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● *Original Contribution*

FEASIBILITY OF *IN VIVO* TRANSESOPHAGEAL CARDIAC ABLATION USING A PHASED ULTRASOUND ARRAY

JACOB WERNER,* EUN-JOO PARK,† HOTAIK LEE,† DAVID FRANCISCHELLI,§ and NADINE BARRIE SMITH†‡

*Animal Resource Program and Department of Dairy and Animal Science, The Pennsylvania State University, University Park, PA, USA; †Department of Bioengineering, College of Engineering, The Pennsylvania State University, University Park, PA, USA; ‡Graduate Program in Acoustics, College of Engineering, The Pennsylvania State University, University Park, PA, USA; and §Medtronic, Inc., Minneapolis, MN, USA

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Abstract—Over 2.2 million Americans suffer from atrial fibrillation making it one of the most common arrhythmias. Cardiac ablation has shown a high rate of success in treating paroxysmal atrial fibrillation. Prevailing modalities for this treatment are catheter based radio-frequency ablation or surgery. However, there is measurable morbidity and significant costs and time associated with these invasive procedures. Due to these issues, developing a method that is less invasive to treat atrial fibrillation is needed. In the development of such a device, a transesophageal ultrasound applicator for cardiac ablation was designed, constructed and evaluated. A goal of this research was to create lesions in myocardial tissue using a phased array. Based on multiple factors from array simulations, transesophageal imaging devices and throat anatomy, a phased ultrasound transducer that can be inserted into the esophagus was designed and tested. In this research, a two-dimensional sparse phased array with the aperture size of 20.7 mm × 10.2 mm with flat tapered elements as a transesophageal ultrasound applicator was fabricated and evaluated with *in vivo* experiments. Five pigs were anesthetized; the array was passed through the esophagus and positioned over the heart. The array was operated for 8 ∼ 15 min at 1.6 MHz with the acoustic intensity of 150 ∼ 300 W/cm^2 resulting in both single and multiple lesions on atrial and ventricular myocardium. The average size of lesions was 5.1 ± 2.1 mm in diameter and 7.8 ± 2.5 mm in length. Based on the experimental results, the array delivered sufficient power to the focal point to produce ablation while not grossly damaging nearby tissue outside the target area. These results demonstrate a potential application of the ultrasound applicator to transesophageal cardiac surgery in atrial fibrillation treatment. (E-mail: Jrw140@psu.edu) © **2010 World Federation for Ultrasound in Medicine & Biology.**

Key Words: **Ultrasound, Phased array, Transesophageal, Cardiac ablation, *In vivo*.**

INTRODUCTION

Atrial fibrillation is one of the most common arrhythmias affecting millions of people around the world (Fuster et al. 2006). Approximately 2.2 million people are suffering from this disorder in the United States alone (Thom et al. 2006). Atrial fibrillation can occur for various reasons from genetic predisposition and metabolic disorders such as thyroid disease to aging. Despite multiple factors that trigger atrial fibrillation, age is the most common predisposing factor. Roughly six percent of people over the age of 65 suffer from atrial fibrillation. As people live longer lives and the average age continues to rise, the prevalence of atrial fibrillation is expected to increase.

Address correspondence to: Jacob R. Werner, The Pennsylvania State University, 101 Centralized Biological Laboratory, University Park, PA 16802 USA. E-mail: Jrw140@psu.edu

Atrial fibrillation occurs when the normal electrical conductivity from the atria to the ventricles is disrupted resulting in uncoordinated activity in the atrial muscle causing irregular heart beat, abnormal contractions and reduced cardiac output. The irregular heart beat can cause extreme discomfort in people. Yet beyond discomfort, more serious health risks can occur such as clot formation in the atria with subsequent ejection into the circulation resulting in strokes or other cardiopulmonary disorders. Thus, atrial fibrillation is a major cause of stroke; roughly 15% of all strokes occur in people with atrial fibrillation making this condition a major public health concern (Bakir et al. 2007;Go et al. 2001).

Current therapies for atrial fibrillation either treat symptoms or attempt to convert the arrhythmia to normal sinus rhythm. In cases where pharmaceuticals do not work to achieve cardio-conversion, cardiac ablation or surgery may be needed. Catheters that deliver radio-frequency

energy are placed centrally to lie within the atria to ablate myocardial tissue. Surgical procedures like the Maze procedure require thoracotomy and open heart cardiopulmonary bypass surgery to allow a surgeon access to the heart to cut directly into the atria (Backer et al. 2008; Cox et al. 1991; Gillinov and Saltman 2008; Srivastava et al. 2008). Ablation and surgical procedures cause scar tissue within the atrial muscle that forms a barrier to electrical activity. The new altered electrical pathways allow for normal coordinated muscle contractions. Radio-frequency ablation has been effective as a prevailing modality of atrial fibrillation treatment; however, there is measurable morbidity and significant costs and time associated with this procedure (Jais et al. 2003; Proclemer et al. 2008; Saliba et al. 2008). To address these issues, demands for nonsurgical approaches for cardiac ablation have increased. Ultrasound energy has gained interest for clinical application for decades due to its noninvasive characteristics. Since the early 1940s (Lynn et al. 1943), the therapeutic use of focused ultrasound to destroy tissue has been investigated (ter Haar and Coussios 2007). Specifically for atrial fibrillation, surgical studies using catheter-based ultrasound transducers to treat arrhythmias have been reported (Gentry and Smith 2004; Meininger et al. 2003; Natale et al. 2000; Zimmer et al. 1995). Because ultrasound phased arrays have the advantage of electronically moving the focal point and modifying the focal area without mechanical steering, they have been extensively studied since the 1990s to evaluate the feasibility of focused ultrasound surgical applications (Daum et al. 1999; Held et al. 2006; Hynynen et al. 2004). In addition, recent feasibility studies indicate that it is possible for focused ultrasound to include transesophageal treatment as an alternative to open chest surgery (Melodelima et al. 2005; Pichardo and Hynynen 2007, 2009; Yin et al. 2006).

The goal of this study was to find an alternative method to cardiac ablation from a nonsurgical approach. Passing a probe into the esophagus to lie over the heart would limit the need for intravenous central catheter placement in the radio-frequency ablation procedure or open chest surgery resulting in less complications and quicker recovery. This study was designed to assess the feasibility of transesophageal cardiac ablation in atrial fibrillation treatment using therapeutic ultrasound energy without surgical incisions or blood contact.

MATERIALS AND METHODS

Acoustic pressure calculations

To design a transducer array capable of beam focusing and steering, the ultrasound fields of the array were numerically determined using the Rayleigh-Sommerfeld integral (Zemanek 1971). The Rayleigh-Sommerfeld integral gives the pressure field produced in a medium at x from a planar piston source:

$$p(\vec{x},\omega) = \frac{j\omega\rho U_0}{2\pi}\int_S \frac{\exp(-jkr)}{r}\,dS, \qquad (1)$$

where ω is the angular frequency [rad/s], ρ is the density of the medium [kg·m^{-3}], U_0 is the particle speed on the aperture surface [m/s], k is the wave number [m^{-1}], r is the distance from a point on the aperture surface to field point $\vec{x}$ [m] and S is total transducer surface area in m^2. Based on the single element beam model, the focused ultrasound field radiating from the phased array is predicted by superposition of the pressure field of each element with appropriate phase delays of the driving signals, the phase of i^{th}element, ϕ_i [rad] is given by:

$$\phi_i = \frac{2\pi}{\lambda}(d_i - d_0), \qquad (2)$$

where λ is the wavelength in the interrogated medium [m], d_i is the distance from the center of i^{th} element to the focal point [m], and d_0 is the distance from the center of the array to the focal point [m]. Therefore, the total acoustic pressure at any field point, $\vec{x}$, produced by an array with n number of elements can be written as:

$$p(\vec{x},\omega) = \sum_{i=1}^{n}\frac{j\omega\rho U_0}{2\pi}\int_{S_i}\frac{\exp[-j(kr_i-\phi_i)]}{r_i}\,dS_i, \qquad (3)$$

where r_i is the distance from a point on the surface of i^{th} element to the field point $\vec{x}$ [m].

Sparse phased array

Phased arrays use multiple small transducer elements to produce a focal area that can heat a large volume of tissue in a single exposure. By controlling the phase and amplitude of the sound wave generated from each element of the array, beams can be focused electronically at different depths and steered or shifted automatically. A transesophageal ultrasound applicator must be small enough to allow insertion into the esophagus and to avoid possible damage to the esophagus while being inserted. Also, the applicator must be capable of generating sufficient acoustic intensity and of steering beams. For the design of the transesophageal ultrasound transducer, various layouts of transducer arrays and the corresponding ultrasound pressure fields were modeled. The aperture size for array design was 20.7 mm × 10.2 mm, which is based on the dimensions of the human esophagus and throat anatomy (Tsao et al. 2006). The phased array design examined in this research was constructed using piezoelectric ceramic (PZT-8) elements. Because of the small array element sizes and subsequent low capacitance and high impedances, a ceramic having a very high relative