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Design And Evaluation Of A 3 x 21 Element 1.75 Dimensional Tapered Ultrasound Phased Array For The Treatment Of Prostate Disease

Received: *29 September 2003*
Revised: *22 March 2004*
Accepted: *30 September 2003*

Keywords *Transducer*
1.75-D array
Focusing
Matching layer
Necrosis

This paper describes the design, construction, and evaluation of a 1.75 dimensional (1.75-D) tapered ultrasound phased array to be used in the treatment of benign prostatic hyperplasia and prostate cancer. The array was designed to be able to focus and steer in a three dimensional volume with a maximum steering angle of ±13.5° in the transverse direction and a maximum depth of penetration of 11 cm, which allows the treatment of large prostates. A piezoelectric ceramic (PZT-8) at a frequency of 1.2 MHz was used as the material of the transducer since it can handle the high power needed for tissue ablation and two matching layers were used for maximum acoustic power transmission to tissue. To verify the capability of the transducer for focusing and steering, exposimetry was performed and the results correlated well with the calculated field.

Introduction

Focused ultrasound surgery (FUS) has been shown to give promising results in treating benign prostatic hyperplasia (BPH) [1, 2, 3, 4]. Although BPH is not life threatening, treating it is necessary since normal urine flow and function can be disrupted as a result of the prostate pushing against the urethra and the bladder. The goal of this research was to construct, computationally and experimentally, a 1.75-D tapered phased array suitable for tissue ablation in the prostate. Part of the design criteria was that a specific region in a target volume will be ablated by focusing the ultrasound beam at that region using short, high temperature sonications. Additionally, for magnetic resonance imaging (MRI) monitoring and temperature guidance, a magnet compatible ultrasound phased array was designed for the treatment of BPH [5].

Previous one dimensional (1-D) prostate array transducer geometries include a 64 x 1 aperiodic linear array which reduced grating lobes and could electrically adjust the focus at distal and proximal locations along the urethra, and a 60 x 1 linear array with a mechanical rotation which could electrically steer the focus along the urethra and mechanically steer left and right of the mid-saggital urethra [6, 7]. A design which had better focusing capabilities than a 1-D array was a 64 x 4 spherically curved 1.5 dimensional (1.5-D) array that could, but had restrictions to the focusing volume, focus and steer in the three directions [8]. The drawbacks behind these prostate arrays are that they can only focus at distal or proximal locations along the urethra or complex mechanics which move the focus. The advantage with a 1.75-D array is that it can electrically focus at distal and proximal locations along the urethra and left and right of the mid-saggital line by changing the phase to the elements. One difficulty with designing a 1.75-D array is in dicing the ceramic 100% through its thickness while maintaining a common grounding for all of the elements. To overcome this problem, two matching layers (the first one being conductive) were designed and constructed. The two matching layers not only help make a common ground, but they also increase, to a large extent, the acoustical power efficiency, and facilitate in maintaining the structural integrity of the array. This research presents a 3 x 21 element 1.75-D tapered ultrasound array designed to ablate tissue while overcoming many problems involved with transducer fabrication.

Materials and Methods

Simulations

Computer simulation programs were written to determine the number and the size of the phased array elements in addition to determining the pressure and temperature field from the device. The array was modeled (Fig. 1) as a 1.75-D tapered array in order to have focusing and steering capabilities in both x and z directions (x = transverse, y = longitudinal and z = radial). Focusing in the y direction is done in a different way; the array is divided into three identical rows, each one represents a single linear array. If the focus is required at y = 0, the middle row should be used. A focus at y = -0.9 mm requires driving the lower row, while a focus at y = +0.9 mm requires the operation of the upper row. Although the degree of freedom in the y direction is not perfect, the size of the lesion generated by a single sonication compensates for that, since the focus length is about 9 mm in the y direction. The driving phase of each element was determined such that signals from individual elements were all in phase only at the focal point. Huygen's principle was used to model the pres sure field as a summation of simple sources [9]. With these requirements, this array was capable of focusing and steering with a steering angle of ±13.5° with maximum focal depth of 11 cm.

Off-axis focusing and the grating lobe level are directly related to each other since increasing the steering angle causes a nonlinear increase in the grating lobe level. Another factor that affects the grating lobe level is the periodicity of the elements widths (tapered versus equal size). Tapered or aperiodic element arrays have been shown to reduce significantly the grating lobe level [10, 11]. Figure 2 shows a comparison of the grating lobe levels for both tapered and equal size arrays as a function of off-axis focal point position x_f. At zero steering angle ($x_f = 0$), the tapered array has 6% less grating lobes than the equal size array. Although this is not a great improvement, at large steering angles, this improvement becomes more significant. The grating lobe for the tapered array was reduced (compared to the equal size array) by about 8, 14, 14, 16 and 14% for x_f = 2, 4, 6, 8 and 10 mm, respectively.

Initially the simulated design for the intensity used equal size elements of 9 x 2.1 mm^2, and although it was capable of focusing and steering, it suffered from large grating lobes outside the focus. For example, at a focus of (x, y, z) = (2, 0, 50) mm (i.e. the 0, 0, 0 position is at the center of the transducer face in Fig. 1), the grating lobe level was 4.95 dB which was not desirable since this high level can cause an increase in tissue temperature outside the focus. Removing the periodicity of the array or tapering it has been shown to reduce the grating lobe level. The maximum possible steering angle was calculated to be $\tan^{-1}(1.2/5.0)$ =13.5° with maximal focal depth of 11 cm. Improvements to the tapered array design started with a 27 x 53 mm^2 solid piezoceramic cut into a 3 x 21 pattern with 63 individual elements with lengths (L_i) of 1.68, 1.73, 1.81, 1.91, 2.02, 2.14, 2.26, 2.36, 2.43, 2.48, 2.50, 2.48, 2.43, 2.36, 2.26, 2.14, 2.02, 1.91, 1.81, 1.73, 1.68 mm for elements i = 1 through 21, respectively, and widths (W_i) of 9.0 mm for all elements i = 1 through 3, respectively (Fig. 1). Simulations have shown that the grating lobe level of the tapered design has decreased to –6.20 dB at a similar focus location of 2, 0, 50 mm. Temperature simulations were also used to verify the potential to increase the tissue temperature to 60 °C with short sonications [12]. Figure 3 shows an example of the temperature distribution as a function of x and z corresponding to an intended focal point position of (2, 0, 50) mm.

Transducer construction

Choosing an appropriate piezoceramic material to be used in this application is essential since it affects both electrical and acoustical properties of the array. Lead zirconate-titanate (PZT-8) can handle the large electrical power needed for tissue ablation and has an extremely high mechanical quality and extremely

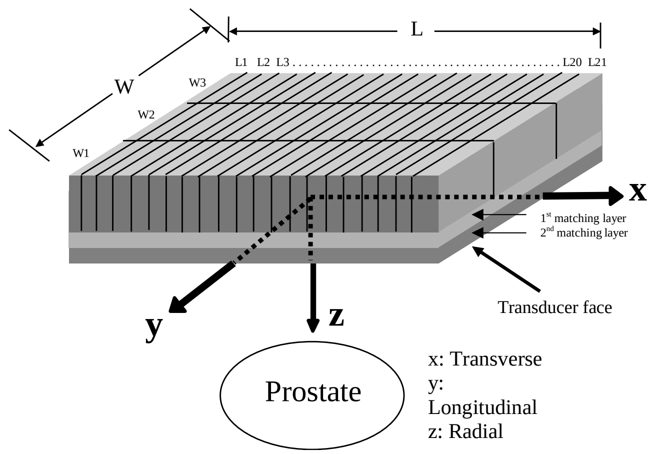

Fig. 1. *Based on the simulations, a diagram of the 1.75-D 63 element (3 x 21) tapered array with total size of 27 x 53 mm2 with the proportions of the ceramic and matching layer illustrated. The diced face of the ceramic was cut 100% through and each individual element was attached to the electrical cabling using low temperature soldering material*

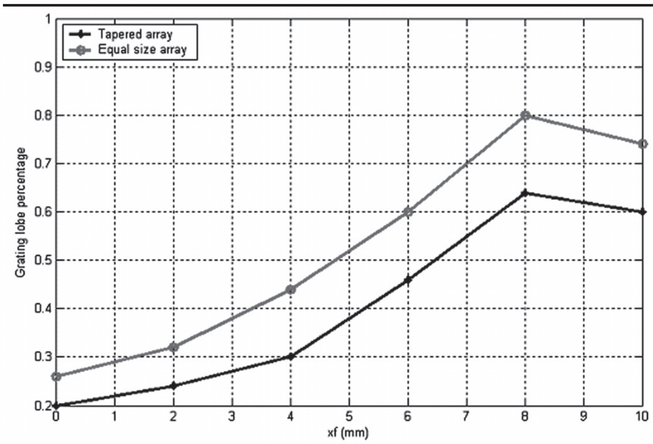

Fig. 2. *Simulation results showing the relationship between element size and the grating lobe level as a function of off-axis focal point position* x*f, and thus the steering angle. Plotted for both tapered and equal size arrays, the grating lobe level was decreased by a percentage of 6, 8, 14, 14, 16 and 14 % for* x*f = 0, 2, 4, 6, 8 and 10 mm, respectively, when compared to an equal size array*

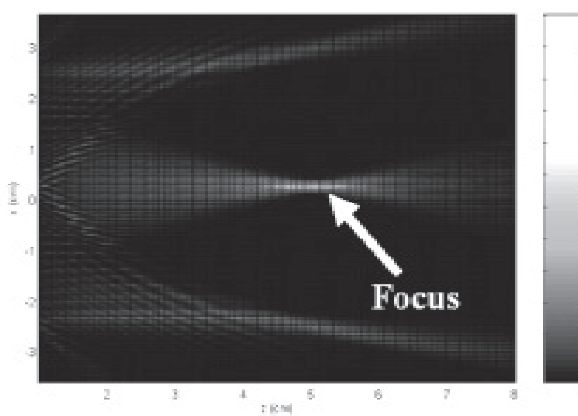

Fig. 3. *A temperature map for a focal point at (x, y, z) = (2, 0, 50) mm was numerically solved using the bioheat transfer equation. This simulated figure shows an increase in tissue temperature to the target of 60 °C at the focal point using a 10 sec sonication while outside the target region the temperatures were normal as indicated from the temperature color bar*

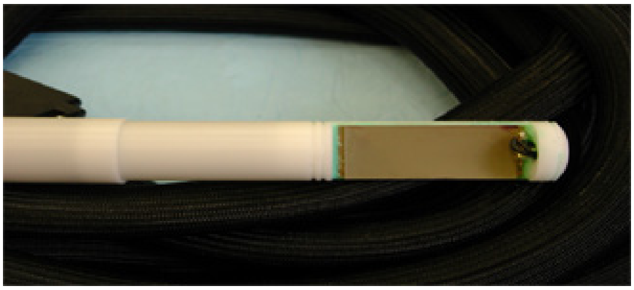

Fig. 4. Photograph of the constructed, waterproof array machined from Delrin® with 8.3 m low capacitance cable that connected to the amplifier system

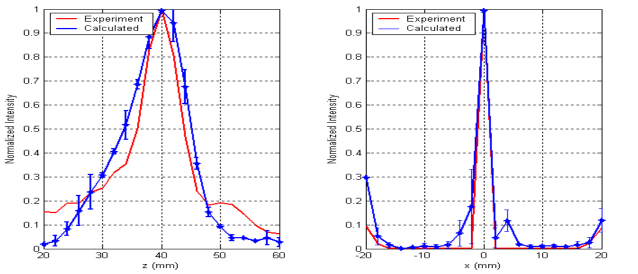

Fig. 5. Comparison of calculated and experimental normalized intensities for a focus at 0, 0, 40 mm plotted along the (a) z axis and (b) x axis

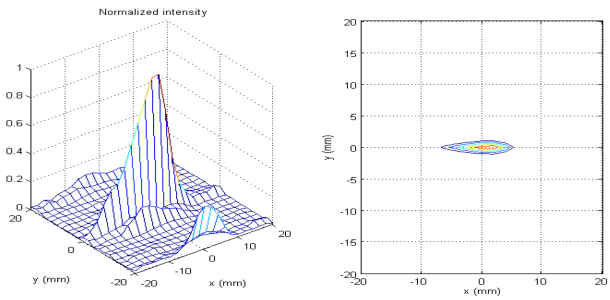

Fig. 6. Exposimetry results of the normalized intensity for off-axis focusing with the focal point aimed at 0, 0, 40 mm plotted as a (a) mesh or (b) contour with levels indicated at 90, 70, 50, 30, 10%. These results indicate acceptable grating lobes of less than –7.0 dB

low loss factor. Thus PZT-8 material (TRS Ceramics, State College, PA, USA) was chosen at a frequency of 1.2 MHz and diced, in house, into 3 x 21 elements forming the complete array. The cuts were made by dicing the material 100% through its thickness with a kerf width of 300 mm using a dicing saw (Model 780, K & S-Kulick and Soffa Industries, Willow Grove, PA, USA) in our lab. For maximum acoustical power transfer from the individual elements to the tissue, two matching layers were designed and constructed. The thickness and material selection of the matching layers were designed based on the solution to a four layer problem (transducer, first matching layer, second matching layer, and tissue), which ensured the required maximum power transfer. Each of the two matching layers was designed for a quarter wavelength thickness. Accordingly, the thickness of the first and second matching layers was determined to be 0.396 and 0.429 mm, respectively [11]. The first matching layer, mixed in-housed, was a 2:1 epoxy to silver mixture of Insulcast 501 (Insulcast, Roseland, NJ, USA) and 2-3 micron silver epoxy (Aldrich, Milwaukee, WI, USA), while the second matching layer was a SPURR (Spi Supplies, West Chester, PA, USA) four-part low viscosity material. For this array design (Fig. 4), the specially machined, waterproof cylindrical applicator housing (30 mm diameter) was made from magnet compatible Delrin® (Dupont, Wilmington, DE, USA) at the Penn State engineering shop.

To drive the array, a specially built amplifier driving system (Advanced Surgical Systems Inc., Tucson, AZ, USA) was used [13]. Briefly, this amplifier system was a multi-channel high power, ultrasound phased-array transducer driver for 64 elements which is capable of delivering 60 W per channel with ±1° phase resolution each. To match the impedance of the elements to the amplifier, individual LC (L = inductor and C = capacitor) circuits were built for each of the 63 elements to match each one to the common value of 50 ÙÐ0°.

Exposimetry

Initially, multiple on-axis (i.e. where the focus is along the major z axis, z_f) exposimetry experiments were performed. With the focus set to 0, 0, z_f mm, z_f was varied from 10 mm to 110 mm with a step size of 5 mm. To determine the repeatability or standard deviation of the focusing, 5—10 experiments were performed at each location. For off-axis studies (i.e. where the focus was not on z but aimed toward the x axis, x_f), the focus was located at x_f, 0, 60 mm while the steering angle was adjusted to the desired value by choosing appropriate values for x_f. The steering angle was varied from -13° to +13° with a step size of 2° in both x and y directions with multiple experiments (5—10) performed at each angle. In both the on-axis and off-axis experiments, the scanning step size was 0.5 mm while the scanning area was 20 x 20 mm^2. The hydrophone voltage recordings were used to calculate the normalized intensities based on the pressures that were plotted as the mean and standard deviation of the results (x ± s.d.) and compared against the calculated values [14, 15].

Results

To test the correlation between experimental and theoretical results, numerous exposimetry experiments were performed throughout the desired ablation volume to determine the focusing capability of the array. As an example of a typical exposimetry result at the location (x, y, z) = (0, 0, 40) mm, Fig. 5a shows a comparison plot along the z axis of the calculated and experimental normalized intensities. Figure 5b plots similar theoretical and experimental data, but instead, along the x axis for the same focus (0, 0, 40 mm). As can be seen for both plots, the theoretical intensity data correlated well with the experimental results.

To evaluate the feasibility of the array to steer the focus, a typical three dimensional normalized intensity result from a focal point was directed at 0, 0, 40 mm. The results were plotted as a mesh (Fig. 6a) and contour (Fig. 6b) with contour levels at 90, 70, 50, 30 and 10% of the maximum intensity with the grating lobe levels at about 7.0 dB or less.

Discussion

Intracavitary ultrasound offers an attractive means of focused ultrasound treatment for benign prostatic hyperplasia with significant advantages over other treatment methods due to the relatively short treatment time, its noninvasive nature and reduced complications. One compelling reason for using an intracavitary device with focused ultrasound is that the prostate is easily accessible via transrectal applicators, which allow for heating of the target volume in the prostate with minimal heating of normal tissue. Using phased arrays to electrically focusing the ultrasound beam provides a controlled localized power deposition into tissue and reduces significantly the treatment time since the focus is electronically scanned instead of manually.

Previous focused ultrasound array designs were problematic since they required complex methods to move the focus, or had linear (one dimensional) designs that were only capable of focusing along one axis. These drawbacks were the motivation to design a new array that can be used in FUS and at the same time be systematically controlled to reposition the focus throughout a specific volume with an acceptable level of grating lobes. Care was taken with this new 63 element, 3 x 21 array, to account for capacitance issues between the ceramic and cables by modeling the system and impedance testing with various cables.

In designing this array, several issues were taken into account to address its application for BPH treatment. The dimensions of the array were designed for an intracavitary rectal device. With appropriate housing, a dimension of 2.7 cm x 5.3 cm array is suitable. Another issue concerning this design was the grating lobe level, which was significantly reduced by tapering the elements widths of the array.

To treat the prostate, this array was aimed toward the intended target volume, and the elements were driven at a calculated amplitude and phase to generate either a single focal point with electrical steering, or generate multiple focal points simultaneously to increase the necrosed volume per sonication.

With phased arrays a focal pattern can be arranged such that there is enough time for the heat to dissipate by sonicating nonneighboring regions within the tumor [16]. A treatment planning routine can be plotted over the entire tumor region such that the volume is ablated through distant and nonadjacent ablations to avoid thermal build-up yet destroy the volume in the least amount of time. This research demonstrates the feasibility of an electrically steered array which can be used to ablate tissue for the intended treatment of benign prostatic hyperplasia. Future plans will apply this design for potential clinical evaluation with animal *in vivo* studies.

Acknowledgements

This work was supported by the Whitaker Foundation (RG-00-0042) and the Department of Defense Congressionally Directed Medical Prostate Cancer Research Program (DAMD17-0201-0124).

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Paper Volume 10-2 online at:
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