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Ring Array Transducers for Real-Time 3D Imaging of an Atrial Septal Occluder

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Abstract

We developed new miniature ring array transducers integrated into interventional device catheters such as used to deploy atrial septal occluders. Each ring array consisted of 55 elements operating near 5 MHz with interelement spacing of 0.20 mm. It was constructed on a flat piece of copper-clad polyimide and then wrapped around an 11 French O.D. catheter. We used a braided cabling technology from Tyco Electronics Corp to connect the elements to the Volumetrics Medical Imaging (VMI) real-time 3D ultrasound scanner. Transducer performance yielded a –6 dB fractional bandwidth of 20% centered at 4.7 MHz without a matching layer versus average bandwidth of 60% centered at 4.4 MHz with a matching layer. Real time 3D rendered images of an *en face* view of a Gore Helex septal occluder in a water tank showed a finer texture of the device surface from the ring array with the matching layer.

Keywords

2D array transducer; real-time 3D imaging; septal occluder

Introduction

Previously we developed PZT-based matrix array catheter transducers (Lee et al. 2004) and endoscopes (Pua 2004; Light et al. 2005) for real time 3D ultrasound imaging. More recently we have fabricated forward viewing ring array catheters for 3D image guidance of interventional devices such as the vena cava filter and aortic aneurysm stent graft (Light et al. 2008) and trans-apical heart valves (Light et al. 2011). Other laboratories are developing side viewing 3D catheters (Lee et al. 2011) and forward-viewing CMUT ring arrays for electrophysiological applications and real time 3D IVUS (Degertekin et al. 2006; Yeh et al. 2006; Hochman et al. 2010; Nikoozadeh et al. 2010) (Khuri-Yakub and Oralkan 2011).

Atrial septal defects (ASD) comprise up to 7% of total congenital heart lesions and as much as 25% of congenital heart disease in adults (Kaplan 1993). ASDs may go undetected for decades. If the ASD is small and the patient is asymptomatic, no action is taken. Otherwise, treatment options include open-heart surgery to repair the hole or catheter deployment of an atrial septal occluder. This minimally invasive procedure is often preferred by patients. The procedure is typically done under fluoroscopic guidance combined with transesophageal

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echo (TEE) and Doppler ultrasound (Ko et al. 2009) as well as 2D intracardiac echo (ICE) catheters (Hijazi et al. 2009) and even 3D TEE (Perk et al. 2009). However since the procedure already calls for the insertion of a catheter, we believe a catheter-based transducer capable of generating real-time 3D images integrated into the occluder deployment kit might reduce the need for the other imaging modalities with the associated x-ray exposure of fluoroscopy and complexity and discomfort of TEE ultrasound. Real time 3D ultrasound enables continuous monitoring of cardiac structures and interventional devices before, during and after deployment. However, the integration of 3D ultrasound imaging catheters into the deployment kits of interventional devices presents major challenges due to the requirement for dozens of active transducer channels to improve 3-D image quality and the severe fabrication difficulties in electrical connection to the sub-millimeter 2D array elements. It is also important not to disrupt the original design of the device deployment kit. Figure 1 shows a schematic of an integrated ring array transducer, connected to the scanner via the system flex circuit, and septal occluder deployment catheter. The real-time 3D ultrasound pyramidal scan originates from the distal tip of the device, with the occluder exiting through the lumen. In this paper we describe the fabrication of such ring arrays operating near 5 MHz and the acquisition with a commercial scanner (Volumetrics Medical Imaging, Inc., Durham, NC) of real-time 3D ultrasound images of the Gore Helex septal occluder.

Materials & Methods

We modified a commercial catheter deployment kit for our ring array transducers. This product uses an 8.5 Fr sheath (I.D.) resulting in an approximately 11 French (O.D.) catheter. This outer diameter determined the ring array diameter. We previously described ring array transducers using a small flexible circuit connected to our scanner system cable using Tyco Medical cabling (Light et al. 2009).

Figure 2 shows a schematic of the construction steps to build the ring array transducers. Construction begins with a metal-clad polyimide flexible circuit. This substrate has a shelf area where there is no metal (Figure 2A). A beam of PZT ceramic (TRS Technologies, Inc., State College, PA) was prepared that was 0.30 mm tall (thick), 0.18 mm wide and 11 mm long. In this work, we developed transducers with and without a single acoustic matching layer. The matching layer consists of a plate of the #107 matching layer from EBL Products, Inc. (East Hartford, CT). Before attaching the PZT beam to our flex circuit, a .19 mm thick plate of the matching layer was metallized on both sides with 500 Å of nickel and 1000 Å of gold. The plate was then bonded to PZT layer using a thin layer of Epotek 301 two-part epoxy (Billerica, MA).

This beam / matching layer was attached to the polyimide with a low viscosity epoxy such that the beam was on its side (figure 2B1 / 2B2). With the beam on its side, the electroded portion of the PZT is pointed in the forward direction. After attaching the PZT, silver paint (SPI Supplies, West Chester, PA) was applied such that it contacted the bottom electrode of the PZT and the flex circuit traces (figure 2C) on the polyimide. The transducer beam was then diced into 55 elements at a spacing of 0.2 mm and the entire device wrapped around a lumen with the same O.D. as the catheter lumen. A 0.012 mm thick layer of metallized liquid crystal polymer (LCP) was wrapped around the outer circumference of the PZT and polyimide substrate (figure 2D) and attached with epoxy (Hysol® E-60NC epoxy potting compound). The LCP keeps the transducer in a cylindrical shape. The Hysol epoxy fills the kerf so that there is an even surface on the front end of the transducer. We then sputter gold onto the face of the transducer and LCP. The transducer assembly was then attached to the clinical catheter and sent to Tyco Electronics Corp. for the cabling to be attached. After returning, a short piece of heat shrink (Advanced Polymers, Inc., Salem, NH) was attached

to seal the LCP and cover the wiring. For both transducers, the face of the elements was sealed with a thin layer of ultraviolet (UV) curing adhesive.

Figure 3 compares photographs of the 55 element ring arrays without matching layer (Fig. 3A) versus with matching layer (Fig. 3B) after bonding to the LCP, but before cabling and adding the electrical grounding. Figure 3B includes the blue delivery catheter sheath. Figure 4 shows a close up of the cabling for the ring array transducer. The overall shield braid increases the lumen O.D. to 13 French.

The overall shield braid increases the lumen O.D. to 13 French

We used standard three-dimensional (3D) phased array beaming forming techniques to generate our real-time 3D images. Real time 3D ultrasound was developed in our laboratories at Duke University (Smith et al. 1991; von Ramm et al. 1991) and first commercialized for cardiovascular applications by VMI. The Duke/VMI 3D system scans a 65° – 120° pyramid with matrix array transducers of up to 500 active channels to produce 3D scans at rates up to 30 volumes/sec using 16:1 receive mode parallel processing. Real time display options include up to five simultaneous image planes oriented at any desired angle, depth and thickness within the pyramidal scan as well as real time 3D volume rendering, 3D pulse wave Doppler and 3D color flow Doppler.

We scanned a 30 mm diameter Gore HX1530 Helex Septal Occluder (Newark, DE) in a water tank. This device consists of a 10 Fr catheter delivery system and an implantable endoprosthesis comprised of a nickel-titanium (Nitinol) wire frame covered with expanded polytetrafluoroethylene (ePTFE). The ePTFE is treated with a proprietary coating to facilitate echocardiographic imaging of the occluder during implantation. When fully deployed, the occluder assumes a double disc configuration that bridges the septal defect to prevent shunting of blood between the right and left atria.

Results

Figure 5 shows a typical pulse echo response (A) and power spectrum (B) of the control transducer without matching layer. For twelve elements mean center frequency is 4.7 MHz and the -6 dB bandwidth is 20%.

Figure 6 shows the pulse-echo response (A) and spectrum (B) of a single element from the ring array transducer with matching layer. For twelve elements mean center frequency is 4.28 MHz and the -6 dB bandwidth is 68%. The pulse echo sensitivity increased by 5% compared to the control array. Figure 7 shows a photograph of the W.L. Gore & Associates, Inc. HELEX[®] septal occluder (A), a B-mode image plane from a real-time 3D scan of the occluder (arrow) (B), a real time 3D rendered view of the occluder using the ring array without matching layer (C), and a real time 3D rendered view using the ring array with matching layer (D). The B-mode image shows the depth and thickness of the occluder. However, the figures show the immediate advantages of real time 3D imaging since the information content of the single B-mode image is minimal compared to the 3D rendered views (C, D). The *en face* rendered images show the circular shape of the occluder, the nitinol ring as indicated by the arrows in Figures 7C,D, as well as the speckle pattern associated with the ePTFE fabric. A comparison of the rendered views also shows the finer speckle texture associated with the broader bandwidth of the matching layer array. Faint scan convertor artifacts are also present.

Discussion and Conclusions

We developed new miniature ring array transducers integrated into interventional device catheters such as used to deploy atrial septal occluders. Such a catheter-based transducer capable of generating real-time 3D images integrated with the occluder deployment kit might reduce the need for x-ray fluoroscopy and TEE ultrasound during the occluder deployment.

The ring arrays consisted of 55 elements operating near 5 MHz with interelement spacing of 0.20 mm. The development of matching layers and increased bandwidth for PZT ring arrays has been challenging. Boundary conditions for the transducer elements differ radically in each dimension since there is virtually no backing material, and each element is bonded to the flex circuit on one side and the catheter surface on the other side. Development of the matching layer thus proceeded by a trial and error process. Transducer performance yielded a -6 dB fractional bandwidth of 20% centered at 4.7 MHz without a matching layer versus average bandwidth of 60% centered at 4.4 MHz with a matching layer. The 5% increase in pulse-echo sensitivity is modest and reflects the problem of anisotropic boundary conditions on the array elements.

Real time 3D rendered images of an *en face* view of a Gore Helex septal occluder in a water tank showed a finer texture of the device surface from the ring array with the matching layer. Previous studies have shown improved detection of speckle targets in tissue, such as the occluder surface, associated with the finer speckle texture linked to improved spatial resolution and higher bandwidth (Smith et al. 1983). However, image quality of the 3D ring array catheters is still not acceptable. Image quality may be improved through the use of ring arrays of multiple rings to increase signal to noise ratio or synthetic aperture processing to reduce side lobe clutter associated with the ring geometry (Wang et al. 2002).

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Figure 1. Schematic of the integrated transducer and septal occluder deployment device. The real-time 3D ultrasound pyramidal scan is directed outward from the distal end of the device and is co-axial with the deployment of the septal occluder.

Figure 2.

A schematic of the steps to build the ring arrays. We start with a metallized polyimide substrate (Figure 2A) having a metal-free shelf area to attach the PZT. We next attach the PZT beam / matching layer (Figure 2B1 / 2B2) with non-conductive epoxy. After the epoxy cures, silver paint is used to connect the back electrode of the PZT with the metal trace (Figure 2C). The PZT is then diced, and wrapped around a catheter lumen. A 0.012 mm thick layer of liquid crystal polymer (LCP) is wrapped around the outer circumference of the PZT and polyimide substrate (Figure 2D). This LCP layer is metallized with gold (shown in black) on one side only, the outer side, so that it does not risk shorting the traces together. A layer of gold is sputtered on the face of the elements and connected to the gold on the outside of the LCP (Figure 2E1 / 2E2).

Figure 3.
Close up of ring arrays without matching layer (A) and with matching layer (B) after dicing and bonding to the LCP.

Figure 4.

Close up of the cabling for a 55 element ring array transducer. The signal wires are hidden by the green ground wires. The overall shield braid increases the lumen O.D. to 13 French. After wiring, the extra shield braid is cut back, and the exposed wires are sealed with 0.013 mm thick heat shrink.

Figure 5. Typical pulse echo response and spectrum of control array. The center frequency is 4.7 MHz and the -6 dB bandwidth is 20%.

Figure 6. Pulse echo response(A) and spectrum (B) from the transducer constructed with a single matching layer. The center frequency is 4.2 MHz and the -6 dB bandwidth is 68%.

Figure 7. Gore Septal Occluder photograph (A), B-mode plane with 1 cm scale marks (B), En face 3D rendered view from control array (C) versus matching layer array (D).