

**Title:** 13-year interim results for transrectally delivered, outpatient MRI-guided laser focal therapy of prostate cancer in a treatment naive cohort

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**Introduction and overall goal:** Lasers have been used for soft tissue necrotization for decades. Our goal was to use a commercially available MR-guided biopsy system for insertion of a laser fiber into biopsy proven cancerous lesions facilitating ablation of MR-visible tumor with real-time thermometry.

**Specific Aims:** We aimed to investigate the efficacy of using MR-guided laser focal therapy for MR-visible prostate cancer using a transrectal approach in an outpatient setting for initial treatment.

**Rationale and background:** In the United States, new prostate cancer (PCa) cases for 2023 are estimated at 288,300 and deaths at 34,700 according to the American Cancer Society. Focal therapies for low risk and intermediate risk localized prostate cancer and salvage treatment are increasingly being explored. We sought to establish the efficacy of laser focal therapy to avoid side-effects of whole-gland therapy.

**Methods and Materials:** We used a 1.5 Tesla MRI system for both image acquisition and real-time thermometry. Commercially available CAD software was used for image analysis and laser fiber placement into the area of biopsy-confirmed tumor. Laser focal therapy was delivered using a 15W, 980nm-1064nm diode laser and cooled or non-cooled laser fiber introduced transrectally using an MRI-compatible positioning device. MR imaging was used to monitor energy deposition, thermal maps, irreversible damage estimates and coagulation necrosis. Prostate specific antigen (PSA), validated surveys and mpMRI with 6 mo. follow-up biopsy were performed for assessment of outcomes.

**Results:** At 6 mo. post-procedure biopsy, 24% were positive for clinically significant PCa (csPCa) while 67% were negative. The remaining 9% had clinically insignificant PCa at 6 mos. Of the csPCa tumors at 6-months, 92% were in-field and 8% were out-of-field. We observed a 47% decrease in mean PSA at 12 months post therapy and no statistically significant change in International Prostate Symptom Score (IPSS) and Sexual Health Inventory for Men (SHIM) scores. As our data has matured over the years, we observed a 94% failure-free survival rate and 98% metastasis-free survival.

**Discussion and conclusions:** Our data indicate that outpatient, transrectally delivered MRI-guided laser focal therapy for prostate cancer is both safe and feasible. The precision and controllability achieved under MRI-guidance may have favorable results for cost effectiveness and quality of life without eliminating the possibility of whole-gland treatment in the patient's future. We will continue to follow these men for twenty years as part of an IRB-approved clinical trial (NCT# 02243033). The demonstrated efficacy of laser focal therapy over thirteen years warrants randomized controlled trials.