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DEVELOPMENT OF HIGH-OUTPUT THERAPY SYSTEMS FOR TRANSCUTANEOUS APPLICATION OF BOILING HISTOTRIPSY

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Boiling histotripsy is an experimental therapy that produces noninvasive mechanical tissue ablation by high-intensity focused ultrasound (HIFU). Under this modality, millisecond-long pulses containing shock waves cause rapid, localized heating, leading to boiling at the focus and disruption of the tissue structure without significant thermal injury. As boiling histotripsy is dependent on the formation of high-amplitude shocks at the focus, the transducer must generate sufficient power to overcome attenuation losses in tissue and by bones and deliver high pressures to the focus in situ. This presentation describes the design approach and realization of boiling histotripsy systems capable of transcostal therapy and treatment through significant overlying tissue paths. We have developed two transducers for boiling histotripsy. The first device is a 1-MHz, 7-element array with circular elements. The transducer is driven with a custom amplifier system that can generate high-power pulses for up to 10 ms duration. The second transducer is a 1.5-MHz 12-element sector array designed for use with the same amplifier, as well as a Verasonics HIFU research platform. Both are designed based on nonlinear acoustic simulations used to estimate the shock amplitudes for different driving conditions, and fabricated using a rapid prototyping method. The transducer elements are designed in such a way to minimize mechanical stress and potential failure during operation. Because of the large focal pressures produced, the field cannot be directly measured in water over their entire power range. Instead, the transducers are characterized by a combination of acoustic holography and nonlinear modeling using the Westervelt equation. These results are compared with focal pressure measurements using a fiber optic hydrophone at lower pressures. The devices are tested by generating lesions in ex vivo liver and kidney through porcine body wall and rib sections, for total tissue paths up to 6 cm. At maximum electrical output, the transducers produced up to an estimated 11.5 kW pulse-average acoustic power at 1% duty cycle without measurable damage or degradation of the elements. Simulations of the pressure field have been performed up to the maximum output, and give good agreement with the measured waveforms at lower output. Histotripsy lesions could be generated without overlying tissue in liver and kidney at as low as 360 W acoustic power, corresponding to in situ shock amplitudes of approximately 70 MPa. Lesion generation at different depths in liver up to 6 cm indicated that the threshold for boiling can be predicted by derating the acoustic output based on an attenuation coefficient of approximately 0.6 dB/cm/MHz. With the 1 MHz system, we have been able to generate boiling histotripsy lesions in liver through body wall sections containing ribs using 4.4-11.5 kW power. We have developed transducer systems capable of performing boiling histotripsy through clinically-relevant tissue paths. The design process provides estimates for the required shock amplitudes needed to generate lesions and flexibility in producing necessary power to compensate for losses from tissue and bone. The combined approach of measurements and modeling provides a valuable process for treatment planning and accurate characterization of transducers over their entire output range. Work supported by NIH 2T32DK007779-11A1 and 2R01EB007643-05 and NSBRI through NASA NCC 9-58.