Annular and Cylindrical Phased Array Geometries for Transrectal High-Intensity Focused Ultrasound (HIFU) using PZT and Piezocomposite Materials

Ralf Seip[1], Wohsing Chen[1], Roy Carlson[1], Leon Frizzell[2], Gary Warren[2], Nadine Smith[3], Khaldon Saleh[3], Gene Gerber[3], Kirk Shung[4], Hongkai Guo[4], and Narendra T. Sanghvi[1]

[1] *Focus Surgery Inc., Indianapolis, IN., USA.*
[2] *University of Illinois at Urbana-Champaign, Urbana, IL., USA.*
[3] *The Pennsylvania State University, University Park, PA., USA.*
[4] *University of Southern California, Los Angeles, CA., USA.*

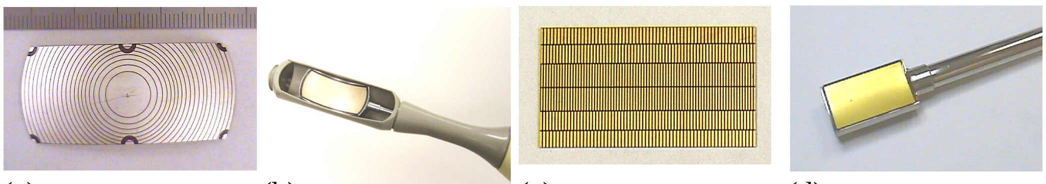
Abstract. This paper presents engineering progress and the latest *in-vitro* and *in-vivo* results obtained with a 4.0 MHz, 20 element, PZT annular transrectal HIFU array and several 4.0 MHz, 211 element, PZT and piezocomposite cylindrical transrectal HIFU arrays for the treatment of prostate cancer. The geometries of both arrays were designed and analyzed to steer the HIFU beams to the desired sites in the prostate volume using multi-channel electronic drivers, with the intent to increase treatment efficiency and reliability for the next generation of HIFU systems. The annular array is able to focus in depth from 25 mm to 50 mm, generate total acoustic powers in excess of 60W, and has been integrated into a modified Sonablate®500 HIFU system capable of controlling such an applicator through custom treatment planning and execution software. Both PZT- and piezocomposite cylindrical arrays were constructed and their characteristics were compared for the transrectal applications. These arrays have been installed into appropriate transducer housings, and have undergone characterization tests to determine their total acoustic power output, focusing range (in depth and laterally), focus quality, efficiency, and comparison tests to determine the material and technology of choice (PZT or piezocomposite) for intra-cavity HIFU applications. Array descriptions, characterization results, *in-vitro* and *in-vivo* results, and an overview of their intended use through the application software is shown.

INTRODUCTION

It is desired to improve the current fixed-focus spherical shell HIFU transducers used to treat prostate cancer with the Sonablate®500 (Focus Surgery, Inc., Indianapolis, IN., USA) clinical device by substituting them with 1-D and 2-D HIFU arrays to: (i) enhance treatment capabilities, (ii) reduce treatment planning and execution time, (iii) increase probe reliability, and (iv) reduce the reliance on the transducer mechanical positioning system. Previous work focused on the development of the optimum HIFU array geometry given the requirements of this application [1,3], driving electronics development, and initial laboratory evaluation of several HIFU array prototypes [2]. The purpose of the current work is to show progress made towards the clinical evaluation and implementation of 2 HIFU arrays: annular (1-D) and cylindrical (2-D), supporting systems (user interface software, treatment software, driving hardware, interconnection strategies, etc.), and transducer materials.

MATERIALS AND METHODS

Two designs were built and evaluated as part of this effort: a 20-channel annular array, capable of focusing in depth from 25 mm to 50 mm in front of the transducer at 4.0 MHz, shown in Figure 1(a,b), and a 211-channel (422 element) cylindrical array, capable of focusing in depth from 25 mm to 50 mm in front of the transducer, and laterally over the range of ±20 mm, shown in Figure 1(c,d). The specifics of both arrays have been described previously [2], with the following exceptions: the annular array is constructed using a laser-scribed PZT shell (Nova 3B, Keramos, Indianapolis, IN., USA), and the cylindrical array's length has been changed to 40 mm.



(a) (b) (c) (d)

FIGURE 1. (a) Annular Array electrodes laser-scribed on convex side, (b) Annular Array installed in Sonablate®500 HIFU probe, (c) Cylindrical Array electrodes laser-scribed on convex side of piezo-composite material prior to forming, and (d) completed Cylindrical HIFU Array transducer assembly.

Two PZT annular arrays and 3 cylindrical arrays were built, one out of piezocomposite material (K270, Keramos, Indianapolis, IN., USA), and the remaining two out of diced PZT-4 and PZT-8, respectively, for clinical evaluation and transducer material performance comparison purposes.

Custom driving electronics were constructed, both for the annular array (which requires a low channel count but high power output capability for each channel), and for the cylindrical array (which requires a high channel count but low power output capability for each channel) [2].

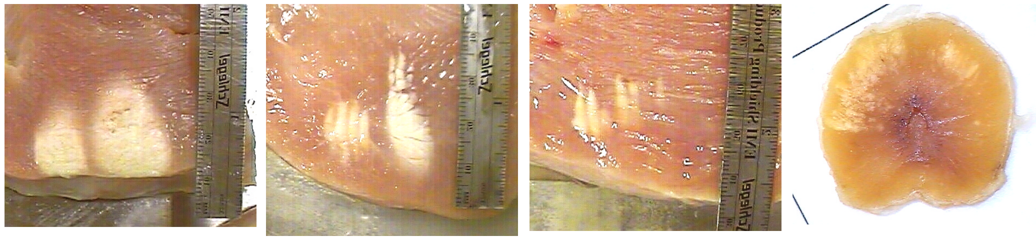
Custom software with a novel user interface was developed for the commercially-available Sonablate®500 device to control the HIFU arrays and associated electronics. This software enables the user to simultaneously plan the HIFU treatment under image guidance for up to 5 treatment depths, exploiting the new capabilities of the developed HIFU arrays.

All arrays were extensively characterized for element impedance, operating frequency, element cross-coupling, acoustic power output, efficiency, focus quality, focusing performance over the region of interest, piezocomposite and piezoelectric performance and manufacturability differences, and their ability to create HIFU lesions *in-vitro* and *in-vivo.*

RESULTS

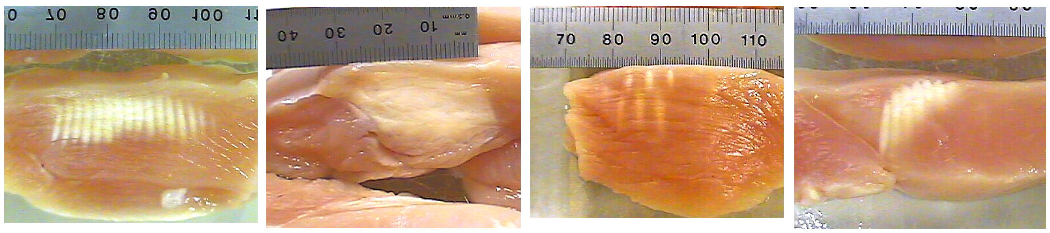
The annular array was capable of creating defined lesions at the desired depth, as shown in Figure 2. Elementary lesions as well as compound lesions were easily created by adjusting HIFU exposure parameters. Its simple design makes it an ideal candidate for incorporation into the Sonablate® clinical system in the near future.

The cylindrical array was capable of creating both elementary and compound lesions at depth and laterally, as shown in Figure 3. Its ability to create lesions over a large extent with respect to its aperture (±15 mm lateral, 25-50 mm depth; aperture: 40 mm) within a few seconds demonstrate the effective focusing gain and the range of the focal zone placement for the cylindrical geometry as a HIFU array.



(a) (b) (c) (d)

FIGURE 2. Annular array *in-vitro* depth lesion creation results, all with 30/40mm focusing, 3s ON/6s OFF HIFU time: (a) 7 adjacent sectors treated; (b) 2 adjacent sectors treated; (c) a single sector treated. (d) *In-vivo* canine prostate (8.2 cm^3) treated with the annular array, 35mm focusing contiguous lesion volume shown.



(a) (b) (c) (d)

FIGURE 3. (a) Cylindrical array *in-vitro* depth and lateral lesion creation results: (a) 35mm focusing over ±15mm range, 6s ON/6s OFF, 2mm spacing; (b) 35mm focusing over ±15mm range, 6s ON/6s OFF, 1mm spacing; (c) 35/25mm focusing, 6s ON/6s OFF, 2mm spacing; (d) "ladder" focusing from 35mm to 25 mm, 6s ON/6s OFF, 2 mm spacing. Full electronic focus placement - no mechanical positioning.

CONCLUSIONS

Steady progress toward the clinical evaluation and implementation of HIFU arrays (1-D and 2-D) and supporting systems has been made. Both annular and cylindrical geometries are effective as transrectal HIFU arrays. For cylindrical geometries, piezocomposite and piezoceramic technologies show similar complexities in manufacture and performance. HIFU arrays have a range of key design parameters (Focusing Gain, Range of Focal spot placement, HIFU "ON" Time) that distinguish them from lower intensity therapeutic arrays.

ACKNOLEDGEMENTS

This work was partially funded by the NIH SBIR grants 1R43 CA81340-01, 2R44 CA081340-02, and NEDO, MITI, Tokyo, Japan. We thank the staff of LARC from the Indiana Univ. School of Med. for their approval and help with the animal study and Russell Fedewa from Focus Surgery for his help with the *in-vivo* experiments.

REFERENCES

1. J.S. Tan, L. Frizzell, N. Sanghvi, Shih-jeh Wu, R. Seip, and J. Kouzmanoff, “Ultrasound Phased Arrays for Prostate Treatment,” *Journal of the Acoustical Society of America*, Vol. 109, No. 6, June 2001, pp. 3055-3064.
2. R. Seip, W. Chen, J. Tavakkoli, L.A. Frizzell, and N.T. Sanghvi, "High-Intensity Focused Ultrasound (HIFU) Phased Arrays: Recent Developments in Transrectal Transducers and Driving Electronics Design," *Proc. of the Intl. Symp. on Therapeutic Ultrasound*, 2003, pp. 423-428.
3. L. A. Frizzell, J. Tan, and G. Warren, "Theoretical Results for New Cylindrical Ultrasound Phased Array for Prostate Treatment," *Proc. of the Intl. Symp. on Therapeutic Ultrasound*, 2002, pp. 384-390.

Email: rseip@focus-surgery.com