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Comparison of Split-Beam Transducer Geometries and Excitation Configurations for Transrectal Prostate HIFU Treatments

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Abstract – Six split-beam transducer configurations have been examined using computer simulations and *in-vitro* experiments. The goal of this study was to identify a simple split-beam transducer configuration capable of reducing transrectal HIFU prostate cancer treatment time without sacrificing treatment safety and efficacy. Lesion volume, lesion and rectal wall temperatures, sonication ON/OFF time, and total acoustic power parameters were used as comparison criteria. The most promising split-beam configuration generates necrosed tissue volumes 5 times larger than the single-element transducer with the same sonication time, while keeping maximum focal zone temperatures below 90°C. These parameters yield approximate overall treatment time reductions by a factor of 1.85 as compared to single-element transrectal HIFU PC treatments, mainly due to longer tissue cooling time required to maintain current safety levels.

I. INTRODUCTION

Single-element high intensity focused ultrasound (HIFU) transducers have been successfully used in clinics for the treatment of both benign and malignant cancer tissue. The elementary lesion produced by HIFU is generally very small. Superposition of many individual focal lesions is therefore required to treat a large tumor volume.

In the case of prostate cancer (PC) treatment with HIFU, it is presently required to treat the entire prostate gland (with tissue margin) to achieve long-lasting and complete response [5], as prostate cancer is a multi-focal disease. To ablate prostate glands between 25 cm^3 and 40 cm^3, it currently takes 3 to 6 hours of operating time. This length of treatment time is clinically not desirable as it adversely affects the patient and increases treatment cost. For this reason, approaches to reduce treatment time are being investigated by our team. These approaches should not require a complete redesign of our HIFU system, must maintain clinical efficacy, and would increase safety through treatment time reductions.

One such novel approach is to split the primary HIFU beam into several lobes that can deliver the same total amount of energy (at lower peak intensities) as a single beam but can create a larger elementary lesion and a more uniform heating pattern for each ultrasound exposure [3, 4]. Such split-beam transducers (also known as asymmetric focusing transducers [1]) are simple to implement and do not require complex driving electronics. They can generate a complex field pattern, but lack the flexibility to produce a multitude of patters such as those generated by transducer arrays [2]. They produce the spatial equivalent of ultrasound array mode scanning [7] or temporal switching [6] accomplished with ultrasound arrays, and share the same goals with these methods, namely the reduction of treatment time, the decrease of peak intensities, and the generation of more uniform treatment temperatures.

The present study evaluates the performance of six split-beam transducer configurations for treatment time reduction, subject to the constraints of the present transrectal HIFU probe that is being used in the clinic for PC treatments, the Sonablate^{TM}500 (Focus Surgery, Inc., Indianapolis, IN). The selected split-beam transducer geometries are presented, together with the simulation and *in-vitro* evaluation methodologies and results.

II. MATERIALS AND METHODS

Split-Beam Transducer Configurations

Six different transrectal split-beam HIFU transducer configurations (2-7) were compared in this study to reduce HIFU PC treatment time (Table 1). The single element transducer (configuration 1) was used as a comparison baseline, since it is currently used clinically for prostate treatments.

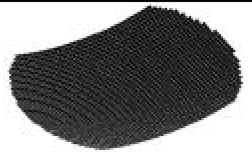
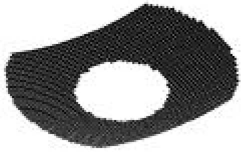
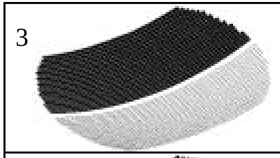
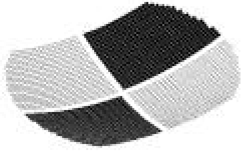
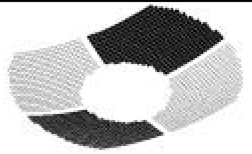
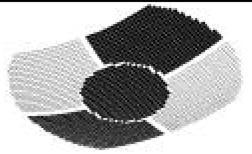
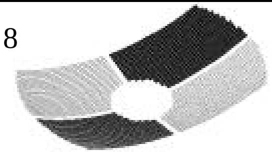
1 	Single Element 30 mm x 22 mm fl = 36 mm, f = 4.325 MHz **BASELINE** (imaging used in therapy)
2 	Sonablate™ 500 Split-Beam 30 mm x 22 mm fl = 36 mm, f = 4.325 MHz **PC CLINICAL TRIALS** (confocal imaging)
3 	Dual Element (0°, 180°) 30 mm x 22 mm fl = 36 mm, f = 4.325 MHz (no imaging capability)
4 	Alt. Polarity Split-Beam (0°, 180° drive) 30 mm x 22 mm fl = 36 mm, f = 4.325 MHz (no imaging capability)
5 	Alt. Polarity Split-Beam (0°, 180° drive) 30 mm x 22 mm fl = 36 mm, f = 4.325 MHz (confocal imaging), **Fig. 1a**
6 	Alt. Polarity Split-Beam (0°, 180° drive) 30 mm x 22 mm fl = 36 mm, f = 4.325 MHz (imaging used in therapy)
7 	4-Sector Split-Beam (0°, 90°, 180°, 270° drive) 30 mm x 22 mm fl = 36 mm, f = 4.325 MHz (confocal imaging)
8 	Alt. Polarity Split-Beam (0°, 180° drive) 40 mm x 22 mm fl = 39 mm, f = 4.225 MHz (confocal imaging), **Fig. 1b**

Table 1
Transrectal HIFU Split-Beam Transducer Geometry Configurations and Description.

Configuration 8 is a variant of configuration 5. All configurations were evaluated through computer simulations using lesion size, maximum lesion temperature, total acoustic power (TAP), sonication ON/OFF times, and pre-focal temperature as comparison criteria. Configurations 5 and 8 were built, characterized, and also evaluated *in-vitro*. The transducer configurations were kept as simple as possible to minimize the impact on driving electronics (Equal amplitude drive for each segment, and 0°, 90°, 180°, or 270° phase control only). The impact of including/excluding the center imaging element during high-power sonication was also examined.

Temperature and Lesion Size Simulations

The maximum lesion temperatures were obtained by numerically solving the transient bioheat transfer equation (BHTE) in 3D utilizing the following prostate tissue parameters:

Body temperature	T	37	°C
Frequency	f	4.325	MHz
Speed of Sound	c	1561	m/s
Tissue Density	ρ	1045	kg/m^3
Absorption/Attenuation	α	9	Np/m MHz
Conductivity	k	0.55	W/m °C
Blood perfusion	w	6	kg/m^3 s
Specific Heat	$c_{t,b}$	3639	J/kg °C

10 mm water standoff between transducer and tissue.

The lesion size was computed using the accumulated thermal dose, defining the threshold dose for necrosis as 120 equivalent minutes at 43°C.

Probe Characterization

Probe characterization included transducer impedance, operating frequency, TAP, efficiency, and acoustic field (hydrophone, Schlieren) measurements.

In Vitro Experiments

The performance of the split-beam transducer configuration 5 were evaluated in a series of *in-vitro* experiments using fresh turkey breast tissue maintained at 37°C in a degassed waterbath. The transducer was mounted inside a standard HIFU transrectal probe (Figure 1), and was controlled with a Sonablate™500 HIFU therapy system (Focus Surgery, Inc., Indianapolis, IN).

III. RESULTS

Simulation Results

Lesion size and maximum temperatures obtained for all split-beam configurations while maintaining the total acoustic power at the surface of the transducer at 30 W are shown in Table 2.

Transducer Number	Maximum Temperature [°C]	Lesion Size [mm^3]
1	103	19
2	89	13
3	77	14
4	64	9
5	64	8
6	69	10
7	70	10
8	62	4

Table 2
Simulation Results for Ton = 4 seconds, Toff = 12 seconds, and Total Acoustic Power = 30 W.

Lesion size and corresponding total acoustic power at the surface of the transducer needed to generate a maximum lesion temperature of 90°C for all investigated split-beam configurations are shown in Table 3.

Transducer Number	Total Acoustic Power, TAP [W]	Lesion Size [mm^3]	Maximum Focal Intensity [W/cm^2]
1	24	11	1068
2	31	14	1124
3	39	28	895
4	58	62	701
5	57	52	710
6	50	46	809
7	47	35	504
8	64	42	827

Table 3
Simulation Results for Ton = 4 seconds, Toff = 12 seconds, and Maximum Temperature = 90°C.

The cooling time (Toff) required for the maximum temperature of configuration 5 at z = 25 mm (approximately half-way between the focus and the rectal wall) to reach levels equivalent to the baseline configuration 1 temperature is 37 seconds. Acoustic field simulations for configurations 1, 2, and 5 also revealed low average intensities of 6.6 W/cm^2, 8.5 W/cm^2, and 15.7 W/cm^2 at the rectal wall (z = 10 mm) respectively, proportional only to the total applied power. The above configurations did not show any unwanted hot-spots at the rectal wall.

Probe Prototypes

Configuration 5 generated the largest lesion (out of all split-beam configurations examined) while maintaining imaging capability for treatment planning and monitoring. It was built, characterized, and evaluated in a series of *in-vitro* experiments (Figure 1). A simple 1:1 transformer with a single primary- and two secondary windings was used to generate the 0°/180° out-of-phase CW RF driving signals.

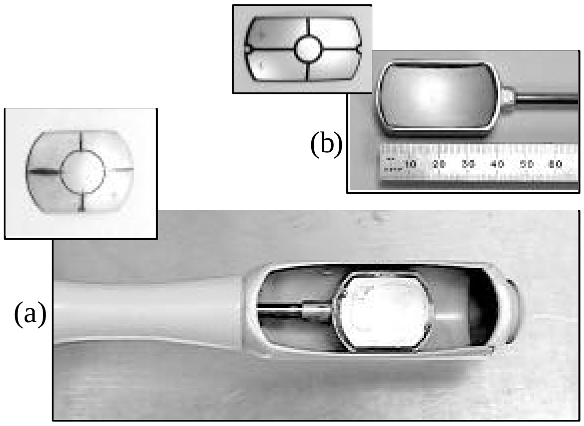


Figure 1
Split-Beam HIFU transducer configuration 5 in transrectal probe (a), and transducer configuration 8 (b).

Characterization results showed that this split-beam probe is able to generate total acoustic powers exceeding 60W at 70% efficiency. N3B (Keramos, Indianapolis, IN) was chosen for the crystal material.

In-Vitro Results

Figure 2 shows a typical split-beam lesion generated by the transducer/probe (configuration 5). A power level of 41 W (Acoustic) was chosen for the *in-vitro* experiments (between the power levels shown in Tables 2 and 3), partly because of the non-existent blood perfusion in the turkey samples. Experimental lesion volumes of 21 ± 4 mm^3 agreed well with those simulated for these configurations: 22 mm^3. Details such as the 4 individual lesion “fingers” that result from the segmenting of the transducer electrodes for this particular split-beam configuration were clearly visible.

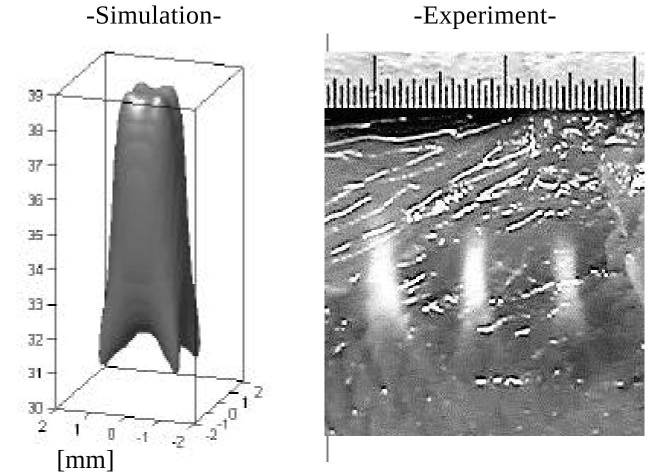


Figure 2
In-vitro elementary lesions created with the split-beam probe configuration 5 (4 s on, 12 s off, 41 W).

IV. DISCUSSION AND CONCLUSIONS

We define the split-beam treatment time reduction factor (referenced to the single-element treatment time) as:

$$TTRF = \frac{v_{sb}}{v_{se}} \cdot \frac{t_{se}}{t_{sb}}$$

where v_{sb} and v_{se} are the lesion volumes of the split-beam and single-element transducers (configuration 5 and 1) assuming equal maximum lesion temperature, and t_{sb} and t_{sb} are the treatment times (Ton+Toff) required to produce a single lesion *such that the maximum pre-focal temperatures for both configurations are the same at the end of this time*. Variations in TAP among transducer configurations are thus captured in this expression. Split-beam configuration 5 yields a treatment time reduction factor of 1.85 referenced to configuration 1, and a treatment time reduction factor of 1.56 referenced to configuration 2. Treatment safety was not compromised.

These are encouraging results. They show that treatment time lost due to longer Toff times (due to higher power levels) allocated to tissue cooling between subsequent sonications is recuperated faster by the larger lesion volumes created. The results also show that it is possible to reduce treatment time in transrectal HIFU PC treatments without sacrificing safety (by maintaining comparable pre-focal temperatures to current clinical treatments) or resorting to phased array transducers with large number of elements and complex driving electronics. *In-vivo* verification of these results in a canine model are planned for the near future.

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