Characterization of TRANBERG|Laser Applicator for Focal Laser Ablation (FLA) for prostate cancer

Cristina Pantaleone[1], Emily Emilsson[1], Manuela Schwagmeier[2], Verena Knappe[2]

[1] Clinical Laserthermia Systems AB, Medicon Village, Scheelevägen 2, 22381 Lund, Sweden
[2] Clinical Laserthermia Systems GmbH, Johann-Hittorf-Strasse 8, 12489 Berlin, Germany

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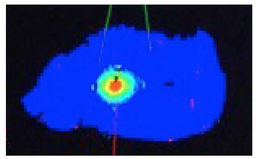
Introduction

The use of ablative techniques in patients with low grade and intermediate localized prostate tumors represents a treatment option between active surveillance and radical prostatectomy. Focal laser ablation (FLA) appears to be a potential candidate to reach the goal of focusing energy delivery on the identified targets. Prostate tissue is particularly well suited for laser ablation due to its optical absorption rate and lack of excessive vascularity. FLA is magnetic resonance (MR)-compatible, it offers a significant imaging advantage over other surgical and ablative techniques that utilize transrectal ultrasound to guide and monitor treatment.

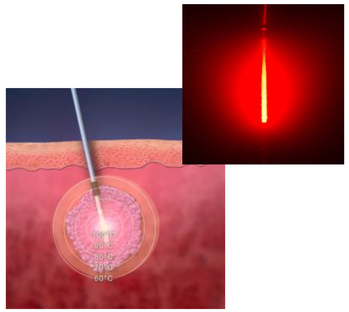
With the introduction of the TRANBERG|Thermal Therapy System on the market, already CE marked and FDA approved, a need of demonstration of the lesions sizes was identified. This work aims at characterizing the TRANBERG System for laser ablation of soft tissue to be used as a pre-planning tool for MR- or MR/US-fused-guided treatments in clinical settings.



Chicken breast *ex vivo* 10°C
15mm diffuser 15W 2min
24x23 mm

Method

The minimal invasive TRANBERG|Thermal Therapy System for FLA consists of a laser unit and non-cooled laser fiber applicators with circumferential radiation. The light source used is a laser diode that emits light at 1064nm with a power of up to 25W (TRANBERG|Mobile Laser Unit, Clinical Laserthermia Systems AB, Sweden). The unit was also used to record temperatures by means of temperature probes; these were used for the sole purpose of monitoring the treatment. The laser applicators used are of non-cooled diffuser type and have active lengths of 15mm and 25mm (TRANBERG|Laser Applicator Non-Cooled, Clinical Laserthermia Systems AB, Sweden).



The evaluation was performed ex vivo in slabs of bovine cardiac tissue that was kept at 37°C during treatment; this model is a meaningfully comparable in terms of optical and thermal properties with human prostate.
Different power settings and exposure time were tested in the range of 5-25W and 1-4 minutes each with 10 repetitions.
After manual dissection, the dimensions of the coagulated zone were measured on the slab and volumes were calculated. The treatment results were documented with pictures.

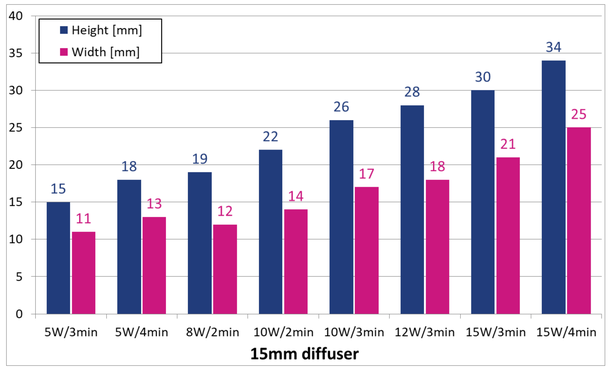
Results

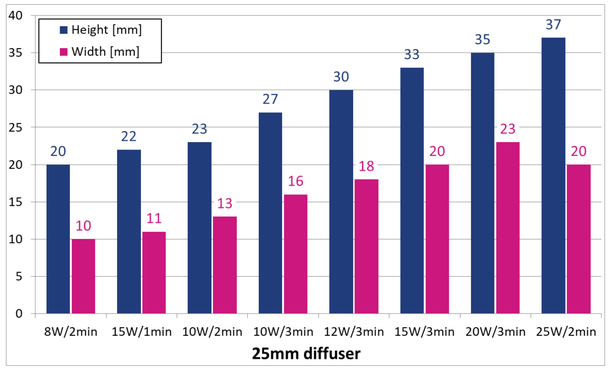
Macroscopic appearance of coagulation areas of FLA corresponds to well-demarcated foci of necrosis, no charring was observed during the tests with the chosen settings. In this model the lesion size obtained on average within the mentioned settings range are:

a) for the 15mm diffuser between 0.9cm^3 (5W/3 min 15x10 mm) to 11cm^3 (15W/4 min 34x25 mm);
b) for the 25mm diffuser between 1cm^3 (8W/2min 20x10 mm) to 9.1cm^3 (15W/4 min 36x22 mm).

The standard deviation on height and width was less than 3 mm on both dimensions.

The data shows that it is possible to achieve different lesion shapes using fibers with different diffusing length. As expected, the 25mm diffuser produces more elongated coagulation volumes than the 15mm one. Although the extent and shape of the coagulation depends on the tissue type, the lesion size and partly its shape can also be modified by varying the treatment parameters such as power and treatment time.





Conclusion

The System is well fitted for highly precise and reliable ablation. The laser diffusing technology enables tailoring of heat distribution depending on tumor size and shape. Adaption of the ablation shape, in parallel with a temperature monitoring of surrounding sensitive structures, is essential for treatment of prostate cancer. The evaluation of ongoing clinical trials will show the potential of the laser ablation to become a widely applied method with demonstrated oncologic effectiveness.