Program Digest, 2019 IEEE International Ultrasonics Symposium (IUS)
Glasgow, Scotland, October 6-9, 2019

DEVELOPMENT OF A TOROIDAL HIFU TRANSDUCER FOR FAST, LARGE AND SELECTIVE ABLATION OF BREAST TUMORS. PRELIMINARY EXPERIMENTS IN HUMAN SAMPLES.

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Background, Motivation and Objective

Impacting 2.1 million women each year and causing 15% of cancer-related deaths among women in 2018, breast cancer is still the most frequent cancer among women and the leading cause of cancer mortality in women. Surgery, eventually combined with adjuvant therapies, is the standard of care. However, to ensure a better quality of life, less invasive treatments (radiofrequency, laser, HIFU) have shown reduced morbidity and hospital stay. Among these technologies, HIFU is the only non-invasive technique. However, it is still limited by the size of single lesions which leads to a considerable amount of time to achieve a complete ablation of the tumor volume.
We recently developed a new generation of HIFU transducer allowing fast, large and selective ablations by using a toroidal geometry. We report here the first preclinical results of a completely non-invasive treatment of human breast tissues using a toroidal HIFU device.

Statement of Contribution/Methods

The toroidal transducer has a radius of curvature of 70 mm, a diameter of 70 mm and was divided into 32 concentric rings of equal areas (78 mm^2). The operating frequency was 2.5 MHz.
Due to the geometrical characteristics of a torus, the focal zone observed in the focal plane is a ring of 30 mm in diameter. The toroidal transducer is based on a spindle torus. Therefore, the ultrasound beams coming from all 32 emitters intersect between the focal ring and the transducer to form a secondary focal zone called an “overlapping area”. We previously demonstrated that these two focal zones allow large, fast and homogeneous ablations (up to 8 cc/min) even in highly perfused organs like the liver.
A 7 MHz ultrasound imaging probe was placed at the center of the HIFU transducer to guide the treatment.
Experiments were conducted in 23 human samples of normal breast tissues recovered from mastectomies. The free-field acoustical power used for treating the breast varied between 100 to 140 watts and was applied from 45 to 180 seconds. The tissue attenuation was measured using pulse-echo method before and after HIFU.

Results, Discussion and Conclusions

Ten HIFU ablations were created with an average diameter of 22.5 ± 4.4 mm. Ablations were placed at an average depth of 15.1 mm while preserving skin integrity. The HIFU-treated breast tissues exhibited higher attenuation (0.27 ± 0.08 $Np.cm^{-1}.MHz^{-1}$) when compared to untreated tissues (0.16 ± 0.09 $Np.cm^{-1}.MHz^{-1}$). The treated zone was immediately visible after HIFU treatment as hyperechoic areas in ultrasound images. Histological analyses confirmed homogeneous ablations in the breast. Ablations of this size, obtained after just a few seconds, allow for the treatment of breast tissues without resorting to mechanical scanning.

This study shows that a fast and fully noninvasive treatment of 10-15 mm diameter breast tumors using a toroidal transducer is conceivable. Based on these results, Phase I-II clinical trials will be conducted with the toroidal HIFU transducer to treat breast cancer.