A Pilot Study to Evaluate Trans-Rectal, Outpatient Magnetic Resonance Thermal Image-Guided Laser Focal Therapy of Prostate Cancer: Results of the First 112 Treatments

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Article

A Pilot Study to Evaluate Trans-Rectal, Outpatient Magnetic Resonance Thermal Image-Guided Laser Focal Therapy of Prostate Cancer: Results of the First 112 Treatments

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Simple Summary

Prostate cancer is one of the most common cancers in men, and this study explored whether laser energy, delivered through the rectum and guided by real-time MRI imaging, could safely destroy these visible cancers in an outpatient clinic. After treating over one hundred cancer sites in eighty-one men, the procedure was found to be safe. At six months, most men showed no sign of significant remaining cancer, and PSA dropped meaningfully within a year. These results suggest that image-guided focal laser therapy is a promising, minimally invasive option that may offer men effective cancer control while preserving quality of life.

Abstract

Background/Objectives: In the United States alone, new prostate cancer (PCa) cases for 2023 are estimated at 288,300 and deaths at 34,13700 [1]. Prostate imaging is increasingly evaluated by artificial intelligence and computer-assisted targeting which opens new opportunities in biopsy and the focal therapy of visualized lesions [2]. Our objective was to investigate the safety and feasibility of using MR-guided focal laser (light amplification by the stimulated emission of radiation) therapy for these visible cancers using a transrectal approach for both laser applicator placement and therapy delivery in an outpatient setting. **Methods:** We used a 1.5 Tesla MRI scanner (Philips Healthcare, Best, The Netherlands) for both image acquisition and real-time thermometry. In addition, we used a commercially available CAD system and targeting hardware (Philips, Best, The Netherlands) for image analysis and interventional planning. Laser focal therapy of biopsy-proven lesions was delivered using a U.S. Food and Drug Administration (FDA) 510(k) cleared laser emitter, laser fiber and thermal mapping visualization software (Medtronic, Minneapolis, MN, USA) introduced transrectally under MRI-guidance. **Results:** 112 cancer foci were treated in 81 men, from Gleason Grade 1 (GG1) to GG3 for treatment-naïve patients and all Gleason Grades for salvage patients. With pre-treatment lesion volumes ranging from 0.03 cc to 6.6 cc, with a mean of 1.1 cc and a median of 0.49 cc (25% and 75% quartiles of 0.25 cc and 1.4 cc respectively). The mean MRI volume of coagulation necrosis was 7.1cc and ranged from 0.6cc to 22.9cc. No serious adverse events or morbidity were reported. At six-month MR-guided in-bore biopsy 25 treatment regions were positive for clinically significant disease (GG>1), consistent with in-field residual or recurrent cancer rate of 22% of regions and 23% of subjects. We observed a 40% decrease in mean PSA at 1 year post therapy in the entire cohort. **Conclusions:** Our data indicate that transrectally delivered MRI-guided laser focal therapy for prostate cancer is both safe and feasible in an outpatient setting and results in a significant biochemical response and acceptable cancer control rate at 6 months.

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1. Introduction

The topic of focal therapy [3] remains a subject of great debate, beginning in the mid-1950's [4], where male "lumpectomy" was proposed, performed, debated and in some cases abandoned. Early investigators proposed a variety of energy sources and injectable substances, but most recently the FDA cleared a select few of these techniques designated for soft tissue ablation, including laser [5], cryotherapy [6]and high intensity focused ultrasound (HIFU) [7].

As biopsy strategies evolve [8] and become more accurate through the use of MRI targeting [9,10,11], a convergence of events begs the question: if a lesion can be detected with multiparametric MRI (mpMRI), then biopsied with an MRI-guided targeting strategy, could that same targeting mechanism and approach also be used to deliver energy or other therapy concurrently? This convergence conforms with our better understanding of the natural history of prostate cancer and the concept of the "index lesion" as described by Ahmed et al [12]. To answer the question, we conducted this study to assess transrectally delivered laser interstitial thermal therapy and real-time MR thermometry treating prostate cancer in an outpatient setting.

Our preference of energy source was a commercially available 980 nm cooled laser and visualization platform (Medtronic, Minneapolis, MN) both of which have broad FDA clearance [13,14] for soft tissue necrotization. The system was combined with commercially available biopsy planning software and hardware (Philips, Best, The Netherlands) for computerized localization and image-guided transrectal access to the prostate. The unique precision and controllability of laser therapy is due to the conversion of raw MR data to thermal mapping data, making laser ideal for real-time thermal monitoring and precise ablation volume estimates as therapy is delivered [15, 16]. Additionally, the safety profile and clinical success of Visualase laser applications in the liver, brain, spine, thyroid, kidney and breast at other institutions lends support to its use in the prostate gland as well [17].

The purpose of this study was to investigate the use of MR-guided focal laser therapy for MR visible, localized prostate cancer utilizing a transrectal approach for laser applicator placement and therapy delivery in an outpatient setting. Our HIPAA-compliant, prospective, single institution observational study was registered on ClinicalTrials.gov (NCT 02243033) and was conducted under IRB (Institutional Review Board) approval (WIRB Copernicus Group, Puyallup, WA). Patients provided verbal and written informed consent. Our study included treatment-naïve men with organ confined ISUP GG (International Society of Urological Pathologists Grade Group) 1, 2 or 3 diseases. GG1 was included because sometimes the more advanced Gleason Score of 4 (as in "3+4") can be missed, and thus GG1 may benefit from focal therapy. A second cohort of men with recurrent PCa was treated in the salvage setting. We recognize that treating both salvage patients and treatment-naïve patients in this study may skew the results as compared to studies which only accept treatment-naïve patients. Here we describe the results of those treatments.

2. Materials and Methods

Patient inclusion: (https://clinicaltrials.gov/ct2/show/NCT02243033)

- **Ages Eligible for Study:** 45 Years to 90 Years (Adult, Older Adult)
- **Sexes Eligible for Study:** Male
- **Accepts Healthy Volunteers:** No
- **Sampling Method:** Non-Probability Sample
- **Study Population:** Men with prostate cancer

The inclusion criteria for treatment- naïve patients was as follows:

- Male, 45 years of age or older.
- Diagnosis of prostate adenocarcinoma.

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- Clinical stage T1c or T2a.
- ISUP Gleason Grade 3 (GG3) or less.
- Three or fewer biopsy cores with prostate cancer.
- PSA (prostate specific antigen) density not exceeding 0.375 ng/mL/cc.
- One, two, or three tumor suspicious regions identified on multiparametric MRI.
- Negative radiographic indication of extra-capsular extent.
- Karnofsky performance status of at least 70.
- Estimated survival of 5 years or greater, as determined by treating physician.
- Tolerance for anesthesia/sedation.
- Ability to give informed consent.
- At least 6 weeks since any previous prostate biopsy.
- MR-guided biopsy confirmation of one or more MRI-visible prostate lesion(s) with ISUP GG3 or less.

Salvage candidates will be accepted upon physician referral. The motivation for including salvage patients was when a patient who had previously received proton therapy wanted to avoid androgen deprivation and did not have any other options - the IRB accepted a protocol modification for including salvage therapy patients. Salvage patients were not always necessarily medically risky or ineligible for other treatments but preferred to undergo laser treatment.

The exclusion criteria were as follows:

- Presence of any condition (e.g., metal implant, shrapnel) which is not compatible with MRI.
- Severe lower urinary tract symptoms as measured by an International Prostate Symptom Score (IPSS) of $\geq$20.
- History of other primary non-skin malignancy within the previous three years.
- Diabetes - Diabetics can have coagulation problems, and we wanted to avoid bleeding issues.
- Smoker - Smokers can have coagulation problems and we wanted to avoid bleeding issues.

The MR-guided laser ablation employed a system comprised of a 980nm surgical diode laser, a fiberoptic laser applicator with a heat diffusing tip and a coaxial cooling catheter, a cooling circulation pump, and a computer workstation for processing and display of MR images, thermal maps, irreversible damage estimates and temperature graphs. This interface facilitated treatment planning.

A transrectal biopsy guidance system directed all MR-guided biopsies and laser applicator placement were performed using a transrectal biopsy guidance system. All devices followed the labeled indications for use as cleared by the FDA and the IRB-approved off-label use for malignant lesions

An MRI technique called Magnetic Resonance Temperature Imaging (MRTI) was used to collect temperature-sensitive parameters throughout the imaged volume. During tumor ablation, MRTI data was collected and analyzed to display real-time tissue temperatures and an estimate of thermal ablation zone size.

This method allowed the treating physician to apply laser energy over a controlled duration to affect an effective zone of ablation covering both the tumor plus a prescribed margin.

Immediately after completion of therapy, post-contrast (Gadavist, Bayer, Berlin, Germany) MRI confirmed the ablation zone size, shape and location. These images (Figure 1a) were compared to the pre-ablation treatment-planning MRI images (Figure 1b) allowed an accurate estimation of ablation size and anticipated treatment efficacy.

We used an MRI-compatible interventional device for transrectal prostate procedures (Figure 1c). It is a removable device that attaches to an imaging table with an open design that allows for flexibility in coil choice and patient comfort.

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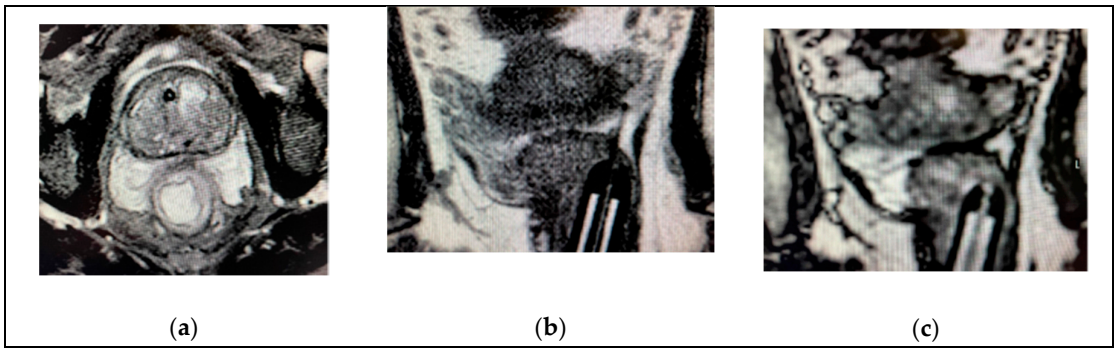

Figure 1. Representative MRI images. (**a**) Pre-ablation treatment-planning image; (**b**) estimation of ablation size; (**c**) MRI-compatible interventional device for transrectal prostate procedures.

A commercially available, FDA cleared image viewing workstation allowed for the targeting and placement of the laser into the prostate. Manipulation of the transrectal needle guide directed a 14g introducing sheath into the prostate target and facilitated the accurate positioning of the cooled laser applicator. Anesthesia included: intrarectal lidocaine HCl 2% gel, a periprostatic nerve block bilaterally using bupivacaine 0.25% and a combination of intravenous Midazolam and Fentanyl. Antibiotic prophylaxis consisted of 1g of intravenous Ceftriaxone at the time of laser surgery. In patients with tumors located in the apex putting the external urethral sphincter at risk, the urethra was cooled with continuous bladder irrigation through a 16 fr 3-way catheter during the laser treatments at that level.

Ablation planning involved a review of T2-weighted images in multiple planes, high b-value axial diffusion-weighted images (DWI) with corresponding apparent diffusion coefficient (ADC) maps with the goal of ablating the MR-visible volume of the tumor with an additional treatment margin of approximately 1 cm for all patients (no change in margin depending on severity of disease).

The ablation itself was performed with a 15-watt laser at 80%-90% energy (depending on the thermal map) at 60 degrees centigrade for less than two minutes. The operator maintained the laser applicator record which was dependent on the size, shape, geometry, and location of the lesion using the UroKit 400 or UroKit 600 system.

Each procedure was performed by one of two expert interventional radiologists with over 50 years of combined experience (S.T.M., J.F.F.). These physicians had the benefit of having performed over 800 in-bore MRI-guided prostate biopsies prior to their first laser patient, so their learning curve was minimal due to their length of experience with the hardware and software, which they also helped to develop [18].

The pre-treatment lesion volume as measured by the radiologist using the ellipsoidal calculation (length x width x height x 0.52) ranged from 0.03 cc to 6.6 cc, with a mean of 1.1 cc and a median of 0.49 cc (25% and 75% quartiles of 0.25 and 1.4 cc's respectively).

The ablative goal was to treat the lesion plus a one-centimeter margin [19]. Patients received mpMRI at 48 hours, 3 months, and 6 months post-laser with mandatory biopsy of the treatment site at 6 months. The push to do a 6-month biopsy was research-funded (not necessarily standard of care) and was generally agreed upon as adequate time to wait to perform a biopsy after laser treatment. Even in the absence of imaging findings, patients had a biopsy as part of the research protocol to evaluate potential MRI occult disease. At 1-year post-laser, patients had an mpMRI (and biopsy, if indicated) with annual mpMRI (and biopsy, if indicated) thereafter for a total of 20 years of observation as part of a continuing Phase II clinical trial (NCT 02243033). At baseline and at each visit research subjects provided recent PSA results and completed three validated surveys: Sexual Health Inventory for Men (SHIM), International Prostate Symptom Score (IPSS) and Personal Health Questionnaire (PHQ-9).

In-field recurrence was any biopsy-confirmed, clinically significant PCa seen at the previously treated site(s). Clinically significant PCa was defined as GG2 or greater. Out-of-field cancers were

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defined as de-novo, biopsy-confirmed, clinically significant PCa outside the original treatment site detected at follow-up.

An outside biostatistician (R.T.) analyzed our data as anonymized data extracted from radiology reports, surveys, clinical notes, and laboratory results. Python and Excel with statistical packages and pairwise Student's t-test were used to determine statistical significance. With the null hypothesis, the measurement (PSA, IPSS, SHIM and/or PHQ-9) was statistically different between pre-treatment and post-treatment.

3. Results

Treatments were delivered to 112 lesions in 81 patients. 70 men and 97 lesions were treatment naïve while 11 men and 15 lesions represented salvage therapy . Total procedure time was between 1.5 and four hours. Salvage patients experienced a mean PSA decrease of 44% and treatment naïve patients' PSAs declined 40% and there were no statistically significant changes in IPSS and SHIM scores at 6 months post-treatment. A lack of damage to the sphincter could have made the IPSS not dip. Of the lesions treated for which we had available ISUP GG data, 26% (28/107) were GG1, 46% (49/107) were GG2, 23% (25/107) were GG3, 2% (2/107) were GG4 (salvage) and 3% (3/107) were GG5 (salvage). The coagulation necrosis volumes ranged from 0.57 cc to 22.93 cc with a mean of 7.1 cc and a median of 6.4 cc (25% and 75% quartiles of 2.9 cc and 10.3 cc respectively). When evaluating the location of the lesions, 5% were from the central zone (CZ), 33% were classified as in the transition zone (TZ), and 59% were in the peripheral zone (PZ) (Figure 2). The pre-treatment lesion volume ranged from 0.03 cc to 6.6 cc, with a mean of 1.1 cc and a median of 0.49 cc (25% and 75% quartiles of 0.25 cc and 1.4 cc respectively). At six-month biopsy, 24 treatment regions were positive consistent with in-field recurrent or residual cancer in 21% of subjects (24% of treated regions). Out-of-field recurrences at 6 months were 6% and later recurrences (after 6 months) are an outcome being measured in our Phase II clinical trial with 20 years of follow-up, with slightly higher recurrences in patients with more aggressive tumors or salvage patients.

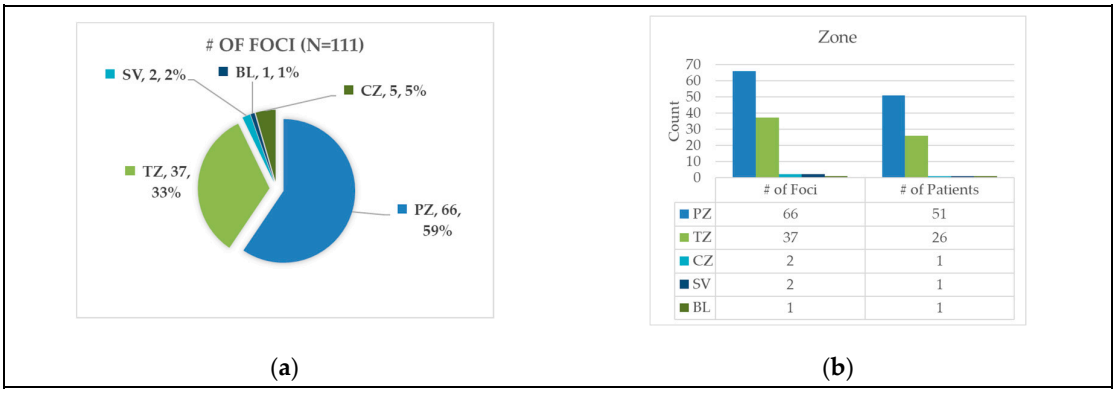

Figure 2. Our patient population had focal areas located at the peripheral zone (PZ), transition zone (TZ), central zone (CZ), the seminal vesicles (SV), and the bladder (BL), shown as (**a**) a pie chart and (**b**) a bar chart.

The mean, median, and standard deviation of PSA values pre-treatment were 6.83, 6.40, and 4.49 respectively. This dropped to 4.07, 3.65, and 2.78 respectively after 12 months ($p < 0.01$) (Figure 3). The SHIM (Figure 4) and IPSS (Figure 5) and PHQ-9 (Figure 6) scores changed slightly, but no statistical significance was observed in such changes. There was no statistically significant change in PHQ-9 scores in the treatment naïve group but interestingly, PHQ-9 scores among the salvage patients improved at 12 months. We observed no serious adverse events; however, in one procedure the laser fiber carbonized the applicator tip, leaving a 1.2cm segment of the applicator in the prostate which the patient later passed spontaneously with urination. This was reported to the device manufacturer and subsequent modifications to Instructions for Use (IFUs) were made. It was also reported to the FDA and our IRB.

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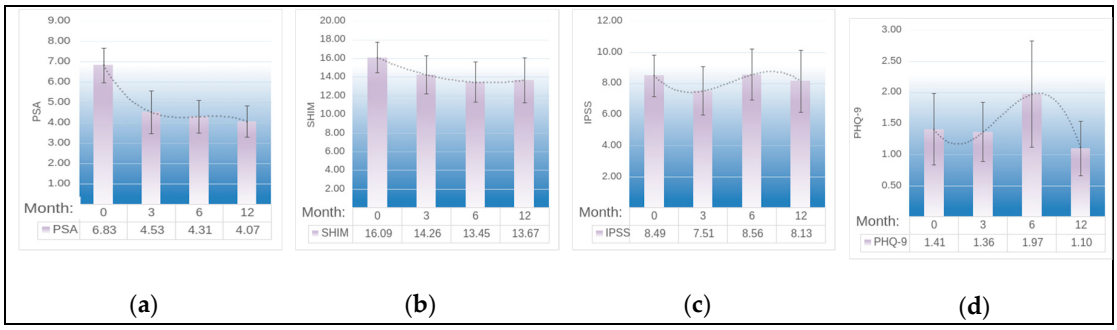

Figure 3. Each patient had their (**a**) PSA measured at treatment time, and then again at 3, 6, and 12 months. In addition, patients wellness was reported via surveys at those time intervals measuring (**b**) SHIM, (**c**) IPSS, and (**d**) PHQ-9.

4. Discussion

For treatment-naïve and salvage prostate cancer patients with MRI visible tumors, laser focal therapy delivered transrectally under MR-guidance with real time MR thermometry is both safe and feasible in an outpatient setting. Our sedation protocol eliminated the requirement for hospitalization, general anesthesia, or an anesthesiologist.

Precise laser delivery under MRI-guidance preserved quality of life with equivalent short-term oncologic control compared to whole-gland therapies without compromising focal or whole-gland retreatment options in the patient's future. An ongoing Phase II 20-year clinical trial (NCT 02243033) will address the intermediate and long-term oncologic control in 200 patients.

Our patients suffered less than 1% erectile dysfunction and less than 1% urinary incontinence. It should be noted that symptoms like erectile dysfunction were not considered explicitly as they are more relative changes than absolute numbers, and incontinence was determined by self-reported concern about leakage rather than quantitatively counting absorbent pads. In addition, despite the transrectal approach, no rectal fistulae occurred. We believe this to be attributed to the safety, precision and controllability of laser energy using MRI for guidance and MR thermometry for monitoring. The crisp transition zone between treated and untreated tissue allows avoidance of important structures such as the neurovascular bundles, external urethral sphincter and the rectal wall, thus facilitating thorough treatment and preservation of quality of life.

In the 12-year interim results of our ongoing Phase II clinical trial we did observe NCI Common Terminology Criteria for Adverse Events (CTCAE) Grade 2 and 3 adverse events in the form of excessive venous (two patients) or arterial (one patient) rectal bleeding. We attributed this to the routine use of a 13g introducer trocar with a sharp cutting tip for multiple rectal wall punctures used to introduce the laser applicator. The first patient was easily managed with a large tampon per rectum to tamponade the bleeding. The second venous bleeding patient was successfully managed initially with gauze and a tampon, then with a 24 Fr. straight 3-way urinary catheter per rectum with the balloon filled to 75cc for 30 min. The arterial bleeding patient required transport and admission for surgical closure of the rectal artery. To prevent excessive rectal bleeding in future patients, we adopted a new method using only the laser applicator and titanium stiffener without the trocar/sheath introducer system. This combination has a smaller outer diameter of 14g, but no cutting tip. A 22g Chiba needle is sometimes repeatedly introduced initially, through the endorectal needle guide to "dotter" a path for the applicator. Currently, we reserve the 13g trocar for situations where we are unable to reach the target with this modified method. Since adopting this modified method we have had no case of excessive rectal bleeding in our Phase II clinical trial.

5. Conclusions

Our data indicate that outpatient, transrectally delivered MRI-guided laser focal therapy for prostate cancer is both safe and feasible in the treatment-naïve and salvage setting. During the study

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five men were converted to whole gland therapy due to recurrence of disease or development of an out-of-field incidence cancer (a biopsy-proven cancer other than the originally diagnosed and treated lesion). One man expired of a cause other than prostate cancer. A firm consensus for patient selection for laser focal therapy of prostate cancer is evolving [20]. Our study recruited men from ClinicalTrials.gov and was limited to men who were very carefully selected based on inclusion criteria (Table 1) as well as tumor size, shape and morphology. The population was predominantly Caucasian with no men of African or Asian ethnicity and only one Hispanic man. This disparity warrants a separate study of access and education.

Author Contributions: John F. Feller: Methodology; Resources; Validation; Visualization; Supervision. Jurgen J. Futterer: Supervision; Writing- review and editing. Bernadette M. Greenwood: Conceptualization; Methodology; Software; Data curation; Writing- Original draft preparation; Project administration; Writing- Review and editing. Ara Karamanian: Writing- review and editing. Robert Toth: Formal analysis; Writing; Reviewing; Editing. R. Jason Stafford: Software; Validation; Writing; Editing.

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Institutional Review Board Statement: Our HIPAA-compliant, prospective, single institution observational study was registered on ClinicalTrials.gov (NCT 02243033) and was conducted under IRB (Institutional Review Board) approval (WIRB Copernicus Group, Puyallup, WA).

Informed Consent Statement: Informed consent was obtained from all subjects involved in the study.

Data Availability Statement: The datasets presented in this article are not readily available because the data are part of an ongoing study.

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Conflicts of Interest: The authors declare no conflicts of interest.

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