A Laparoscopic HIFU Probe with Integrated Phased Array Ultrasound Imaging

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Abstract. Laparoscopic surgery as a minimally-invasive modality is gaining increasing interest among surgeons. We have previously reported on the feasibility of using high intensity focused ultrasound (HIFU) in laparoscopic partial ablation of renal tissue. Here, we report on the design, implementation and characterization of a new hand-held image-guided laparoscopic HIFU probe. The probe consists of a single-element high-power piezoceramic transducer for HIFU energy delivery and an ultrasound convex phased array system for real-time imaging/monitoring of the target region during therapy. The probe body is made to fit in a standard 20-mm surgical trocar. The HIFU transducer has a concave truncated spherical geometry (Focus Surgery, Inc.). The imaging system has a convex phased array transducer (Hitachi Medical Crop., Chiba, Japan) with f_0=6.5 MHz, and DOF=8.0 cm. Schlieren imaging of the HIFU beam was used to evaluate the focusing capability of the HIFU transducer as well as the location of the HIFU focal spot with regard to the imaging screen. Total acoustic power (TAP) measurements showed that the device is capable of delivering TAP values up to 45 W, sufficient to create necrotic lesions in sites up to 4 cm deep in tissue. Computer simulations of the acoustic field coupled with the BHTE temperature response were used to support measurements. The probe prototype was used in an *in vivo* animal study in which necrotic lesions were created in a lobe of pig's kidney through a laparoscopic procedure. A custom-designed probe holder with integrated positioning system was used for precise movement of the probe tip, to create contiguous lesion volumes. Gross pathology and histology examinations showed the generation of well-delineated and homogenous necrotic lesion volumes in a lobe of the kidney.

INTRODUCTION

Laparoscopic surgery is a relatively new technique, which is gaining an increasing interest among surgeons. Comparing to traditional open surgery, the laparoscopic operations are less invasive which may lead to lower mortality and morbidity rates [1, 2]. Several research groups have been investigating novel laparoscopic surgery techniques, including cryo-ablation using extreme cold, radio-frequency ablation, and HIFU (high intensity focused ultrasound) ablation [3-6]. In HIFU surgery, an intensive beam of CW ultrasound is focused in a tight focus within the target tissue volume, which may lie deep within the body. This results in a rapid temperature rise within the focal volume leading to cell death mainly due to coagulation necrosis [7]. The technique has demonstrated promising results in treating organ-confined benign and malignant tumors in different organs such as prostate, liver, kidney, breast, etc., with minimal side effects [8-10].

We have previously reported on the design and development of laparoscopic HIFU probes and their feasibility in partial ablation of renal tissue [6, 11]. Here, we report on the design, implementation and characterization of a new hand-held image-guided laparoscopic HIFU probe. The probe consists of a single-element high-power piezoceramic transducer for HIFU energy delivery and an ultrasound convex phased array system for real-time imaging and treatment monitoring.

MATERIALS AND METHODS

The major limitation in our previous designs of laparoscopic probes was the lack of real-time high quality imaging which is required for target imaging and treatment monitoring. The current design addresses this important issue by integrating a commercial phased array imaging system and a single-element HIFU transducer into a hand-held laparoscopic probe. The HIFU transducer is a 4.0 MHz CW source made of a special high-power piezoceramic material (KEZITE NOVA 3B, KERAMOS Inc., Indianapolis, IN) with a concave truncated spherical shell geometry. The imaging system consists of a 6.5 MHz convex phased array transducer coupled to the EUB-525 Hitachi ultrasound scanner (Hitachi Medical Crop., Chiba, Japan). Table 1 gives the main parameters of the HIFU and imaging transducers.

TABLE 1. Parameters of the HIFU and the imaging transducers.

HIFU Crystal	Imaging Array
• Geometry = Single-element Concave Truncated Spherical Shell	• Geometry = 96-element Convex Phased Array (Fingertip)
• Aperture = 24.0 × 12.5 mm	• Aperture = 19.3 × 11.5 mm
• f_0 = 4.0 MHz	• f_0 = 6.5 MHz
• Radius of Curvature = 30.0 mm	• DOF = 80 mm, FOV = 100°

The probe body was built from a stainless steel tube with 14.5 mm outer diameter and 50 cm length to fit in a standard 20-mm laparoscopic surgical trocar. Figures 1 and 2 show a picture of the probe along with the associated accessories, and two views of the probe tip, respectively. During operation, both the imaging and HIFU transducers are covered by a latex sheath filled with circulating degassed water and supported by a backing sleeve. An active pump/chiller system (SonaChill™, Focus Surgery Inc., Indianapolis, IN) was used in conjunction with the laparoscopic probe to ensure continuous circulation of water with a controlled temperature of ~20°C around the transducers. The water-filled latex balloon not only provides a good coupling between transducers and tissue but also allows the application of higher powers to the HIFU transducer by increasing its efficiency and lowering the risk of transducer overheating.

A custom-designed probe holder with an articulated arm and integrated positioning system was developed for precise manual movement of the probe tip required to create contiguous lesion volumes. The positioning system allows the probe tip to move in the transnational direction with accuracy of ±1 mm and in the rotational direction with accuracy of ±1°.

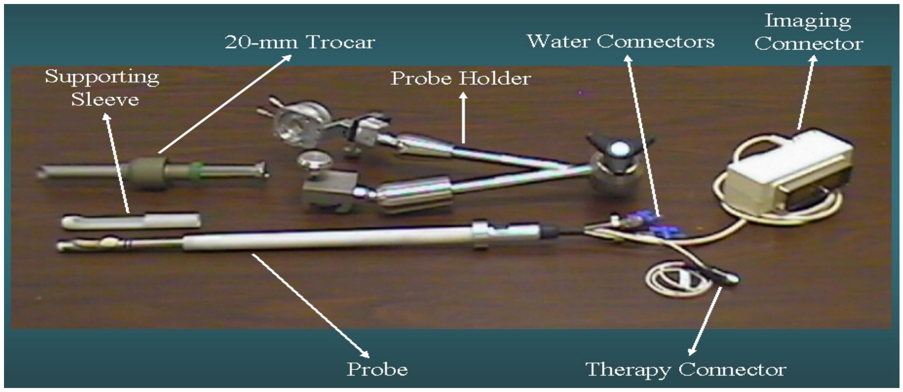

FIGURE 1. Hand-held image-guided laparoscopic HIFU probe and associated accessories.

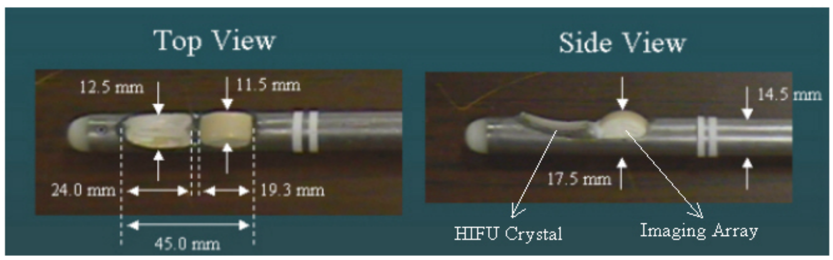

FIGURE 2. Top and side views of the probe tip.

Probe Calibration

The HIFU crystal of the probe was fully characterized by measuring its electrical impedance, frequency response, and total acoustic power (TAP) output. Standard TAP measurement using a calibrated radiation force balance (UPM-DT-10, Ohmic Instruments Co., Easton, MD) showed that the probe was able to deliver TAP levels of up to 45 W at 4 MHz. Acoustic field simulations coupled with the bioheat transfer equations (BHTE) were used to calculate the focal intensity and corresponding temperature response in tissue. Figure 3 shows the results of the BHTE temperature simulations at the end of a 2-s HIFU exposure with a TAP of 32 W. The focal spot is placed at the depth of 3 cm inside kidney tissue. As it is seen, the focal intensity of about 1800 W/cm^2, corresponding to a focal temperature rise of about 30 °C/s, was achieved which leads to rapid focal tissue ablation through a combination of thermal (coagulation necrosis) and non-thermal (cavitation) effects.

A Schlieren imaging system (OptiSon® System, Onda Corp., Sunnyvale, CA) was used to evaluate the focusing quality of the HIFU transducer as well as to register the location of the HIFU focal spot with regard to the Hitachi imaging screen. For this purpose, the position of a point reflector was located in the Hitachi screen when it was placed at the HIFU focal spot under the Schlieren imaging guidance. Figure 4 shows the probe-reflector configuration and the Schlieren image when the point reflector was placed at the focus.

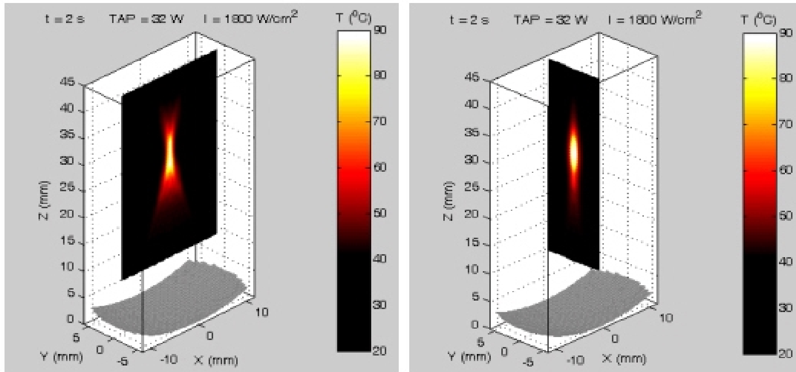

FIGURE 3. Two views of the BHTE temperature simulations of the HIFU beam in kidney tissue. Exposure parameters are given in the figures.

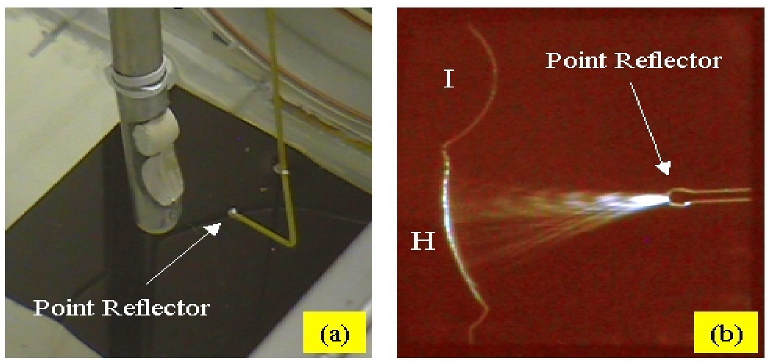

FIGURE 4. (a) Probe/reflector configuration inside the Schlieren water tank, and (b) the Schlieren image (I = Imaging array, and H = HIFU crystal).

Experimental Setup

Figure 5 shows the experimental setup block diagram of the laparoscopic probe. As it is shown, the probe works along with the Hitachi EUB525 scanner, SonaChill™ pump/chiller unit, and a custom-designed HIFU electronic control box. The control box includes a RF power amplifier and associated electronics to adjust the output power and the operating frequency of the HIFU crystal. A footswitch is used to control the HIFU exposure On/Off times during the operation.

IN VIVO ANIMAL STUDY

The probe prototype was tested via a series of feasibility experiments in chicken breast tissue *in vitro* and in pig kidney *in vivo*. Two pigs were treated through standard laparoscopic procedures under an acute study (Figure 6-a). Necrotic lesions were successfully created in the upper pole of the animal's left kidney. The HIFU exposure parameters used in this study were: TAP = 32 W, HIFU On/Off Times = 2/2 s, and No. of Shots/Site = 5. A hyperechoic region consistently appeared at the focal region on the ultrasound image immediately after each HIFU exposure (Figure 6-b). This was used as an indicator for treatment monitoring and control.

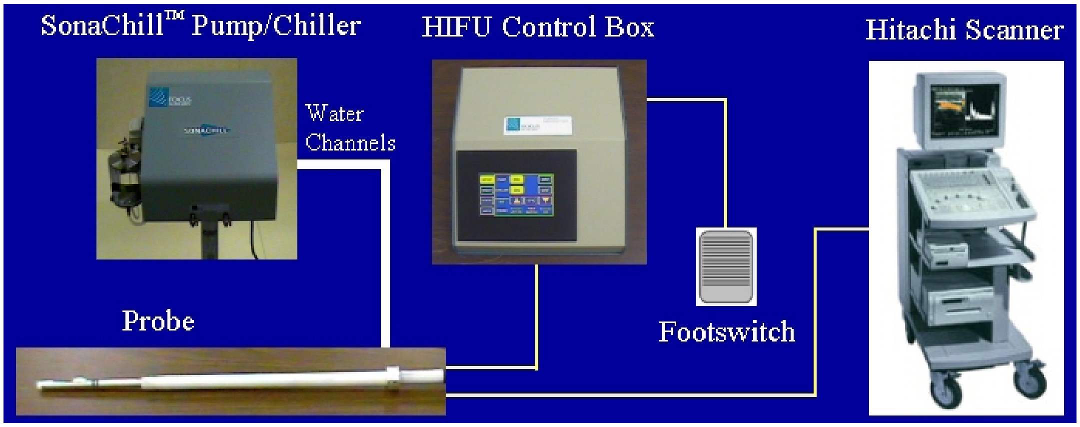

FIGURE 5. System block diagram of the hand-held image-guided laparoscopic probe.

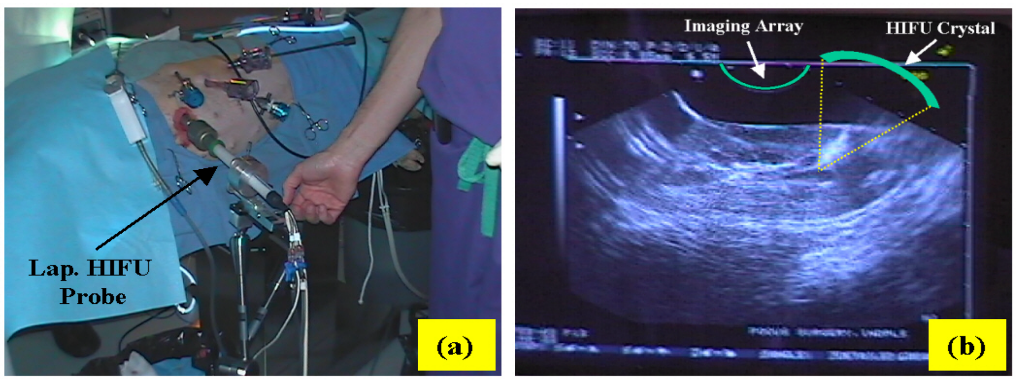

FIGURE 6. (a) Laparoscopic HIFU treatment of the pig's kidney, and (b) the ultrasound image of the target region showing the hyperechoic area at the focus.

The animals were scarified at the end of the treatment and the kidneys were removed for further histopathology examinations. Gross pathology and histology examinations showed the generation of well-delineated and homogenous necrotic lesion volumes with a very sharp demarcation of only a few cells wide between the necrosed and intact kidney tissue (Figure 7).

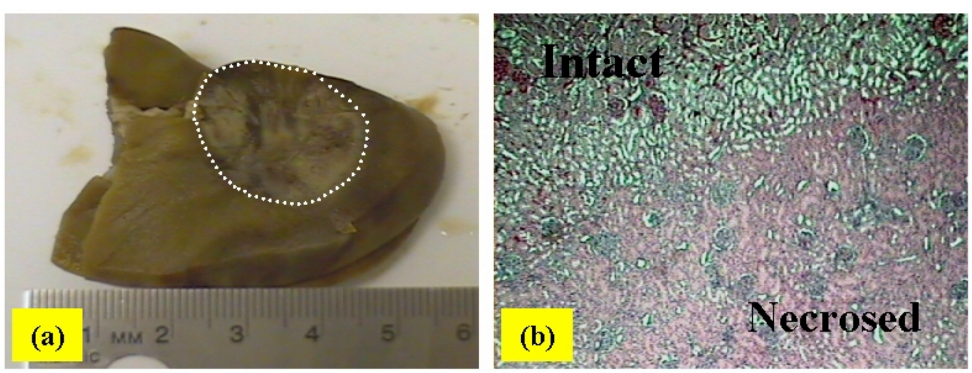

FIGURE 7. (a) Cut section of the lobe of the kidney which shows the necrotic HIFU lesion, and (b) a histology slice to show both the intact and necrosed regions of the kidney tissue.

DISCUSSION AND CONCLUSION

The design and development of a new HIFU probe suitable for laparoscopic operations was presented. The design integrates a commercially available phased array ultrasound imaging system and a HIFU transducer into a hand-held probe. High quality real-time imaging has been shown to be required for accurate and reliable target imaging and treatment monitoring. Besides conventional B-mode imaging, using a state-of-the-art scanner allows the user to apply other imaging modalities such as Doppler and/or harmonic imaging for quantitative treatment monitoring. The *in vivo* animal study has shown the feasibility of the device to create well-delineated contiguous HIFU lesion volumes in a lobe of the kidney through standard laparoscopic operations. It is anticipated that the technique can be used to ablate malignant tumors in various sites and organs in the body including kidney, liver, and prostate. Focus Surgery, Inc. is currently considering the commercialization of this hand-held image-guided HIFU laparoscopic device.

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