

# In Vivo Treatment of Pig Liver Using Steerable Needle Therapeutic Ultrasound with Combined Imaging and Electromagnetic Tracking System

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## BACKGROUND

Hepatocellular carcinoma is considered to be the third most common cause of cancer death in the world. Liver is considered to be a common site for distant metastasis of several common types of cancer such as gastrointestinal cancer, breast, prostate and melanoma. Surgery procedures and liver transplantation are the most common options for treatment of the liver. Liver transplant is a very complex procedure and may lead to various infections such as hepatitis C. Surgical procedure is an effective therapy but only a small percentage of patient are eligible for liver resection due to tumor location, other diseases present, and surgical risk to the patient. Minimally invasive ablative therapy has been investigated to successfully treat unresectable liver tumors.

## PURPOSE

Minimally invasive catheter/needle based procedures are widely investigated for treatment of various diseases since it is one of the least invasive procedures with potential for minimal or no bleeding and can have good to excellent target accuracy. High-intensity ultrasound catheter/needle based devices have been created for several clinical applications. Catheter based ultrasound therapy has been under investigation for treatment of prostate and uterine applications. Synergistic therapy by combining catheter based ultrasound applicator delivery and radiation have shown excellent results. Interstitial ultrasound applicators have been under development, with demonstrated precise ablation patterns using single or multiple interstitial applicators to ablate *in vivo* soft tissue. The purpose of the present study was to investigate the use of electromagnetic (EM) tracking in combination with ultrasound imaging to guide ultrasound interstitial applicator insertion for ablation of *in vivo* porcine liver in human sized animals. The treatment was monitored by inserting several needle thermocouple arrays at various distances from the ultrasound applicator. The dose distribution was estimated from the temperature recorded by each of the thermocouples. Finally, gross anatomical pathology of the ablation zone and surrounding region was performed and documented.

## RESULTS

An acoustic power of 7 W was delivered to the tissue by each of the ultrasound therapy transducers to the tissue. The tissue was exposed to high intensity ultrasound for 7-9 minutes to achieve planned dose. During therapy, a maximum temperature of 55-70 °C and dose of  $10^4$ - $10^6$  equivalent minutes at 43°C was observed at a radial distance 15-20 mm from the center of the ablation transducer for the planned treatment time. The dose distribution was analyzed and compared with the gross pathology (Figs. 6-7) of the treated region. Accurate placement of the acoustic applicator and temperature sensors were achieved using the combined image-guidance and the tracking system. Ultrasound energy direction was controlled based on transducer design and electronic excitation to avoid other structures.

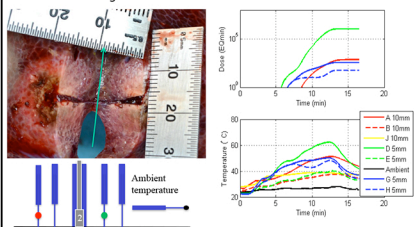


Figure 6: (a) Gross pathology of the ablated liver tissue (b) placement of the thermocouple sensors with respect to the ultrasound energy applicator, and (c) the temperature and dose profiles during the treatment.

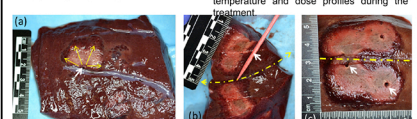


Figure 7: Gross pathology of the ablated pig liver tissue with (a) 180° radiation pattern single needle applicator (yellow solid arrows indicate the beam pattern) avoiding vascular structure and (b) depth of ablated region by 180° pattern applicator for tissue cut along long axis of needle (applicator location indicated by wooden stick). (c) pattern of 360° radiation pattern applicator (white arrows indicate the applicator position, dashed yellow arrow indicates the line of cut for tissue dissection).

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## MATERIALS AND METHODS

Two elemental tubular PZT transducers (10 mm long with 1.5 mm outer diameter) were used to manufacture the catheter based ultrasound interstitial applicator (Fig. 1). The transducers were mounted on a hollow polyamide tube. The applicator was inserted into the tissue for treatment using a 13G implant catheter. Degassed water was circulated through the applicator and the catheter for cooling the transducer during ablation. Transducers with either 360° or 180° active zones (Figs. 1(b) and (c)), were used for the experiments. Typically transducer center frequency ranged from 6.5 – 7.5 MHz with acoustic efficiency of 50 – 60 %. The ultrasound imaging and tracking system for insertion of catheter was first tested in freshly excised chicken breast tissue for verifications (Fig. 2). The EM sensor was located at the tip of the stylus and the stylus was inserted into the excised chicken breast tissue using the ultrasound image guidance. The three-dimensional (upper) and two-dimensional (lower) views of the stylus oriented perpendicular and parallel to the imaging plane are shown in Figs. 2(a)-(b)), respectively. It can be easily noticed that the appearance of the stylus in the B-mode images correlates accurately with the three-dimensional view and vice versa.

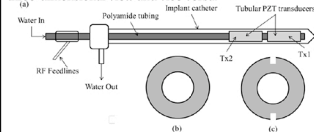


Fig.1: (a) Schematic of a catheter based ultrasound interstitial applicator, (b) cross-sectional view of a 360° tubular transducer, and (c) cross-sectional view of a 180° tubular transducer. An incision was made in the upper abdomen in female pigs (150-200 lbs) to expose and access the liver. A linear array ultrasound imaging probe was used to image the liver and locate the desired treatment region.

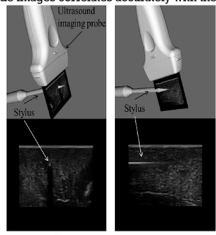


Fig2: Ultrasound imaging and tracking in excised chicken breast tissue with (a) stylus perpendicular to the imaging plane, (b) stylus parallel to the imaging plane.

An EM sensor was inserted into a catheter tip. Using ultrasound imaging together with EM tracking system the catheter was inserted into the liver as per the treatment plan (Figs. 3-4).

After confirming the treatment location and the catheter position, the EM sensor in the catheter was replaced by the ultrasound ablation probe for treatment. Thermocouple array sensors were placed at different distances from the ultrasound applicator and dose was calculated for each thermal sensor. A custom template was used to insert the applicator and thermocouples (Fig 5). Thermal dose was calculated using  $t_{43} = \int_{t_0}^{t_{43}} R^{(43-T)} dt$ ,  $R = 0.25$  for  $T < 43^\circ C$  and  $R = 0.50$  for  $T \geq 43^\circ C$ .

The in-house software architecture was developed to communicate with the hardware, ultrasound imaging (SonixTouch, Ultraason, Richmond, BC, Canada) and tracking system. Specifically the ultrasound imaging and tracking was performed using the PIJUS system and Open ICT Link. Typically 7 W (acoustic power was delivered to the tissue by the ultrasound applicator. Thermocouples at 5 mm, 10 mm and 15 mm radially from the applicator were inserted using the custom template (Fig 5) for the purpose of dose confirmation.

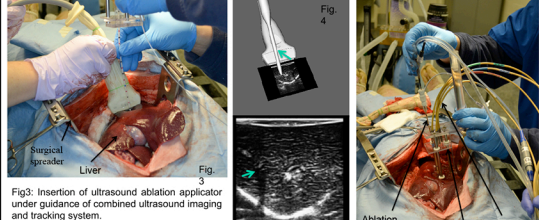


Fig3: Insertion of ultrasound ablation applicator under guidance of combined ultrasound imaging and tracking system. Fig 4: Ultrasound imaging and applicator position in 2D and 3D plane corresponding to the setup shown in Fig. 3. (Arrows indicate the catheter in the 3D view and shadow by the catheter in the B-mode image). Fig 5: Treatment setup.

## CONCLUSIONS

The experimental results demonstrated that the directionality and shape of the ablation zone can be controlled using catheter based high intensity sectorized ultrasound transducers. The 180° sectorized transducers helped in creating desired ablation pattern without damaging the nearby vein/vessels in the tissue verified from gross pathology inspection. Our results suggest that tracked targeting coupled with directionality and shape of the ablated region could accurately control ablation zones using the proposed technology.

## BIBLIOGRAPHY

The list of publications are included on a separate handout available below the poster.

