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Image-Guided High Intensity Focused Ultrasound System for Large Animal Nerve Ablation Studies

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ABSTRACT High intensity focused ultrasound (HIFU) is a form of thermal ablation technique, which can treat a variety of medical afflictions. One promising therapeutic use is the permanent destruction of nerves non-invasively in patients with severe spasticity or certain types of pain (e.g., phantom limb pain). To this end, HIFU requires ultrasound guidance, which allows the non-invasive, target-specific deposition of thermal energy to the targeted nerve, thereby blocking axonal conduction. In this paper, a composite system comprising both ultrasound-imaging and HIFU therapy was developed and used to induce localized non-invasive nerve blockage in an *in vivo* large animal study. Five pigs were used with the femoral nerve as the target. Calibrated needle thermocouples inserted at the target site were employed to monitor the target tissue temperature. The degree of nerve blockage was assessed by measuring compound action potential (CAP) signal with a clinical nerve electrophysiology system before and after HIFU exposures. An average CAP signal amplitude reduction of 49% of baseline with a standard deviation of 9% was observed after 20–30 min post exposure. These results demonstrate the feasibility of the proposed ultrasound-guided HIFU modality as a potential non-invasive nerve ablation method.

INDEX TERMS CAP measurement, non-invasive nerve ablation, porcine femoral nerve, ultrasound-guided HIFU.

I. INTRODUCTION

High intensity focused ultrasound (HIFU) is a form of thermal ablation technique which can treat a variety of medical afflictions in non-invasive fashions [1]. One promising therapeutic use of HIFU is the permanent destruction of nerves in patients with severe spasticity or certain types of pain [2].

Radiofrequency ablation (RFA) of nerve supply to a joint is an emerging field in pain medicine. This technique has been applied to patients with pain related to facet joint and sacroiliac joint [3], [4]. Recently, there is growing interest in managing osteoarthritis of hip and knee with RFA to the nerve supply for those joints [5], [6]. To apply this technique, a needle insertion is required. Furthermore, the needle must be oriented to the long axis of the nerve to achieve maximum effect. HIFU is a non-invasive technique and can produce a larger lesion than percutaneous needle insertion can provide. As the population ages, there will be an increasing need for such medical procedures.

HIFU allows the non-invasive deposition of enough thermal energy to raise the targeted tissue temperature to above 55°C thereby causing rapid coagulative necrosis [7] which blocks axonal conduction in a nerve. The degree of this blocking can be assessed by measuring nerve compound action potential (CAP) morphology and amplitude with a clinical nerve electrophysiology system before and after exposure. In previous studies, reductions in CAP amplitude have been demonstrated resulting directly from HIFU exposures to the *ex vivo* ventral nerve cord in lobsters (Homarus americanus) [8], [9] and the sciatic nerve from

bullfrogs [10]. Foley et al. have employed HIFU to show successful CAP reduction in excised sciatic nerve from rats [2] and have also performed ultrasound image guided HIFU on the sciatic nerve in rabbits *in vivo* [11], [12]. Vaezy et al [13] has developed an ultrasound image guided HIFU system to create thermal lesions in the surgically exposed liver of anesthetized pigs. Vaezy's system includes a synchronizing technique to remove artifacts and interference in ultrasound imaging during HIFU exposure. Ultrasound image guided HIFU has been extensively used in China in various applications. Zhang and Wang [14] has completed a study covering 10 years of clinical experience in China.

In the current study, under an approved animal study protocol, we employed an ultrasound-guided HIFU system to block non-invasively the axonal CAP conduction of the femoral nerve in the hind legs of Yorkshire-cross pigs. This model is considered the one that is physiologically closest to human.

In the Advanced Biomedical Ultrasound Imaging and Therapy Laboratory at the Department of Physics, Ryerson University, we have designed, built, and tested 2 HIFU system prototypes with ultrasound image guidance for non-invasive nerve intervention applications: (1) a lab system for phantom and *ex vivo* tissue studies (not described in this paper) and (2) a portable system that was employed in this approved animal study for *in vivo* porcine experiments. The successful completion of the *in vivo* experiments leads to design an improved HIFU system suitable for human clinical trials as the next stage of this project.

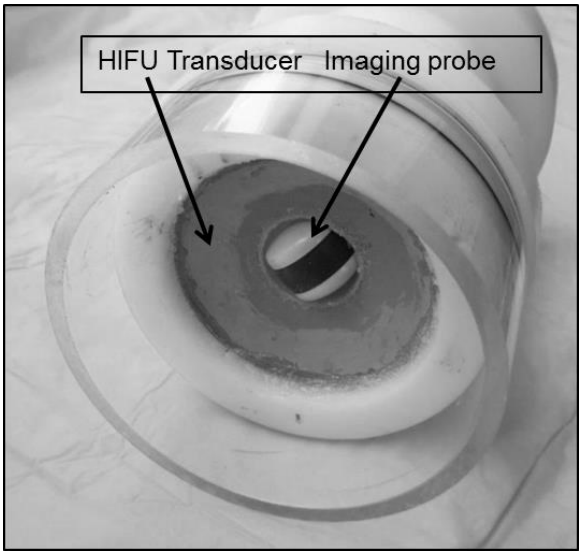

FIGURE 1. **Portable HIFU transducer; OD = 65 mm; ID = 26 mm; Focal length = 66 mm; F# = 1.02. The HIFU transducer is the grey donut with the imaging probe in the middle.**

II. METHODS AND MATERIALS

The portable HIFU transducer (Fig 1) used in our system is a PZT4 crystal with an outer diameter of 65 mm, inner opening diameter of 26 mm, and radius of curvature of 66 mm

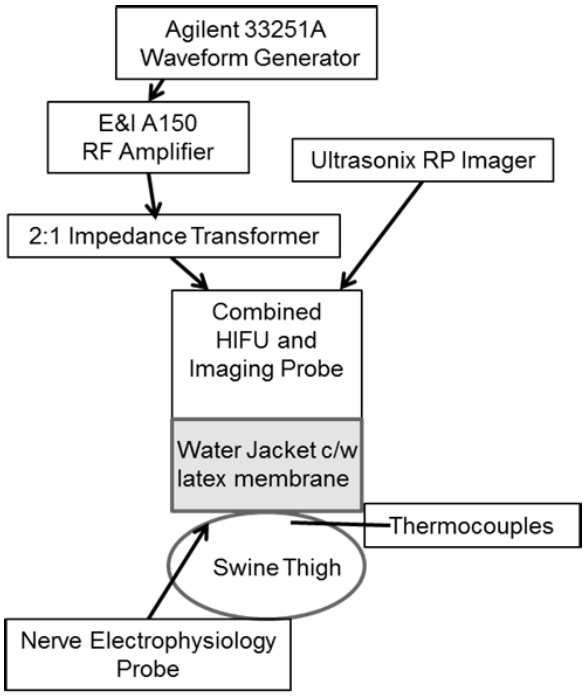

FIGURE 2. **Block diagram of the experimental setup for the porcine nerve blocking study.**

(Boston Piezo-Optics, Bellingham, MA, USA). The holder was designed and built in-house. A burst of sine waves generated by a signal generator (33251A, Agilent, Santa Clara, CA, USA) is fed to a radio frequency power amplifier (A150, Electronic and Innovation Inc., Rochester USA) which in turn feeds the HIFU transducer. The HIFU transducer operates at a frequency of 2.4 MHz. Based on acoustic field simulation and hydrophone measurements at the focus, the beam has a Gaussian shape with a Depth of Field (DOF) of 4.5 mm and a Full Width Half Maximum (FWHM) of 0.9 mm.

The HIFU energy was delivered with a 50% duty cycle: i.e. the power was on for 100 ms, then off for 100 ms over a total exposure time of 60 sec. During the *in vivo* experiments, the transducer was coupled to the thigh of the swine via a water jacket and latex membrane (Figs 2 and 3).

For these experiments, 160 W of electrical power was delivered to the HIFU transducer. This produced ~105 W of ultrasound power as measured with a radiation force balance in water (RFB-2000, ONDA, Sunnyvale, CA). HIFU energy was generated over the 28 cm^2 surface area of the transducer and focused through the FWHM. The low F# results in a small FWHM which in turn leads to a strong focusing gain. Assuming a typical ultrasound attenuation of 1.0 dB/(MHz-cm) in tissue, then at a depth of ~ 2.5 cm and our operating frequency of 2.4 MHz, the ultrasound power at depth will be attenuated to ~ 0.25 of that leaving the transducer. Therefore ~ 26.3 W will be focused through the FWHM (cross sectional area of 0.006 cm^2) resulting in a peak intensity of ~4800 W/cm^2. Equation (1) was used to convert intensity to pressure. The peak acoustic pressure at the focal

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FIGURE 3. Experimental setup during the procedure in the operating room. The pig is on the operating table with the CAP probe against its thigh.

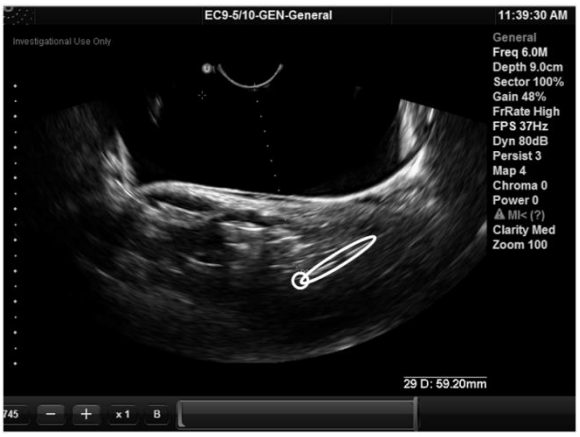

FIGURE 4. Needle thermocouple (straight line in ellipse) implanted next to the femoral nerve (circle) in the right thigh of the pig.

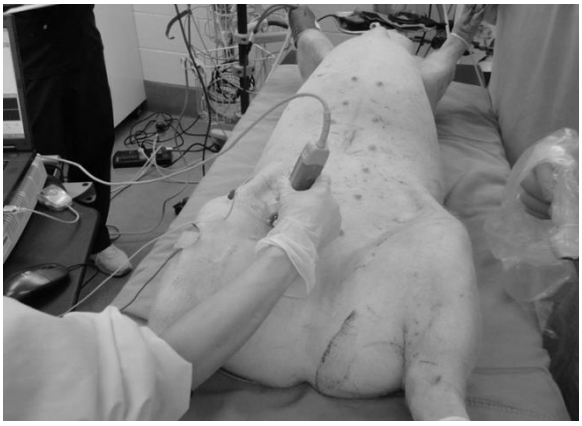

FIGURE 5. Electrophysiology probe stimulating the porcine nerve and recording conduction pre and post exposure.

point is ∼12 MPa.

$$P^2 = 2\rho Ic \tag{1}$$

Here, $I = 4.8 \times 10^7$ W/m^2, P is acoustic pressure in Pa, and in tissue, $\rho = 1000$ kg/m^3, and $c = 1500$ m/sec. The sharply focused transducer (F# ∼1) results in high intensities only in the focal volume while sparing surrounding tissues.

The HIFU transducer was made with a central hole to allow a commercial Sonix® RP intra-cavity EC9-5/10 imaging probe (Ultrasonix Inc., Richmond, BC) to be mounted coaxially with the therapy transducer. The imaging and therapy transducers were aligned by first employing the therapy transducer in pulse-echo mode with a low voltage single cycle pulse. The pulse and its echo were displayed on an oscilloscope (DSO-X 3024A, Agilent). The target was a 0.5 mm diameter wire which was held vertically and translated with respect to the therapy transducer until the received signal was maximized. This occurred when the tip of the wire was positioned at the focal point of the therapy transducer. A transparent overlay sheet was then placed on the display of the Sonix® RP imaging system and the position of the wire marked on the overlay. During HIFU experiments, the overlay on the display of the imaging system allowed the operator to place the HIFU focal point at the region of interest (ROI) and to monitor the ROI pre, peri, and post treatment.

The target tissue in these experiments was the femoral nerve in the hind leg of Yorkshire-cross pigs. The study was approved by the Research Ethics Board for animal study at University Health Network [UHN] and was carried out in the UHN Animal Resource Center. Five male Yorkshire-cross pigs ranging in weight from 45-50 kg were premedicated with intramuscular administration of Azaperone 8mg/kg and Atropine 0.04mg/kg. They were subsequently anesthetized with Isoflurane at 5% by mask technique and were then intubated with a cuffed 8.0 endotracheal tube. The anesthetics were maintained with Isoflurane at 2.0 – 2.5% with mechanical ventilation.

During all experiments, needle thermocouples (made and calibrated in house) were implanted in the ROI using ultrasound guidance (Fig 4).

These thermocouples were connected to a thermometer/data logger (HH306A, Omega, Stamford, CT, USA) which recorded the tissue temperatures in real time. The temperature rise provided an additional confirmation that the focal point of the therapy transducer was correctly positioned at the target nerve on the ROI.

The degree of nerve blocking was assessed by measuring compound action potential (CAP) morphology and amplitude with a clinical nerve electrophysiology system (SierraWave, Caldwell, Kennewick, WA) before and after exposure (Fig. 5).

In this acute study, the animals were all sacrificed with intravenous administration of potassium chloride 1 mEq/kg after HIFU exposure.

III. RESULTS

The HIFU/Imager transducer was mounted on an articulated arm connected to the equipment rack. This mechanism gives

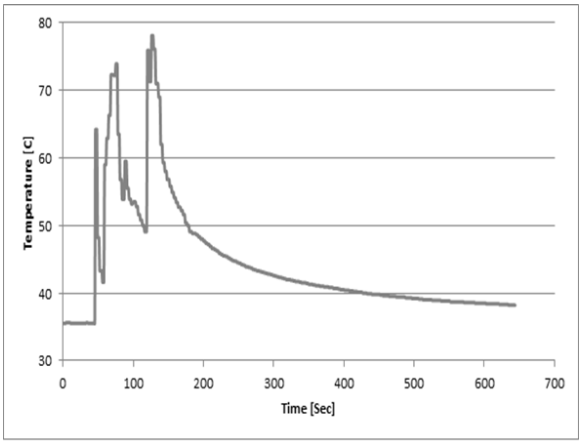

FIGURE 6. Typical measured temperature of the ROI during a HIFU exposure sequence.

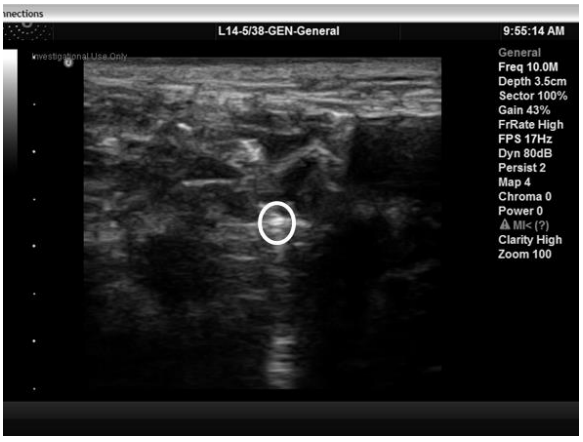

FIGURE 7. Ultrasound B-Mode image of a typical thermal lesion post HIFU exposure. The lesion is visible as a hyperechoic region which coincides with the location of the HIFU focal point in the ROI (ellipse).

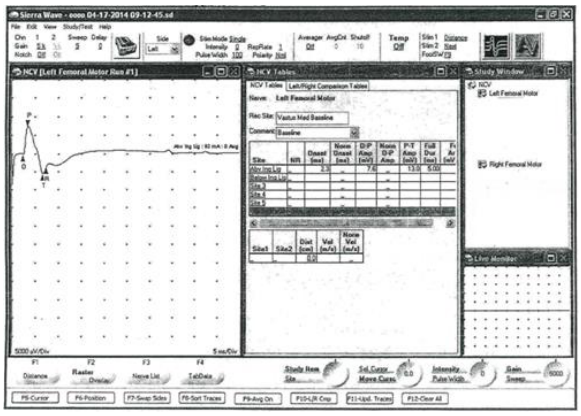

FIGURE 8. Typical femoral nerve CAP measurement display.

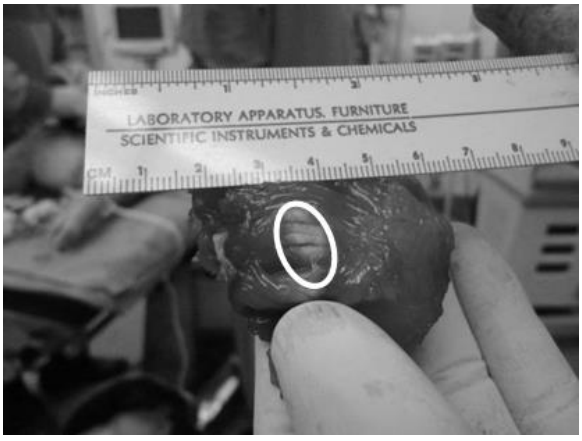

FIGURE 9. Excised tissue showing the ~ 11 × 6 mm thermal lesion created.

enough flexibility and control to the operator to move and place the transducer during the operation.

In all experiments, a needle thermocouple was implanted at the nerve using a 12MHz linear imaging probe connected to a separate ultrasound scanner (M-Turbo, Sonosite Fujifilm, Toronto, Canada). This gave us the real-time thermometry capability in our experiments. Moreover, the presence of a thermocouple made visualization of the ROI easier when using the image-guided HIFU system.

When the HIFU focal point was coincident with the ROI, then the temperature increased to over 70°C in 2 or 3 seconds (Fig. 6). The average maximum temperature increase for all experiments was to 66°C with standard deviation of 9°C. A typical ultrasound B-mode image of the HIFU thermal lesion is shown in Fig. 7 which was taken immediately after the HIFU exposure. The inserted white ellipse specifies the location of the thermal lesion inside the ROI.

A CAP signal was measured before HIFU exposure to the femoral nerve with additional measurements taken immediately post, and 20-30 minutes post exposure. A typical CAP display is shown in Fig. 8. The average immediate CAP amplitude reduction was to 57% of baseline with a standard deviation of 24%. The corresponding numbers for the 20-30 min measurements were 49% with standard deviation of 9%.

In this acute study, after HIFU exposure, the ROI (tissue containing nerve) was excised and the size of the thermal lesion created was measured. Fig. 9 shows a typical thermal lesion which measures 6×11 mm. Finally, the tissue containing the HIFU lesion was sent for a pathological study: these results will be presented and discussed in a future clinically oriented paper.

IV. DISCUSSION AND CONCLUSIONS

This is a proof-of-concept study to examine the feasibility of a co-axial ultrasound imaging and HIFU system applicable to large animals. This study suggested the possibility of the proposed ultrasound-guided HIFU as a potential non-invasive nerve ablation method for large mammals including humans.

The average focal temperature rise to about 66°C which occurred in the ROI during HIFU exposure (Fig. 6) was extremely rapid and then dropped to below the coagulation threshold of 55°C [7] in a few seconds. This resulted in

well controlled focalized thermal damage to the nerve. The strongly focused transducer with its small FWHM deposited large amounts of energy only at the focal point, thus sparing surrounding tissue from any thermal effects. Work is currently in progress in the researchers' group to develop novel ultrasound-based methods to non-invasively estimate tissue temperature in the focal point. This refined thermometry method will eventually eliminate the need for invasive thermocouple-based temperature measurement and will provide real-time feedback to monitor and control the HIFU thermal therapy.

A common problem with combined HIFU/imaging systems is the high degree of artifact and interference in the ultrasound image generated by the high power HIFU transducer when the HIFU beam is on. Vaezy *et al.* [13] created a synchronizing technique to deal with this problem by triggering and gating the HIFU driving signal to be on only when any interference would not obscure the region of interest. It is certainly worthwhile to consider this a useful improvement for future systems.

Foley *et al.* [11], [12] and Vaezy *et al.* [13] used systems where the imaging probe is not coaxial with the HIFU transducer but is mounted to its side. This arrangement allows both transducers to contact small animals or exposed organs but will pose limitations for non-invasive operations for human sized subjects due to overall size and geometry constraints.

The main improvement in our system will be to incorporate a more suitable imaging probe. The present C9-5/10 imaging probe is an endovaginal probe that produces a convex beam spanning 125 degrees. Due to the specifications of the probe, the lateral resolution of the B-mode image at the focal depth image is poor which makes the targeting of the ROI and treatment monitoring of the HIFU procedure challenging. The future version of the system will have a different probe: either linear or mild sector suitable for imaging of nerves.

Zhang and Wang [14] conducted a ten year study of patients whose solid tumors were treated with commercial ultrasound guided HIFU machines such as the Model JC (Chongqing Haidu Technology Co, Chongqing, China) and concluded that the technique is safe and effective. These machines (with coaxially mounted imaging and HIFU transducers) are the size of MRI or CT scanners and require a dedicated room. The main advantages of ultrasound technology are in their relatively inexpensive cost and high level of portability, The portable system described in this study (Fig. 3) consists of one portable scanner and one portable rack for the function generator and power amplifier. Future versions will be combined into a single portable rack.

The current study could potentially have significant clinical implications in non-invasive nerve interventions as ultrasound imaging is emerging as a popular modality for these procedures and needle insertion in pain management [15], [16]. Combination of an ultrasound imaging probe with a HIFU transducer into a single stand-alone application allows the operator to accurately localize the target and interrupt the nerve in a non-invasively manner. This will lead to a novel and efficient method in the pain management field.

The set of five porcine experiments completed the preliminary proof of concept *in vivo* study with promising results. A human clinical trial is being considered for the next phase of this project. To that end, a refined version of the device should be designed, built and tested with improved ultrasound imaging capabilities adapted for nerve interventions in humans.

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