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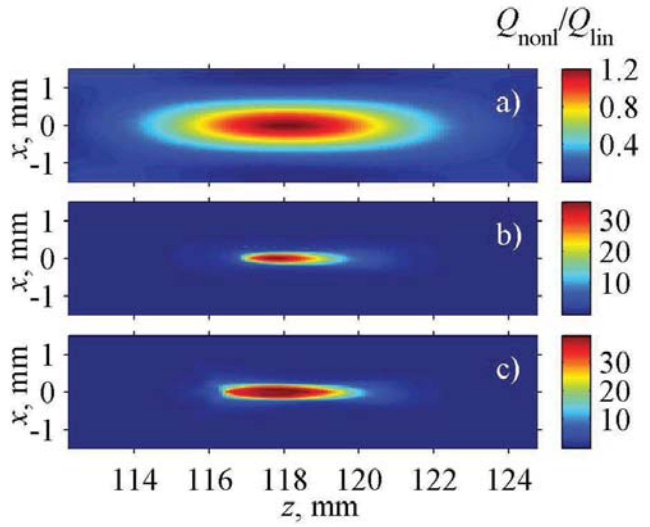

Figure 3: Spatial 2D distributions of heat deposition rates in tissue in the axial plane of the array for different intensities at the array elements: (a) 1.2 W/cm^2, (b) 8 W/cm^2, and (c) 15 W/cm^2. Heat deposition rates are normalized to the heating rates calculated at the same intensities assuming linear wave propagation conditions. The distributions therefore illustrate nonlinear enhancement and better spatial localization of heating using shock-wave exposures.

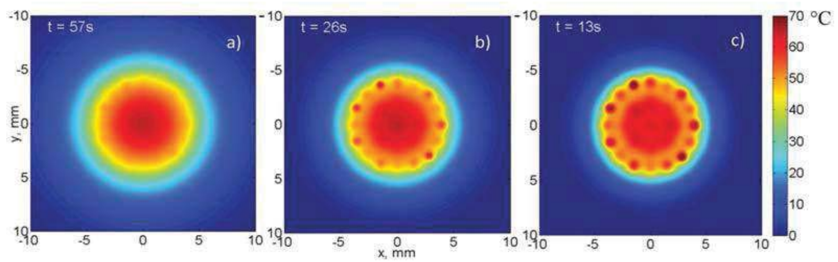

Figure 4: Spatial 2D distributions of temperature rise in tissue in the plane of maximum heat deposition for different peak intensities at the array elements balanced by the pulse length within 40 ms time window between the pulses: (a) 1.2 W/cm^2 and 20 ms, (b) 8 W/cm^2 and 3 ms, and (c) 15 W/cm^2 and 1.6 ms. As indicated in each frame, temperature maps are shown at the time point when temperature rise everywhere inside the circle of 4 mm radius reaches 45°C. This temperature rise would ensure tissue denaturation for *ex vivo* exposures with initial tissue temperature of 20°C.

85 ULTRASONIC HEMOSTATSIS OF DEEP ARTERIAL BLEEDING

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OBJECTIVES

Ultrasonic hemostasis may provide an effective method in surgery and prehospital settings for treating trauma and elective surgery patients. Application of HIFU therapy to hemostasis was primarily initiated in an attempt to control battlefield injuries on the spot. High-intensity focused ultrasound (HIFU) has been shown capable of coagulation of internal bleeding. The main drawback of the thermal hemostasis strategy is low ultrasound absorption ability of blood and, as a result, low heating and coagulation rate at real blood flow.
The purpose of this study was to evaluate the feasibility of HIFU thermal and combinational (cavitation, boiling, non-linear behaviors, and coagulation agents) effects for ultrasonic hemostasis of deep arterial bleeding.

METHODS

In this paper, HIFU therapy and imaging transducer designs, nonlinear acoustic fields modelling and calculations, as well as in vivo hemostasis experiments on lamb's femoral artery confirming enhanced ultrasonic hemostasis at deep arterial bleeding are described. For ex vivo and in vivo hemostasis experiments an ultrasonic applicator was designed and tested. The ultrasonic applicator design had HIFU therapy transducer and imaging probes and was configured to be compatible with 3D mechanical scanning system. HIFU transducers are comprised 1-2 MHz spherical elements made from porous piezoceramics with 80 mm aperture having radius of curvature 40-60 mm. Centre opening with 40 mm diameter was reserved for ultrasonic imaging and Doppler probes such as linear, convex or 3D arrays.
Acoustic measurements of ultrasonic transducers have been performed in 3D Scanning System (UMS3) using the fiber optic hydrophone (FOPH 2000) and using AFB from Precision Acoustics Ltd. Waveforms from the hydrophones and the driving voltage were recorded using a digital oscilloscope Lecroy. The transducer was driven by a function generator Agilent 33521B, a linear RF amplifier E&I model 2400L RF, and operates in a CW or burst modes. The acoustic intensity in the focal
plane measured in water tank at 1000-5000 W/cm^2 (ISAL) was kept for the objects treatment. The experiments were made on acoustic vascular phantoms, as well as on lamb's femoral artery in vivo at different protocols. During ultrasound exposure of lamb's femoral artery, arterial blood flow was temporarily stopped using intravascular balloon. In some protocols intravenous coagulation agents (liposomes) activated by HIFU at the point of bleeding were used. Targeting accuracy was assessed by necropsy and histologic exams and efficacy (vessel thrombosis) by angiography and histology.

RESULTS

New effective HIFU therapy and imaging transducer designs and treatment protocols for ultrasonic hemostasis of deep arterial bleeding were developed and evaluated. The results of theoretical calculations and modelling along with the acoustic measurements of non-linear ultrasonic fields were presented. The results of ex vivo experiments on tissues and vascular phantoms allowed to choose the optimal HIFU treatment protocols. In vivo hemostasis experiments on lamb’s femoral artery confirmed enhanced thermal effect of HIFU in non-linear regimes. Using of HIFU transducers with resonant frequency of 1,6 MHz at intensity of 5000 W/cm^2 (ISAL) allowed to stop bleeding from major blood vessels that were punctured with an 18- or a 14-gauge needles during 3-15 sec.
Thrombogenic evidence (blood clotting) and collagen denaturation (vessel shrinkage) were found in necropsy and histologically in all targeted arterial vessels with minimal damage to adjacent tissue structures. Coagulation cascade behaviors (postponed thrombosis) was also observed during next few hours after treatment. Thrombogenic efficiency of intravenous coagulation agents (liposomes) activated by HIFU at the point of bleeding was also demonstrated.

CONCLUSIONS

We have demonstrated that HIFU can be used to stop active bleeding from vascular injuries including punctures and lacerations. The coagulation strategy that employ thermal and combinational effects (cavitation, boiling, non-linear behaviours, and coagulation agents) for fast ultrasonic hemostasis of deep arterial bleeding has been proposed. The results of theoretical modelling, ex vivo experiments on tissues and vascular phantoms, as well as in vivo experiments in lamb’s femoral artery proved the efficacy, safety and selectivity of developed HIFU transducers and combinational treatment methods that can be used for various therapeutic, surgical and cosmetic applications.

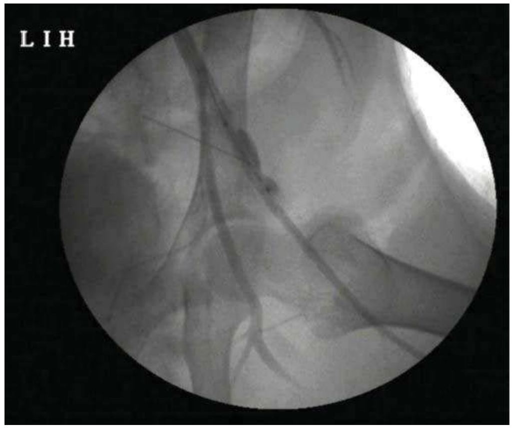

Figure 1: Angiography image of blood vessels.

Figure 2: Photograph of vessel thrombus in dissected femoral artery.

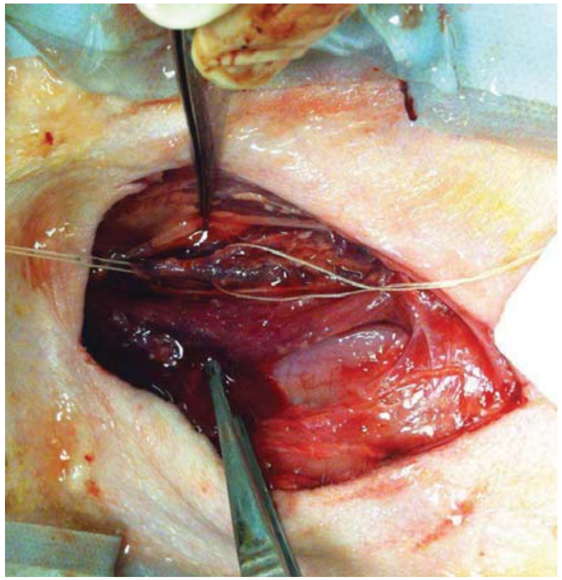

Figure 3: Lamb's femoral artery.