

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

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Introduction and overall goal: Salvage treatment options in patients who have elected whole-gland treatments for primary therapy of clinically significant prostate cancer (csPCa) include focal therapies. Our goal was to evaluate the palliative use of laser focal therapy for salvage therapy.

Specific Aims: We aimed to assess oncologic control with follow-up PSA and mpMRI, and quality of life using International Prostate Symptom Score (IPSS), Sexual Health Inventory for Men (SHIM), and emotional well-being with Personal Health Questionnaire (PHQ-9).

Rationale and background: Androgen deprivation therapy has been the standard of care for recurrent prostate cancer with side-effects many patients wish to avoid. Using focal therapy in the salvage setting may help men live longer while avoiding the unpleasant side-effects of ADT.

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, 27% were positive for clinically significant PCa (csPCa) while 67% were negative. The remaining 6% had clinically insignificant PCa at 6 mos. Of the csPCa tumors at 6-months, 89% were in-field and 11% were out-of-field. We observed a 56% 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. We observed a 46% increase in anxiety at 6 mos., which fell to pre-treatment levels post-biopsy at 12 mos.

Discussion and conclusions: Men seeking alternatives to ADT, radiation therapy or systemic therapy may enjoy both longer life and higher quality of life with salvage laser focal therapy for recurrent prostate cancer. Our data indicate that outpatient, transrectally delivered MRI-guided laser focal therapy for recurrent prostate cancer is both safe and feasible. The precision and controllability achieved under MRI-guidance may have favorable results for quality of life without eliminating the possibility of androgen deprivation (ADT), radiation or systemic therapy 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).