Ultrasound Therapy System and Ablation Results Utilizing Miniature Imaging/Therapy Arrays

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Abstract—**Array-based imaging and therapy systems have several advantages over single element approaches, and it was previously shown that the imaging and therapy functionality may be combined into dual-mode arrays [1]. In this work, minimally invasive, miniature (2.2 mm × 50 mm aperture, 3.3 mm diameter) dual-mode linear arrays have been developed into probes with high acoustic power output (100 W, and >120 W/cm^2 at the source), high transmit efficiency (>65% typical), and good imaging performance (3.4 MHz center frequency, 50% fractional bandwidth, >100 mm deep field of view). These therapy / imaging probes have been integrated into a flexible intense ultrasound surgery platform which also includes conventional diagnostic imaging probes. A system architecture has been developed which includes a 64-channel therapy driver with software selection of array aperture and phasing (1/16th wavelength), frequency (0.5 – 8 MHz), drive amplitude (5 W/channel, nominal), mechanical rotational steering (+/-180 degrees), and temporal sequencing/switching of imaging, and therapy modes. The array-based imaging/therapy system has produced encouraging results in preclinical studies of bulk tissue ablation, imaging, and treatment monitoring of liver *in vitro* and *in vivo*, examples of which are presented. The system can be applied to ablation of other soft tissue pathologies, e.g. kidney, heart, uterus, brain, GI, etc.**

Keywords-ultrasound; therapy; imaging; dual-mode; arrays; ablation

I. INTRODUCTION

Minimally invasive ultrasound therapy using miniature imaging/therapy dual-mode arrays has several clinical and technological advantages over conventional extracorporeal approaches [1].

Conventional therapy with a fixed focus spherical dish transducer has reduced treatment flexibility and a relatively large applicator size. It requires three-dimensional (3-D) mechanical scanning, which slows down treatment, even if using 2-D scanning with an annular array. It employs a transmit only, low frequency, narrowband transducer, which inhibits or precludes good ultrasound imaging. External monitoring techniques, via ultrasound or magnetic resonance imaging, may be in a different image plane than the treatment plane and in addition can increase the size or alternatively reduce the output of the therapy probe. The extracorporeal approach entails that energy must typically pass through several layers of tissue or circumvent bone structure. Deep penetration further requires a low transmit frequency, yet the resulting low acoustic absorption slows treatment. A high intensity gain is needed which results in a small focal volume which increases treatment time, even if scanned. Considerations of treatment duration, physician populations and current practice, and facilities/cost factors have to date slowed widespread adoption of such approaches.

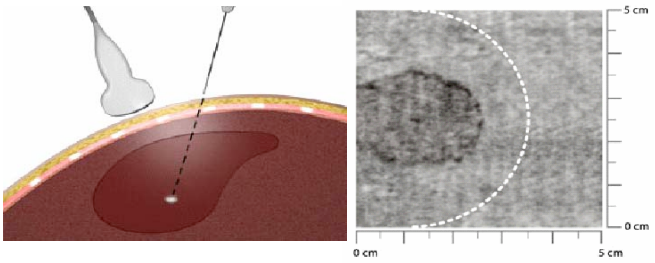

Figure 1. Illustration of clinical application. Percutaneous insertion of minimally invasive therapy probe into liver region-of-interest under transabdominal guidance (left). In situ imaging and treatment planning is possible from a miniaturized dual-mode imaging/therapy linear array (right).

In contrast, imaging/therapy dual-mode arrays offer several benefits to overcome such limitations. These include broadband array-based therapy, imaging, and treatment monitoring; multiple-frequency imaging/therapy, the power of acoustic beamforming techniques and assured spatial registration between localization, treatment, and monitoring. The high transmit efficiency arrays described herein allows small transducer size which enables minimally invasive procedures. Extracorporeal use is possible with proper acoustic configuration. When utilized in a minimally invasive procedure, the miniaturized dual-mode arrays offer close access to the region of interest with less intervening tissue, allowing reduced exposure, higher frequencies, faster tissue heating for the same acoustic power, better spatial resolution for imaging and therapy, treatment in 3-D with reduction or elimination of mechanical scanning, and a high degree of clinical practicality, cost savings and utility. One representative application is in the ablation of soft tissue, such as liver.

A. Clinical Application Requirements

The most prevalent method of minimally invasive liver therapy has been radio frequency ablation (RFA). A needle probe is inserted through skin into a tumor region under transabdominal ultrasound guidance, as shown in Fig. 1. Such

probes lack any *in situ* imaging where it offers the best resolution. In addition, RFA has no selectivity to spare viable tissue and sensitive structures. The unique capability of miniaturized ultrasound dual-mode imaging/therapy arrays to see and treat allows significant clinical benefits versus RFA, such as the treatment planning illustrated in Fig. 1. However, to be fully competitive with RFA procedures ultrasound based techniques must offer a clinically acceptable form factor, lesioning rate and size of ablation.

Specifically, application requirements include:

Interstitial Probe Form Factor (RF Predicate)

- 3 mm nominal diameter,
- 5 cm wide & 5 cm deep field-of-view,
- Treat 3 to 7 cm diameter volumes;

See & Treat Operation

- Transabdominal probe & interstitial probe aid secondary localization,
- Effective treatment planning,
- Ablation Feedback;

Relatively short ablation time

- Competitive with RF, ≈ 30 minutes; and

Technical Requirements

- Simulations and experiments revealed on the order of 100 W could achieve clinically relevant ablation rates and volumes.

A typical RFA procedure using a commercially available system (RITA Starburst XL) *in vitro* in bovine liver produced the following results using the analysis methods described in [2]: ablated volume = 10.5 cm^3, ablation rate = 0.8 cm^3/min, treatment duration = 13 minutes, and ablated radius ~ 12 mm. Preclinical results of this study indicate that miniature imaging/therapy arrays can match or improve upon such results

In this work an imaging/therapy control system and probes were applied to implement a soft tissue ablation system meeting or exceeding application requirements. The system and probes were developed and characterized. Preclinical studies included *in vitro* and *in vivo* imaging and therapy of porcine liver, *in vitro* lesioning of bovine liver, imaging quality studies with phantoms, and development and testing of several treatment monitoring techniques [2]. The array-based imaging/therapy system has produced encouraging results in preclinical studies of bulk tissue ablation and imaging.

II. METHODS

A. System Implementation

The array based imaging/therapy system prototype is shown in block diagram in Fig. 2. An Array Imaging Module (AIM) was used for the imaging subsystem. This 64 channel color flow system (Ardent Sound, Mesa, AZ) was

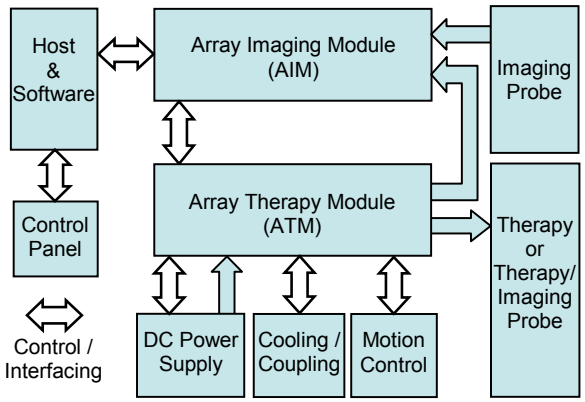

Figure 2. Block diagram of system components.

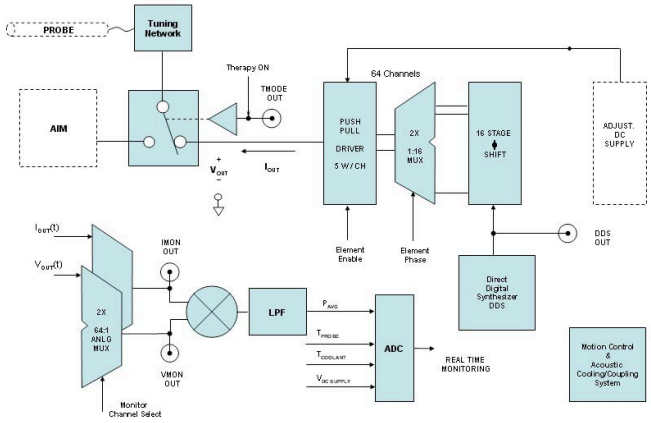

Figure 3. Simplified functional equivalent of array therapy module components, including matching/tuning network, real-time switching between therapy and imaging modes, 64 push-pull driver channels at 5 W/channel nominal with power electronically adjustable via DC supply, λ/16 phase focusing, aperture enable, and frequency selection. Electric power per channel measurement and coolant and probe monitoring allows verification and safety. Probe rotation and acoustic coupling system also are controlled by ATM.

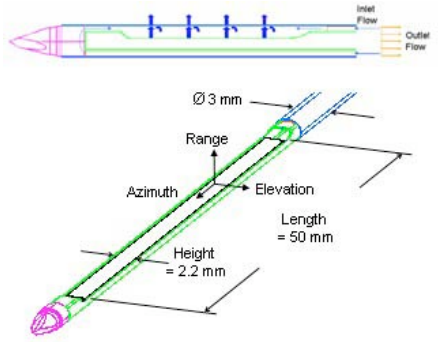

Figure 4. Diagram of probe tip cooling and acoustic coupling mechanism (top) and dimensions (bottom), including tissue-piercing tip.

configured to accept conventional transabdominal probes or interface to an Array Therapy Module (ATM) (GTS, Mesa AZ). The ATM is a 64 channel driver and control system that interfaces to imaging/therapy probes or therapy-only probes. A detailed diagram is shown in Fig. 3. This general purpose therapy/imaging platform and associated control and treatment software was validated and used with a wide variety of probes in pre-clinical studies.

B. Probes Implementation

Probes for percutaneous liver ablation were based upon the schematic design shown in Fig. 4. A 3 mm nominal diameter tube housed a transducer array of 2.2 mm elevation and 50 mm long active length divided into 32 elements. This element count was a compromise based on size and power limits for the electric interconnect. An acoustic coupling balloon provided coupling and cooling. A photograph of a completed probe, with handle, cable and matching box is shown in Fig. 5. Salient features of the probe system include:

3 mm Stainless Steel Housing,

±180° Rotation,

Acoustic Coupling Balloon with Water-Based Cooling & Acoustic Coupling Flow System,

Thermistor Probes (Temperature Monitoring),

Electric Matching,

High Density Interconnect – delivers over 150 watts to 2.2 mm wide 32 element transducer array,

Probe Handle with Quick-Disconnect feature and removable, Disposable Transducer Module, and a

High Efficiency, High Acoustic Output Transducer Array.

Probes were characterized with pulse-echo and acoustic power testing described previously [1]. Image quality testing was also performed with phantoms and tissue [1,2].

C. Ablation Tests

Acoustic and bio-heating simulations were used to help optimize treatment strategy. *In vitro* and *in vivo* tissue ablation tests were performed on porcine liver and bovine liver using methods described elsewhere [2].

III. RESULTS AND DISCUSSION

A. Probe Performance

The transducer module had a pulse-echo fractional bandwidth of 50% (matched) and center frequency of 3.4 MHz. The acoustic power response was measured and results are shown in Fig. 6. Transmit efficiency was 77 % at 3.10 MHz at 10 W, and 67 % at 95 W, continuous. Probes were burned in over four cycles at full measured power (>90 watts) for 5 minutes continuous on time (100% duty cycle). Over 130 probes were fabricated with statistically consistent results and high yields. The constant radiation conductance of 0.26 W/V^2 decreased only 7.7 % over a power range of 4 W to 95 W. Surface intensities of 120 W/cm^2 continuous were measured, and short term output tests yielded over 200 W/cm^2. Probe measurements were cross checked at independent laboratories, including with the acoustic coupling balloon before lesioning.

The imaging performance of the probes is shown in Fig. 7. Fortuitously, the good thermal performance of the array as well as wide bandwidth allows real-time switching between imaging and therapy modes without thermal artifacts or delays.

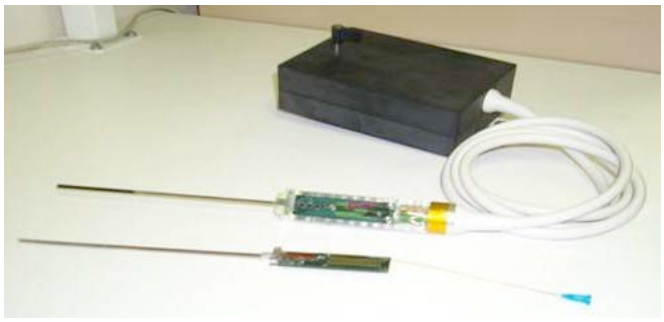

Figure 5. Probe consisting of matching box, cable, probe handle (cover removed) and transducer module. A second transducer module is shown removed from the quick-disconnect probe handle.

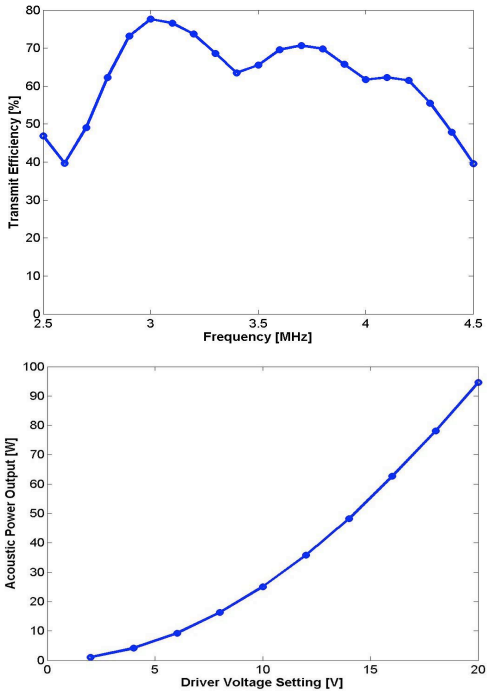

Figure 6. Acoustic power output measurements (without coupling balloon). Electroacoustic transmit efficiency versus frequency (top), at a nominal peak power of 10 watts. Acoustic power output of entire 32 element array versus system driver voltage at 3.10 MHz (bottom). The radiation conductance of the array with respect to system voltage was 0.26 W/V^2 and decreases only 7.7% over the range of 4 watts to 95 watts.

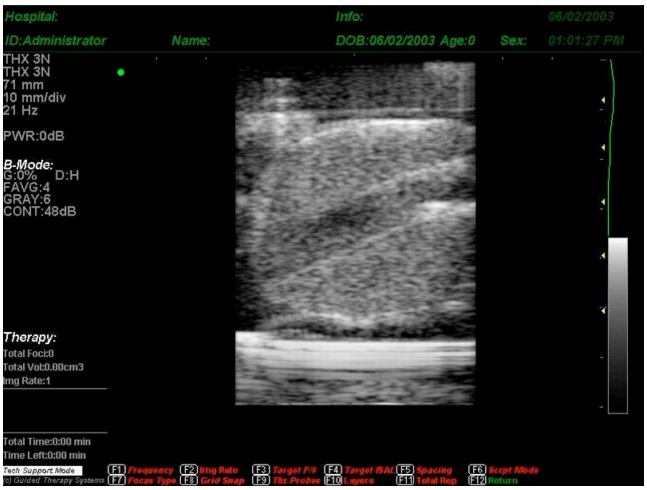

Figure 7. Imaging results from a prostate phantom using 3.4 MHz, 3.4 λ_0 pitch, 32 element probe. Image depth is 71 mm and width is 50 mm. Quantitative studies show resolution and contrast are comarable to transabdominal probes at a depth of 50 mm [2].

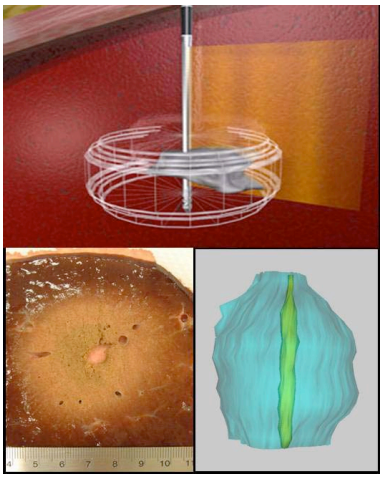

Figure 8. Ablation results. Typical *in vitro* lesioning result in porcine tissue using ± 180° degree repetitive sweeping (top). Gross damage tissue slice (lower left), and 3-D ablation reconstruction (lower right). Exposure parameters are listed in Table I.

B. Ablation Results

A large amount of tissue experiments and simulations were conducted and optimized over several months [2]. A representative in vitro ablation is described in Table I. Continuous back and forth rotational sweeps over ±180 was employed at a moderate rate of rotation. 74 watts of acoustic power was employed with the full array activated at 80% duty cycle.

TABLE I. IN VITRO LESIONING TEST

Exposure Parameters	Exposure Results
360 Scan (± 180 Sweep)	Ablated Volume = 63.9 cm^3
3.1 MHz, 32 Element Array	Ablation Rate = 2.0 cm^3/min
74.3 W, 66.2 W/cm^2	Continuous Depth = 24 mm
31.5 min (80% ON Duty Cycle)	Maximum Depth = 24 mm

The scanned exposure is diagrammed in Fig. 8. Cross sectioned tissue measurements were used to characterize the treatment, and reconstruct the ablated volume, as shown in Fig. 8. Results are summarized in Table I. The rate of ablation was 2.0 cm^3/min. The continuous depth of ablation and maximum depth were both 24 mm. Continuous ablation depths up to 34 mm have been achieved in similar ablation trials, as well as rates over 3 cm^3/min. These results and treatment times are better or comparable to typical RFA ablations. Treatment monitoring and image enhancement techniques employed in both *in vivo* and *in vitro* testing further highlight the flexibility and benefits of the minimally invasive therapy/imaging system in the treatment of soft tissue [2].

IV. CONCLUSION

Imaging/therapy dual mode arrays utilized in a minimally invasive approach are effective in the visualization, ablation, and treatment monitoring of soft tissues. Imaging/therapy dual mode arrays offer significant technological and clinical advantages (e.g. treatment flexibility, imaging, localization, and speed) when compared to conventional therapeutic treatment methods (focused dish). Dual mode arrays and associated system and software have been developed which provide high performance – on the order of 100 acoustic watts in a 3 mm diameter package with high transmit efficiency, > 65%. Image quality is comparable to conventional abdominal probes at depths of 50 mm. Ablation rates of over 2 cm^3/min and depths up to 35 mm (70 mm diameter) have been measured in a large variety of pre-clinical experiments in bovine and porcine liver *in vitro* and porcine liver *in vivo.*

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