to perform both intracardiac volume mapping and integration experiments with the HockeyStick catheter.

III. Results

More than 10 pigs weighing in the range of 34 to 55 kg have been studied. ICE imaging was performed using a Vingmed Vivid 7 ultrasound system in standard imaging modes, including color and pulsed Doppler, tissue Doppler, TVI, SRI, and tissue synchronization (TSI) imaging. High frame rates were commonly used at 150 F/sec. Digital scan line data were transferred to an offline EchoPAC-PC (GE Healthcare, Milwaukee, WI) for further analysis.

The pig studies yielded useful ultrasound imaging-guidance indicators while simultaneous tissue ablation was performed using a separate ablation catheter with 50 Watts of RF power delivery capability. Both the side-looking HockeyStick catheter (Figs. 1, 4, and 6) and the forward-looking MicroLinear catheter designs (Figs. 2, 3, and 5) were successful in the imaging of therapeutic RF catheter ablations. The HockeyStick catheter was tested in color flow mode, successfully imaging both the aortic outflow track and LA pulmonary vein dynamic blood flow.

The short axis view of the LV from the RA in the pig of Fig. 6 shows the ability of the HockeyStick to track tissue synchrony using the high frame rate SRI modality available on the imaging system platform. Cardiac arrhythmias were induced by using external pacing leads to alter the patterns of normal sinus rhythm.

Experiments with HockeyStick ICE catheter and electroanatomical mapping catheter integration have been completed. The EP sensor connector of the HockeyStick ICE catheter was connected directly to the NavX system, which allowed both the HockeyStick and the NavX catheter to be visualized simultaneously on the NavX system. Fig. 1 shows the HockeyStick on the right side of the heart in the RA while the NavX catheter is shown in the LV after completing the 3-D mapping of that chamber.

IV. Discussion

A. Imaging Utility of Multifunctional ICE Catheters

Early animal studies targeted general B-Mode imaging of intracardiac features and ablation catheters with attention to evaluation of resynchronization pacing using the multifunctional nature of the EP-ICE combination catheters equipped with integrated EP sensors. The EP-ICE catheters were usually advanced to the heart to perform studies of the RA and RV without fluoroscopic guidance. In one animal, the EP-ICE catheter entered the patent foramen ovale in the intra-atrial septal wall and entered the LA without difficulty. Clear delineation of bubble production after prolonged RF ablation was observed. Both the side-looking HockeyStick catheter and the forward-looking MicroLinear catheter designs have been successful in obtaining very useful images of therapeutic RF catheter ablations.

The HockeyStick has been used very successfully to track tissue synchrony using the high frame rate SRI modality available on the imaging system platform. This ability can be valuable in the assessment of cardiac arrhythmias. High frame rate SRI imaging allows a mechanical survey of the effects of the electrical activation and improves the ability to detect early contractions in the monitored regions of the myocardium that move first using this tissue-tracking technique.

B. Imaging with 3-D Electroanatomical Guidance

Individual intracardiac ECG channel evaluations of arrhythmias have evolved toward simultaneous, multichannel mapping, producing much more detail in the temporal characterization of specific arrhythmias. With the sheer bulk and complexity of the temporo-spatial information, it has become increasingly more difficult to maintain a clear perspective on the large number of channels of ECG data and as well interpret their significance with respect to their specific anatomic locations. Within the last decade, the development of computer-based mapping that better records and presents both the spatial and temporal characteristics of cardiac activity has become more popular as a natural solution to this issue, and in particular as it addresses the need for procedural guidance of therapeutic ablation treatments for problems related to arrhythmias.

Electro-anatomical mapping in particular has become a significant guidance tool. The technique uses patient-isolated electrical field gradients established by a set of patch electrodes attached to the patient’s body in at least 5 key positions. The electrical field gradients can be sensed by either a single electrode on a single intracardiac catheter or on as many as 64 electrodes from many different catheters. The system can determine the location of any single electrode to a spatial accuracy in the range of ±1 mm with a temporal sampling rate as high as 1200 per second [31], [34]. The key enabling feature of this technology is its adaptability; the only particular requirement for our ICE-imaging catheter is the feature of EP electrodes on the catheter tip with a wire path to a connector compatible with the electroanatomical system inputs.

A series of pre-clinical studies have been performed that have combined ICE imaging capability with catheter localization and tracking in 3-D space in real time. Following an initial volumetric mapping with the NavX catheter, the HockeyStick catheter itself could be

tracked continuously within the volume, and with the multiple electrode feature the orientation of the ICE catheter could also be placed accurately in the intracardiac chamber. Since the HockeyStick has a separate EP connector to allow for ECG signal monitoring, the electrodes connected to this EP connector allow for a very easy means of connection to the NavX system connectors. It is only this simple interconnect that is necessary for the NavX system to track the electrode positions in 3-D space. This capability can potentially yield a very powerful strategy to enhance the clinical utility of ICE by enabling therapeutic procedures, guided by intracardiac echocardiography, with much less dependence on hazardous fluoroscopic image guidance. In one of our studies, the navigation and manipulation time for achieving ultrasound imaging of an ablation procedure was substantially reduced by more than 75% compared with fluoroscopic visualization only.

V. Conclusions

Future intracardiac therapies will likely include devices that have multiple capabilities that can improve clinical outcomes with superior guidance features and less dependence on fluoroscopy with its potential for hazardous radiation exposure.

A 3-D road map projection of the heart anatomy through the use of electroanatomical mapping can be successfully combined with ICE catheters in a very seamless fashion, which portends a great future for the success of this technology integration. The future combination of electroanatomical mapping and ICE may offer a significant means for improving the identification accuracy of therapeutic targets, lessen the lengthy procedural times, and decrease the dependence on potentially hazardous fluoroscopic guidance.

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Biographies

Douglas N. Stephens (M’82) is a lifelong resident of California. He received a B.S. degree in physiology from the University of California, Davis, in 1976, and the B.S. and M.S. degrees in electrical and electronic engineering and biomedical engineering in 1981 and 1983, respectively, from California State University, Sacramento. Prior to his years at EndoSonics, he developed electronics for GE Medical Systems Division, assisted two start-up companies in medical electronics, and in 1984 designed a motion control system for ultrasound scanning at SRI International.

In 1985, Mr. Stephens joined the founding technical group at EndoSonics Corporation as a senior electronic design engineer. As a key contributor at EndoSonics in solid state intravascular ultrasound (IVUS) technology, he was responsible for all catheter electronics and analog signal processing. In 1990, he led the technical effort in the creation of the world’s first commercial 3.5F solid-state ultrasound imaging catheter and was awarded the first EndoSonics Fellowship Award in that year. In 1994, he was a co-inventor for the means and method for IVUS color flow imaging, which allows a real- time intraluminal visualization of blood location and velocity, and in 1995, he was promoted to vice president of strategic technology responsible for the new designs of IVUS solid-state technology.

Mr. Stephens is currently in the Department of Biomedical Engineering at the University of California, Davis, working on methods of ultrasound-based-targeted imaging and liposome-mediated drug delivery, ultrasonic and optical methods of arterial plaque characterization, and providing engineering design and management for a multi-site research partnership developing novel intracardiac imaging catheters for use in electrophysiology procedures. His research interests include piezoelectric transducer applications, efficient methods for synthetic aperture beam forming, and ASIC circuit designs for invasive medical imaging.

Jonathan M. Cannata (S’01–M’04) was born in California on August 4, 1975. He received his B.S. degree in bioengineering from the University of California at San Diego in 1998, and his M.S. and Ph.D. degrees in bioengineering from the Pennsylvania State University, University Park, PA, in 2000 and 2004, respectively.

Since 2001, Dr. Cannata has served as the manager for the NIH Resource on Medical Ultrasonic Transducer Technology at Penn State University (2001 to 2002) and currently at

the University of Southern California (USC). In 2005, he was appointed to the position of research assistant professor of biomedical engineering at USC. His current interests include the design, modeling, and fabrication of high-frequency single-element ultrasonic transducers and transducer arrays for medical imaging applications. Dr. Cannata is a member of the Institute of Electrical and Electronics Engineers (IEEE).

Ruibin Liu was born in Kunming, Yunnan Province, China, on July 18, 1963. He received his Ph.D. degree in materials engineering from the Shanghai Institute of Ceramics, Chinese Academy of Sciences, in 1991.

From 1991 to 1996, he was an engineer in Shanghai Institute of Ceramics. His research interest included development of pyroelectric ceramics for the application in IR detection and imaging. From 1996 to 1999, he did postdoctoral work in the Materials Research Laboratory of the Pennsylvania State University. His research interests included piezoelectric actuators, single crystal thin film, and electrostrictive polymers. From 1999 to 2000 and 2002 to 2003, he worked as postdoctoral and research engineer, respectively, in the Sunnybrook & Women's College Sciences Center, University of Toronto. His studies included composite and transducer for high-frequency imaging. from 2000 to 2002, he worked as a partner of a start-up company Tradetrek.com.

He is currently a research associate of NIH Ultrasound Transducers Resources Center at University of Southern California. His research interests are high -requency (40 to 100 MHz) single-element transducers, intracardiac imaging phased arrays, high-frequency composite and array, HIFU single element transducer, and phased array.

Jian Zhong Zhao received his B.S. degree in physics from Henan Normal University, China, in 1982, his M.S. degree in physics from JiLin University, China, in 1988, and a Ph.D. in materials engineering from the Pennsylvania State (Penn State) University in 1998.

From 1988 to 1991, he was an assistant professor in the Physics Department in ZhengZhou University, China. In 1992, he joined the research team in the Materials Research Laboratory at Penn State and work in the development of new piezoelectric materials for transducer, actuator, and sensor applications. From 1998 to 2000 and 2003 to 2004, he worked in NIH Transducer Resource Center as a research associate working on the development of high-frequency transducer and novel intracardiac imaging catheters.

He joined GE Parallel Design in 2000 as an acoustic design engineer then joined Siemens Ultrasonic as a transducer product engineer from 2001 to 2003. Currently he is an acoustic engineer and project manager in GE HealthCare.

K. Kirk Shung (S'73–M'75–SM'89–F'93) obtained a B.S. degree in electrical engineering from Cheng-Kung University in Taiwan in 1968, an M.S. degree in electrical engineering from University of Missouri, Columbia, MO, in 1970, and a Ph.D. degree in electrical engineering from University of Washington, Seattle, WA, in 1975. He did postdoctoral research at Providence Medical Center in Seattle, WA, for one year before being appointed a research bioengineer holding a joint appointment at the Institute of Applied Physiology and medicine. He became an assistant professor at the Bioengineering Program, Pennsylvania State (Penn State) University, University Park, PA, in 1979 was promoted to professor in 1989. He was a Distinguished Professor of Bioengineering at Penn State until September 1, 2002 when he joined the Department of Biomedical Engineering, University of Southern California, Los Angeles, CA, as a professor. He has been the director of NIH Resource on Medical Ultrasonic Transducer Technology since 1997.

Dr. Shung is a Fellow of the IEEE, the Acoustical Society of America, and the American Institute of Ultrasound in Medicine. He is a founding fellow of the American Institute of Medical and Biological Engineering. He has served for two terms as a member of the NIH Diagnostic Radiology Study Section. He received the IEEE Engineering in Medicine and Biology Society early career award in 1985 and was the coauthor of a paper that received the best paper award for IEEE Transactions on Ultrasonics, Ferroelectrics and Frequency Control (UFFC) in 2000. He was the distinguished lecturer for the IEEE UFFC Society for 2002–2003. He was elected an outstanding alumnus of Cheng-Kung University in Taiwan in 2001.

Dr. Shung has published more than 200 papers and book chapters. He is the author of the textbook *Principles of Medical Imaging* published by Academic Press in 1992 and the textbook *Diagnostic Ultrasound: Imaging and Blood Flow Measurements* published by CRC press in 2005. He co-edited a book *Ultrasonic Scattering by Biological Tissues* published by CRC Press in 1993. Dr. Shung's research interests are in ultrasonic transducers, high-frequency ultrasonic imaging, and ultrasonic scattering in tissues.

Hien Van Nguyen has attended National Ky Thuat Viet Nam University and received a B.S. degree in electrical engineering in 1978 and a second B.S. degree in industrial technology in 1980. Since 1986, he has been an engineer in the medical catheter field with positions of responsibility at Baxter Healthcare, Imagyn Medical, and Hearten Medical. He is currently the manufacturing manager at Irvine Biomedical, Inc., a St. Jude Medical company, where he manages the production of electrophysiology catheters and participates in research support of ICE catheters from concept phase to animal studies and human trials. Mr. Nguyen holds 5 U.S. patents.

Raymond Chia, Ph.D., PE, served as the co-founder, vice president, and chairman of the board at Irvine Biomedical Inc. He received his Ph.D. degree in mechanical engineering from Rice University and has a B.S. degree in civil engineering and an M.S. degree in engineering mechanics from National Taiwan University. Dr. Chia is a Registered Professional Engineer in both California and Texas. He remains an active member in ASME and holds 32 patents.

Aaron M. Dentinger (M’95) received his B.S. degree in engineering physics in 1992 and his M.S. and Ph.D. degrees in electrical engineering in 1994 and 2006, respectively, from Rensselaer Polytechnic Institute, Troy, NY. Since 1995, he has worked as an electrical engineer at GE Global Research, Niskayuna, NY, and is currently a member of the Ultrasound and Biomedical Laboratory. Prior to joining GE, he was employed at Reveo, Inc., Elmsford, NY. His current research interests are in ultrasound signal and image processing for vascular, cardiac, and physiological measurements.

Douglas Wildes received a B.A. degree in physics and mathematics from Dartmouth College in 1978 and M.Sc. and Ph.D. degrees in physics from Cornell University in 1982 and 1985, then joined GE Global Research in Niskayuna, NY. Since 1991, his research has focused on aperture design, fabrication processes, and high-density interconnect technology for multi-row and 4-D imaging transducers for medical ultrasound. Dr. Wildes has 23 issued

patents and 18 external publications. He is a member of the American Physical Society and a senior member of the IEEE.

Kai E. Thomenius (M'66) was awarded B.S., M.S., and Ph.D. degrees in electrical engineering and physiology from Rutgers University, New Brunswick, NJ, in 1968, 1970, and 1978, respectively. His background includes both academic and industrial activities, including teaching at Rutgers University, Stevens Institute of Technology, Hoboken, NJ, and Rensselaer Polytechnic Institute (RPI), Troy, NY. He has worked for the U.S. Army Electronics Command at Ft. Monmouth, NJ, as an RF engineer. He has held research-related positions in medical ultrasound since 1976 for Picker Ultrasound, Northford, CT; Elscint, Inc., Boston, MA; ATL/Interspec, Ambler, PA; and most recently GE Global Research in Niskayuna, NY, where he is currently a chief technologist in the Imaging Technologies Organization. In addition, he is an adjunct professor in the Electrical, Computer, and Systems Engineering Department at RPI. The focus of the industrial work has centered on ultrasound systems design, especially beamformation, miniaturization of ultrasound scanners, ultrasound bioeffects, and the design for ultra-portable imagers. An additional focus deals with novel application of ultrasonic imagers; an example of this is the current publication relating to measurement of cardiovascular parameters using ultrasound.

Dr. Thomenius is a Fellow of the American Institute of Ultrasound in Medicine (AIUM), a member of the American Association of Physicists in Medicine, American Society for Echocardiography, Acoustical Society of America, and the Society of Photo-Optical Instrumentation Engineers (SPIE). He is a member of the editorial board of the *Ultrasonic Imaging Journal* and serves as a reviewer of grant proposal for the National Institutes of Health and of articles for several ultrasound journals. In addition, he serves in the Technical Program Committees for IEEE Ultrasonics Symposium, the annual conference of the AIUM, and the Medical Imaging Conference of the SPIE.

Aman Mahajan obtained his M.D. degree from the University of Delhi Medical School in New Delhi, India, in 1991, and a Ph.D. degree from the Department of Physiology, UCLA School of Medicine and Health Sciences, Los Angeles, California, in 2005. He is currently an associate clinical professor, cardiac anesthesiology, in the Department of Anesthesiology, UCLA Medical Center, UCLA School of Medicine and Health Sciences. Dr. Mahajan is a

member of numerous professional societies and has interests in the areas of arrhythmia biology and stem cell electrophysiology.

Kalyanam Shivkumar received his medical degree from the University of Madras, India, in 1991 and his Ph.D. degree from University of California, Los Angeles (UCLA), in 2000. He completed his cardiology fellowship training at UCLA, and on completion of his training joined the faculty at University of Iowa, where he also served as the associate director of cardiac electrophysiology. In 2002, he was recruited back to UCLA to direct the newly created UCLA Cardiac Arrhythmia Center at the David Geffen School of Medicine at UCLA. His field of specialization is interventional cardiac electrophysiology, and he heads a group at UCLA that is involved in developing innovative techniques for the nonpharmacological management of cardiac arrhythmias. He is an associate professor of medicine and holds a joint appointment in the Department of Radiology at UCLA. Dr. Shivkumar is certified by the American Board of Internal Medicine in the subspecialties of cardiovascular disease and clinical cardiac electrophysiology. He holds memberships in several professional organizations, including the American Heart Association, American College of Cardiology, and the Heart Rhythm Society.

Kang Kim received his B.S. degree in educational physics from Seoul National University, Seoul, South Korea, in 1986, his M.S. degree in physics from University of Paris VI (Universite de Pierre et Marie Curie), Paris, France, in 1989, and his Ph.D. degree in acoustics from the Pennsylvania State University, PA, in 2002.

Following his M.S. degree, he moved to the Agency for Defense Development (ADD), Chinhae, South Korea, as a research associate. He later held an appointment as a senior research associate leading a SONAR development team since 1995. Following his Ph.D. degree in acoustics, Dr. Kim joined Biomedical Engineering Department at the University of Michigan as a postdoctoral fellow mainly working on ultrasound tissue elasticity imaging in medical applications. Currently, he holds a faculty appointment in the same department as an assistant research scientist. His recent research interests include noninvasive ultrasound-based multimodal imaging techniques, including nonlinear tissue elasticity imaging, 3-D elasticity imaging, thermal strain imaging, photoacoustic molecular imaging, and engineered tissue characterization.

As of September 2007, Dr. Kim is an IEEE Fellow.

Matthew O'Donnell (M'79–SM'84–F'93) received B.S. and Ph.D. degrees in physics from the University of Notre Dame, Notre Dame, IN, in 1972 and 1976. Following his graduate work, Dr. O'Donnell moved to Washington University in St. Louis, MO, as a postdoctoral fellow in the Physics Department working on applications of ultrasonics to medicine and nondestructive testing. He subsequently held a joint appointment as a senior research associate in the Physics Department and a research instructor of medicine in the Department of Medicine at Washington University. In 1980, he moved to General Electric Corporate Research and Development Center in Schenectady, NY, where he continued to work on medical electronics, including MRI and ultrasound imaging systems. During the 1984–1985 academic year, he was a visiting fellow in the Department of Electrical Engineering at Yale University in New Haven, CT, investigating automated image analysis systems. In 1990, Dr. O'Donnell became a professor of electrical engineering and computer science at the University of Michigan in Ann Arbor, MI. Starting in 1997, he held a joint appointment as professor of biomedical engineering. In 1998, he was named the Jerry W. and Carol L. Levin Professor of Engineering. From 1999 to 2006, he also served as chair of the Biomedical Engineering Department. During 2006, he moved to the University of Washington in Seattle, WA, where he is now the Frank and Julie Jungers Dean of Engineering and also a professor of bioengineering. His most recent research has explored new imaging modalities in biomedicine, including elasticity imaging, in vivo microscopy, optoacoustic arrays, optoacoustic contrast agents for molecular imaging and therapy, thermal strain imaging, and catheter-based devices.

Amin Nikoozadeh (S'03) received his B.S. degree from Sharif University of Technology, Tehran, Iran, in 2002 and his M.S. degree from Stanford University, Stanford, CA, in 2004, both in electrical engineering. He is currently pursuing a Ph.D. degree in electrical engineering at Stanford University. His research interests include medical ultrasound imaging, image-guided therapeutics, MEMS, and analog circuit design.

Omer Oralkan received the B.S. degree from Bilkent University, Ankara, Turkey, in 1995, the M.S. degree from Clemson University, Clemson, SC, in 1997, and the Ph.D. degree from Stanford University, Stanford, CA, in 2004, all in electrical engineering.

He joined the research staff at the E. L. Ginzton Laboratory of Stanford University in 2004 as an engineering research associate. He was promoted to the rank of senior research engineer in 2007. His past and present research interests include analog and digital circuit design, semiconductor device physics and fabrication, micromachined sensors and actuators, and medical imaging. His current research focuses on the design and implementation of integrated systems for catheter-based medical imaging applications, photoacoustic imaging, and chemical and biological sensor arrays.

Dr. Oralkan has authored and co-authored more than 80 publications and received the 2002 Outstanding Paper Award of the IEEE Ultrasonics, Ferroelectrics, and Frequency Control Society. He is a member of the IEEE, SPIE, and AIUM.

Butrus (Pierre) T. Khuri-Yakub (S’70– S’73–M’76–SM’87–F’95) is a professor of electrical engineering at Stanford University. He received the B.S. degree in 1970 from the American University of Beirut, the M.S. degree in 1972 from Dartmouth College, and the Ph.D. degree in 1975 from Stanford University, all in electrical engineering. He was a research associate (1965–1978) then senior research associate (1978–1982) at the E. L. Ginzton Laboratory of Stanford University and was promoted to the rank of professor of electrical engineering in 1982. His current research interests include medical ultrasound imaging and therapy, micromachined ultrasonic transducers, smart bio-fluidic channels, microphones, ultrasonic fluid ejectors, and ultrasonic nondestructive evaluation, imaging and microscopy. He has authored articles in more than 400 publications and has been principal inventor or co-inventor of 76 U.S. and international patents. He was awarded the Medal of the City of Bordeaux in 1983 for his contributions to nondestructive Ealuation, the Distinguished Advisor Award of the School of Engineering at Stanford University in 1987, the Distinguished Lecturer Award of the IEEE UFFC society in 1999, a Stanford University Outstanding Inventor Award in 2004, and a Distinguished Alumnus Award of the School of Engineering of the American University of Beirut in 2005.

David J. Sahn was raised in New York and received his M.D. degree from Yale University cum laude in 1969. Following his medical internship at Yale, he completed his residency in

Pediatric Cardiology at the University of California, San Diego (UCSD), in 1973 and accepted positions at the University of Arizona as assistant professor of pediatric cardiology in 1974, and professor in 1981. From 1983 to 1992, he held positions as professor of pediatrics and radiology and chief, Division of Pediatric Cardiology, UCSD School of Medicine, La Jolla, California. From 1992, he moved to Oregon Health and Sciences University in Portland, OR, where he currently holds positions as professor of pediatrics, diagnostic radiology and obstetrics and gynecology; director, interdisciplinary program in cardiac imaging; and professor of biomedical engineering.

Dr. Sahn has served on numerous professional journal editorial boards including the American Heart Association journal *Circulation*, the *Journal of the American College of Cardiology*, the *American Journal of Cardiology*, and the *Journal of the American Society of Echocardiography*. He has served on two NIH study sections in diagnostic radiology and medical imaging and has been the recipient of numerous honors and awards during his career, and the author in more than 345 peer-reviewed publications.

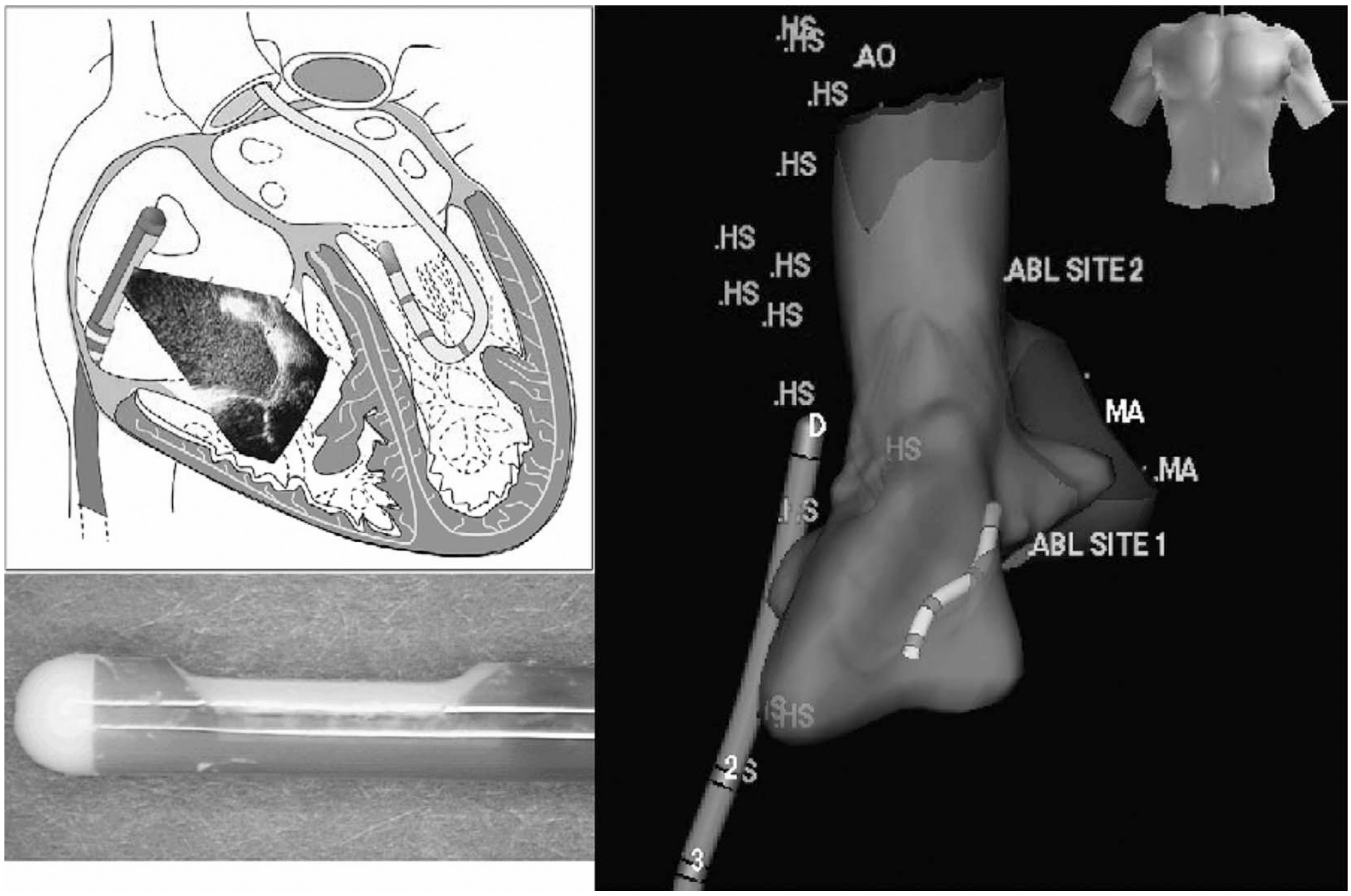

Fig. 1.

A HockeyStick (HS) catheter tip prototype with a tapered acoustic lens is shown at lower left. The upper left shows the HS catheter in approximately the same anterior view right atrial position as the right panel, which shows the NavX mapping result of a partially mapped volume of the pig left ventricle (LV), aortic outflow (AO) tract, and mitral annulus (MA). The HS catheter in the RA is continuously tracked in position along with the light colored EP mapping catheter, which was advanced retrograde past the aortic valve and has been wrapped back upon itself following a left-side volume-mapping exercise.

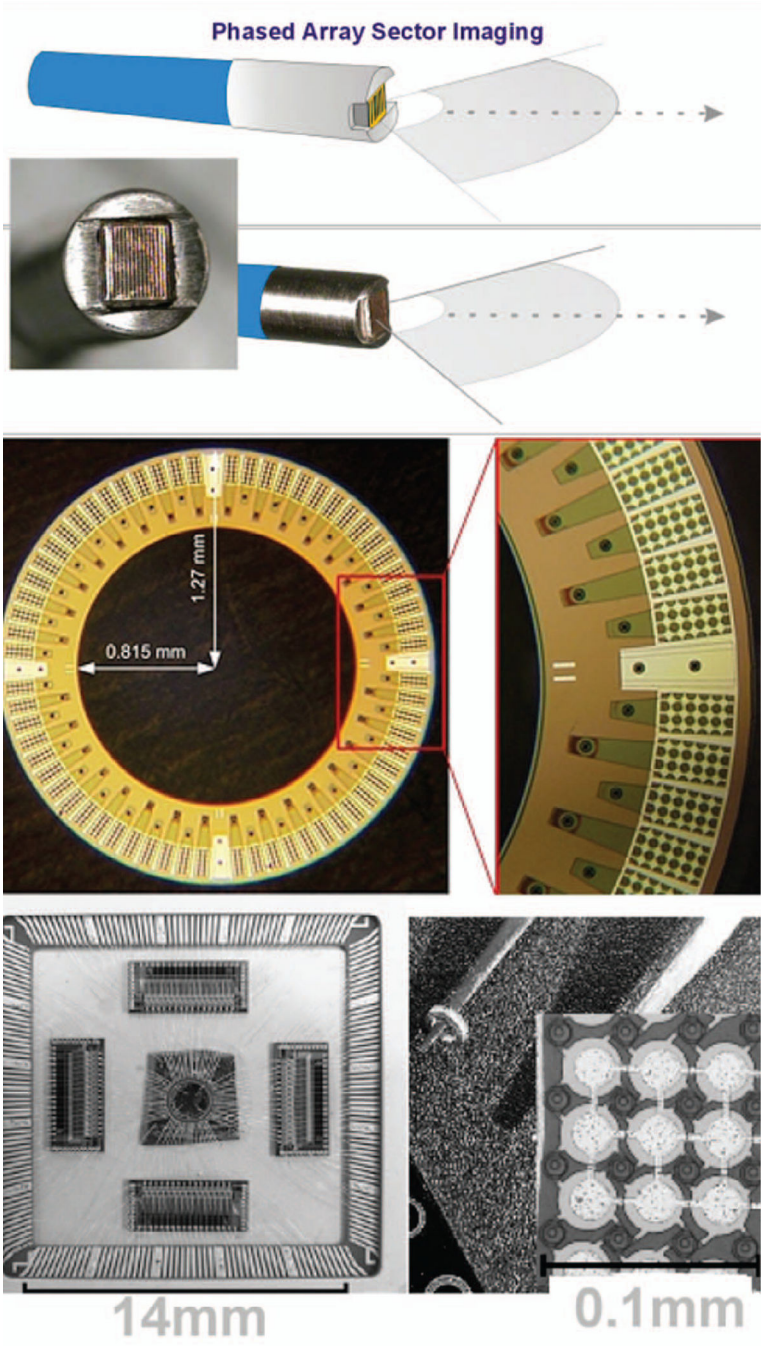

Fig. 2.

The forward-looking devices: the MicroLinear catheter prototype is shown (top panels), and the ring array in recent format (middle panels) along with the earlier ring design in its bench testing configuration and as a singulated ring (bottom panels).

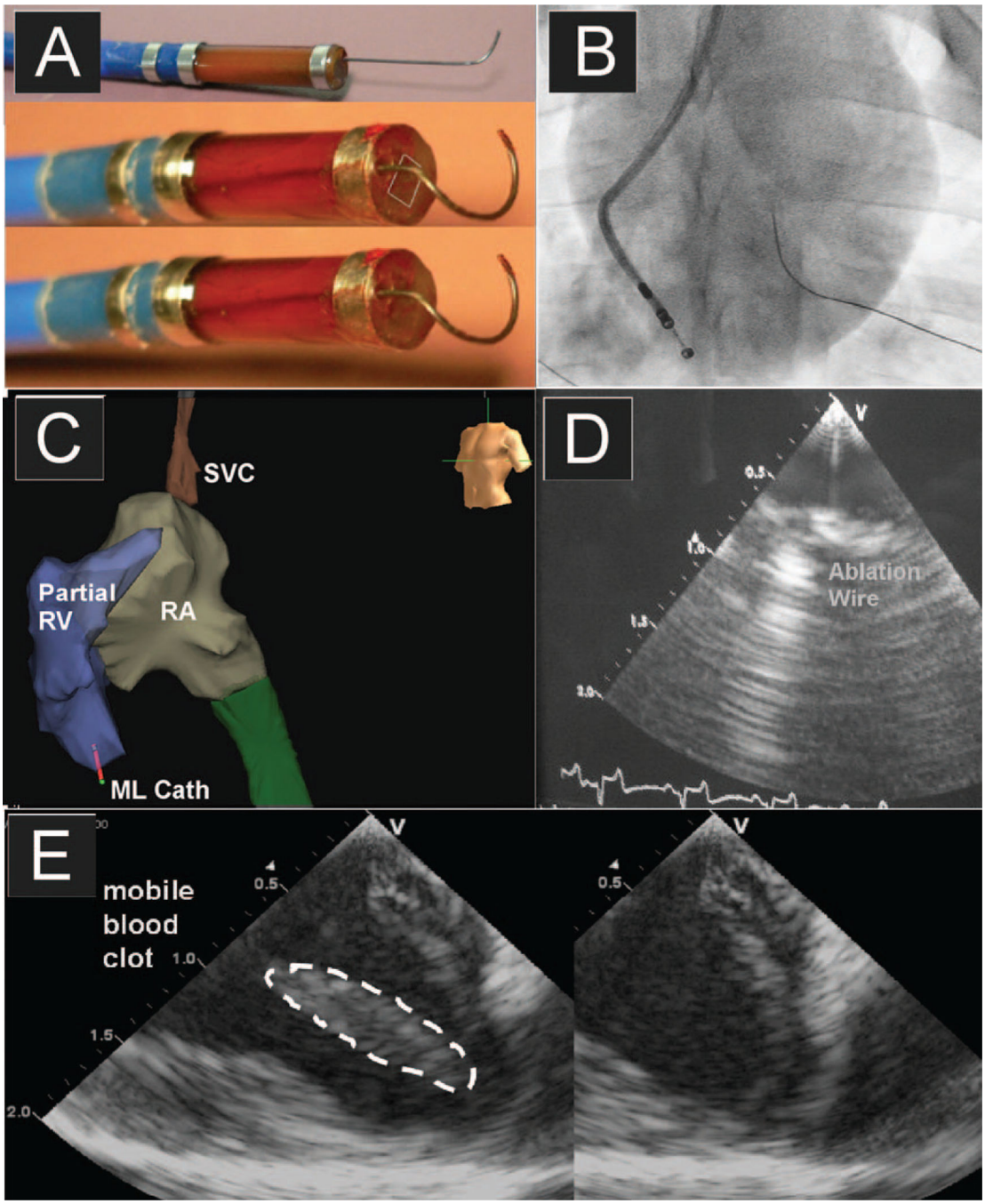

Fig. 3.

The MicroLinear (ML) catheter is shown in panel A with a small RF ablation wire integrated into the device at the tip but under full steering control by the operator. Panels B and C are the fluoroscopic and NavX mapping images, respectively, both showing the MicroLinear catheter near the RV apex in the pig. Panel D shows the clear delineation of the RF ablation wire, and panel E demonstrates the high level of image quality of this small 24-element phased-array forward-looking catheter.

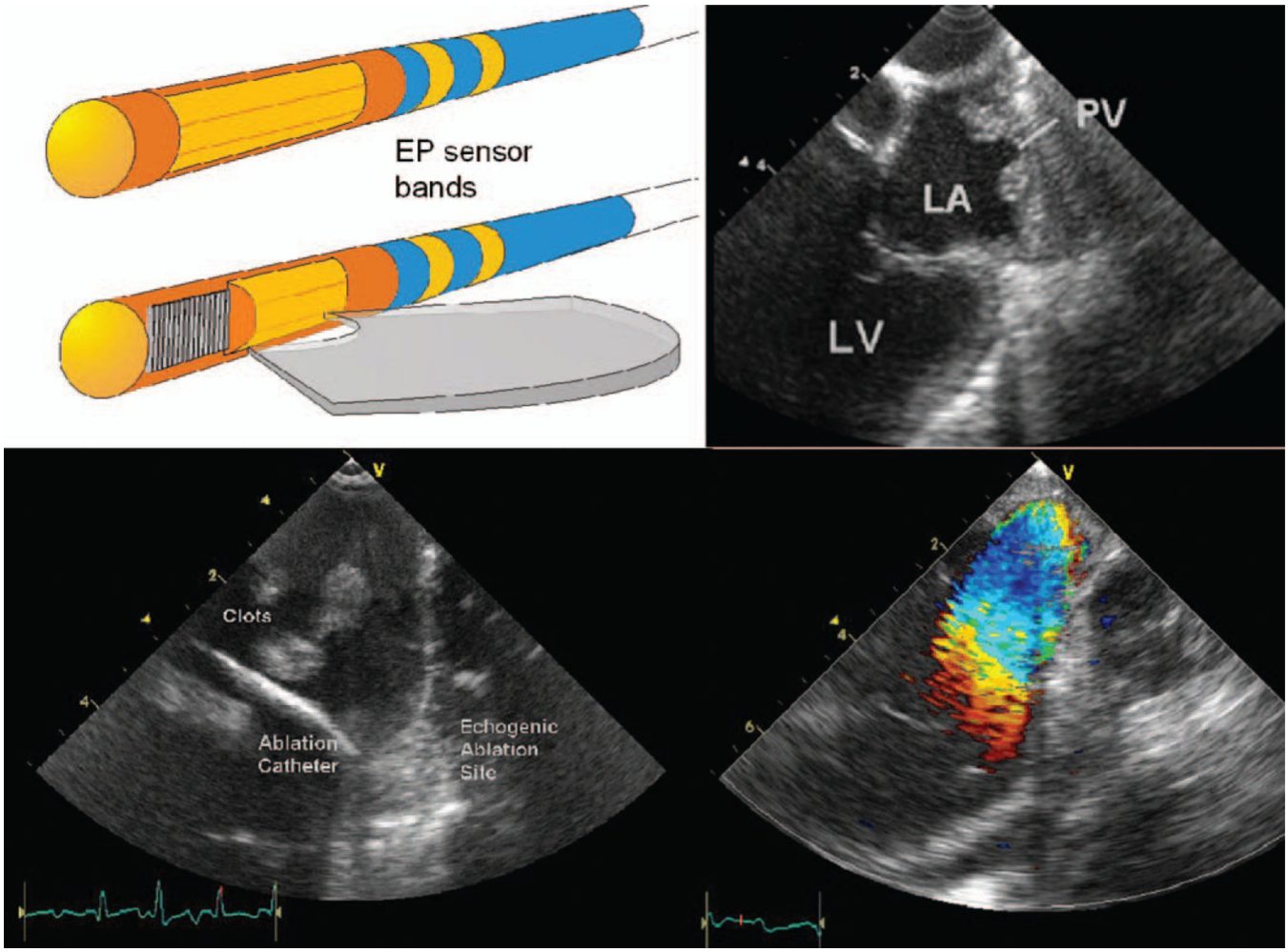

Fig. 4.

HockeyStick catheter imaging the left atrium and left ventricle from the right side of the heart at top right, and at lower left the HockeyStick monitors an RF ablation of the atrioventricular sulcus region in the right atrium of a pig. The lower right shows color Doppler imaging of blood in the aortic outflow tract.

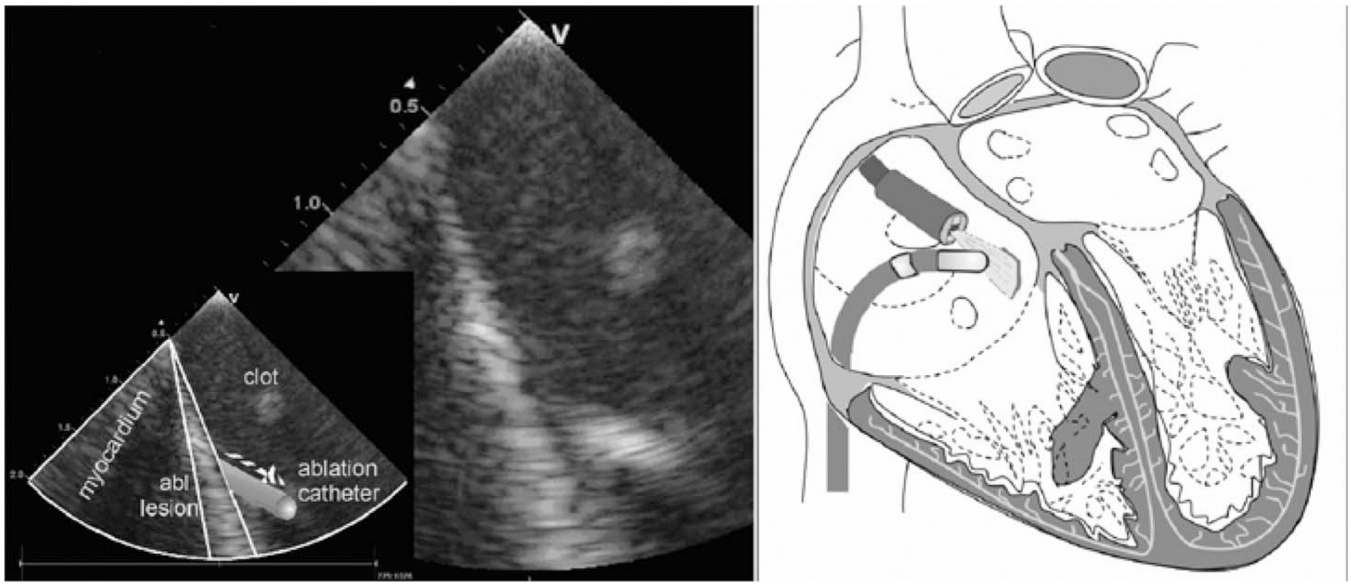

Fig. 5.

The forward-looking 14 MHz MicroLinear catheter is shown imaging an RF ablation catheter during an ablation sequence while in the RA of a pig. The echogenic tip of the ablation catheter and lesion region is clearly seen in the left panel while RF ablation pick-up noise is absent. Note the maximum depth displayed here is 2 cm.

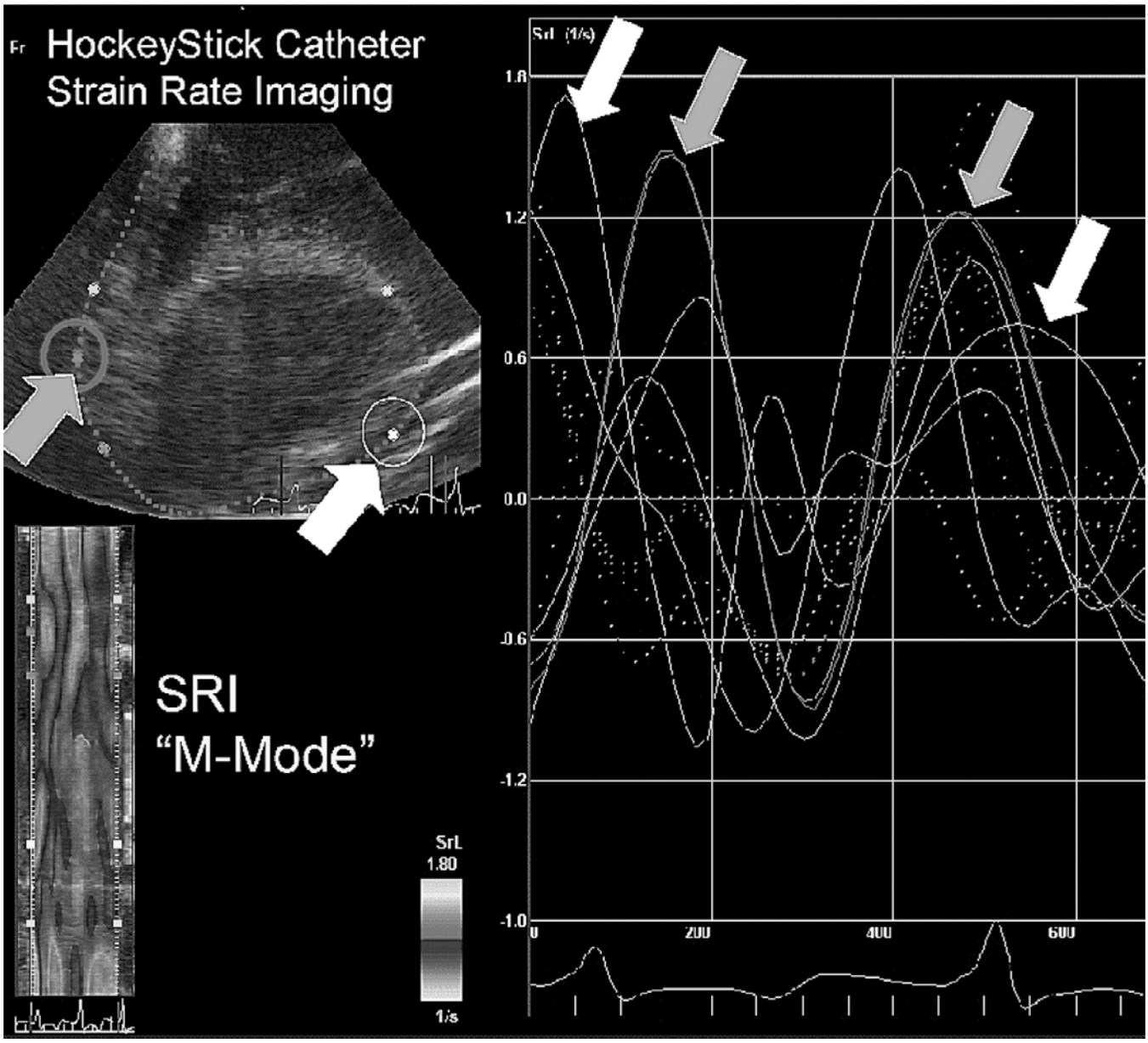

Fig. 6.

A HockeyStick catheter used for intracardiac strain rate imaging while open chest pacing is conducted in the pig. The image frame at upper left shows 5 SRI tissue "target points" at various LV wall positions in the short axis view from the RA. Two of the wall target points (white and gray arrows at left), tracked according to their 2-D strain rate time plot at right, show a loss in phasic synchrony as a result of epicardial pacing electrode stimulation. The plot limits are −1.0 to 1.8 s^{-1} in strain rate, and 0 to 700 msec in time duration. The pig heart rate is approximately 150 min^{-1}.