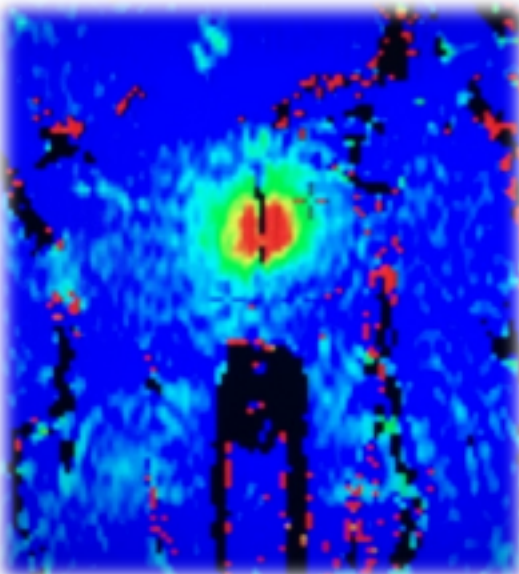


Outpatient Trans-Rectal MR-Guided Laser Focal Therapy Phase II Clinical Trial: 10-Year Interim Results PD17-01



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Disclosures

- Patent pending
- CLS Consultant

**Foley Ref. 117224-0101:
Reporting Application
Filed, Filing Receipt, IDS
& Assignment |
SYSTEMS AND
METHODS FOR MRI-
GUIDED INTERSTITIAL
THERMAL THERAPY**

April 6, 2018 at 4:28 PM

 Found in Inbox

Re: U.S. Patent Application
No. [15/894190](#)

Filing Date: 2/12/2018

Title: SYSTEMS

AND METHODS FOR MRI-
GUIDED INTERSTITIAL
THERMAL THERAPY

Our Ref.: 117224-0101

Methodology

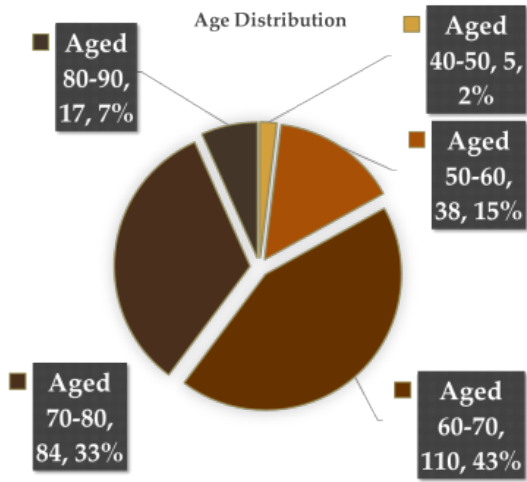
- IRB approved, 510(k) cleared technology
- NCT# 02243033
- Outpatient trans-rectal laser therapy (15W, 980 nm diode laser) guided with 1.5T MRI system (image acquisition & real-time thermometry)
- True focal therapy
- Goal to eliminate MRI abnormality + 1cm
- 255 cancer foci treated in 161 patients from 2010 – 2019
- 6-Month biopsies performed with MRI active surveillance follow-up
- Evaluation of PSA, PSAD, mpMRI, recurrence rates (marginal, incidence), IPSS, SHIM, PHQ-9

Patient Population At A Glance:

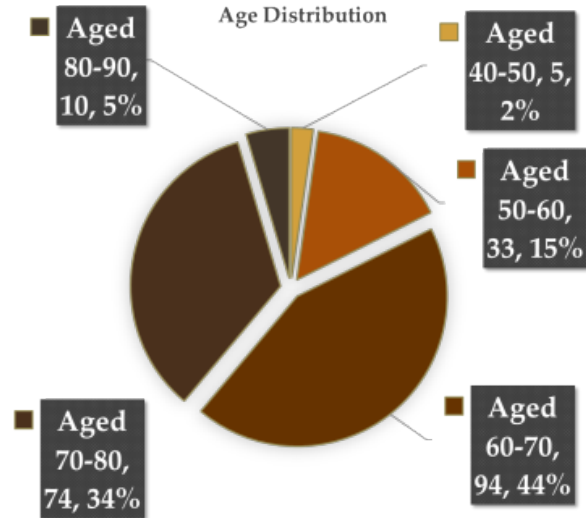
| Statistic | Data |
|--------------------------------|-----------------|
| # of Patients: | 161 |
| # of Treatment Naïve Patients: | 139 / 161 (86%) |
| # of Salvage Patients: | 22 / 161 (14%) |
| # of Total Lesions Treated: | 255 |
| # of Treatment Naïve Lesions: | 216 / 255 (87%) |
| # of Salvage Lesions: | 39 / 255 (13%) |
| Mean Initial PSA: | 7.28 |
| Mean Nadir PSA: | 3.65 (50% drop) |
| Min Age: | 44 |
| Max Age: | 87 |
| Median Age: | 67 |

Patient Age

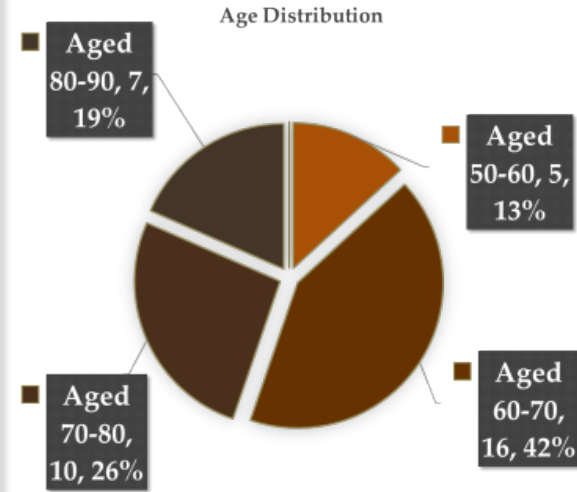
All Patients



Treatment Naïve

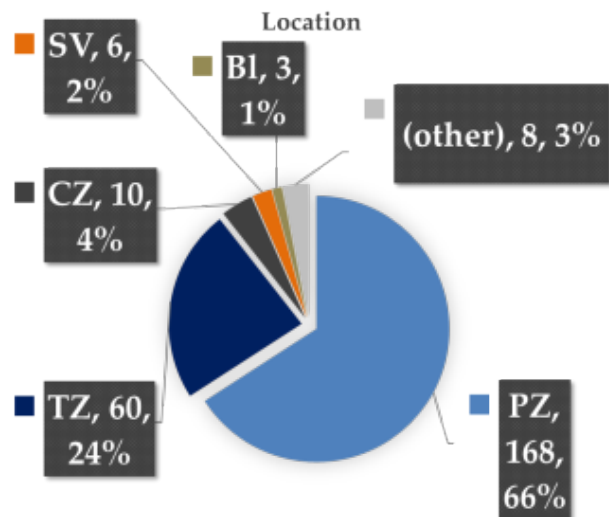


Salvage

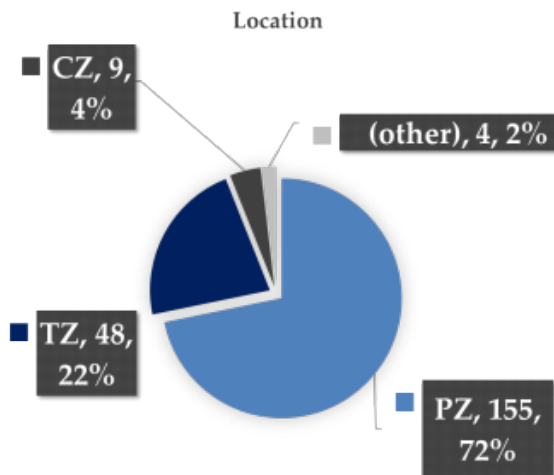


Tumor Location Statistics

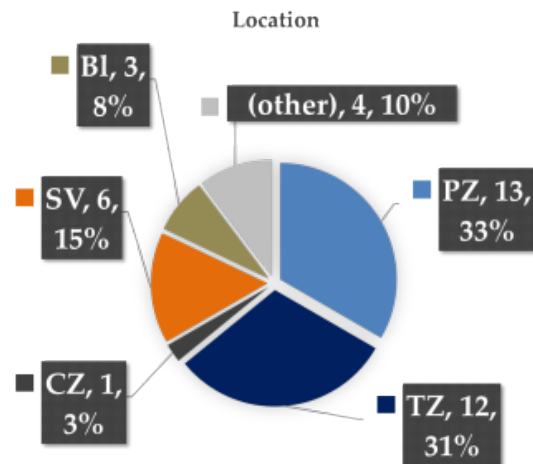
All Patients



Treatment Naïve

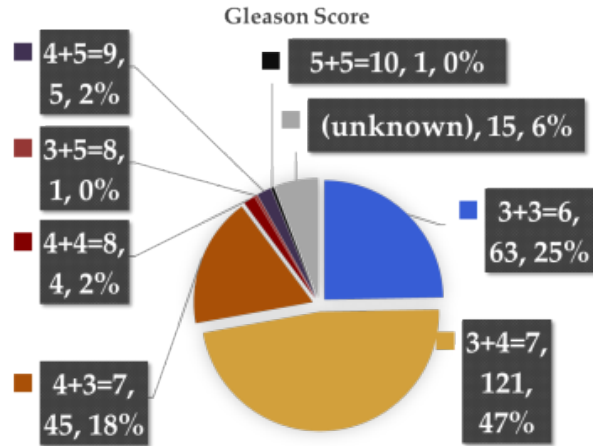


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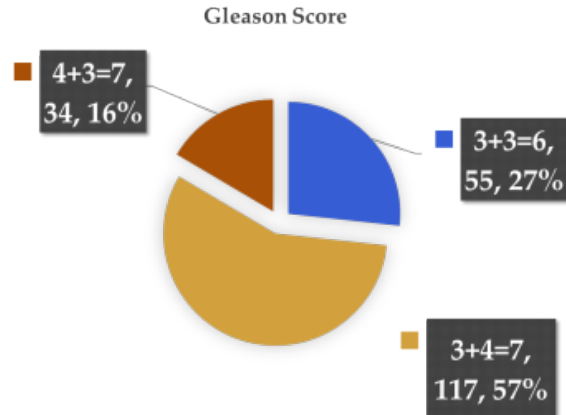


Gleason Score Breakdown

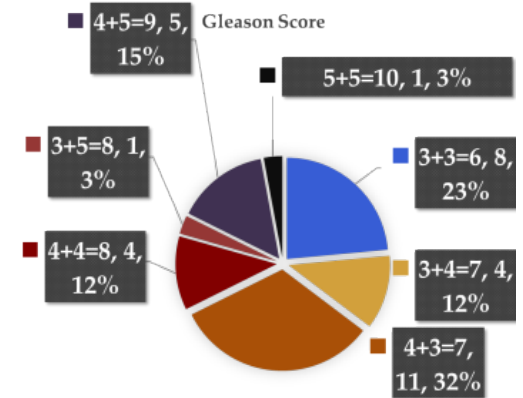
All Patients



Treatment Naïve

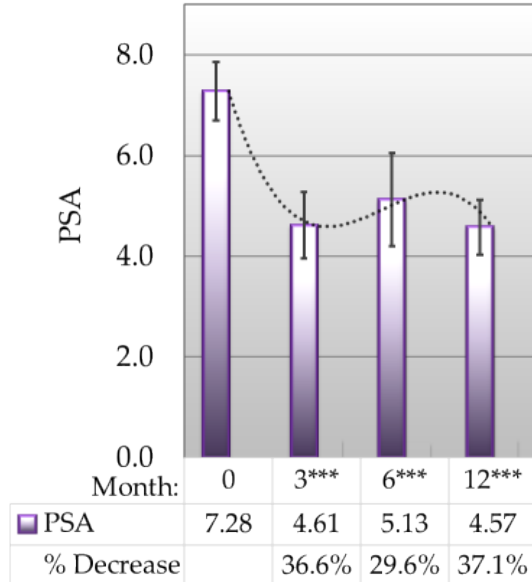


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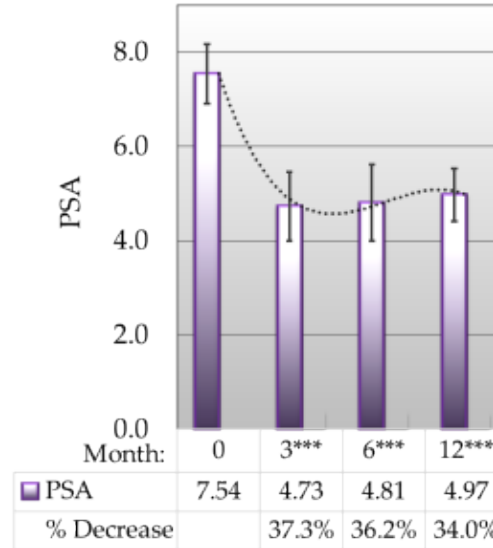


PSA Results

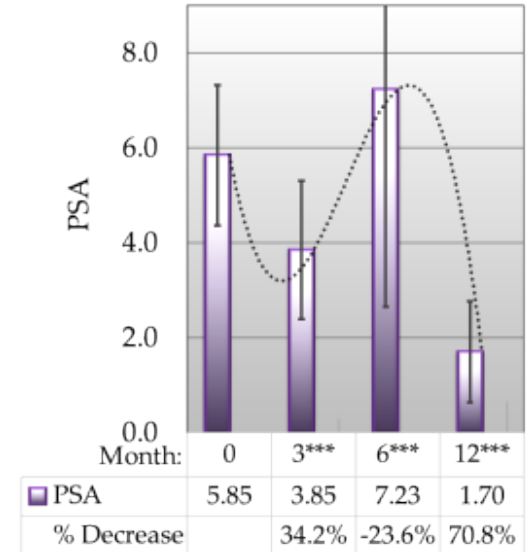
All Patients



Treatment Naïve

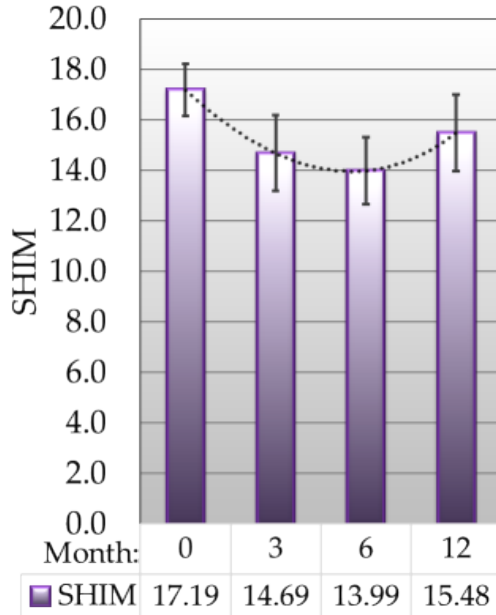


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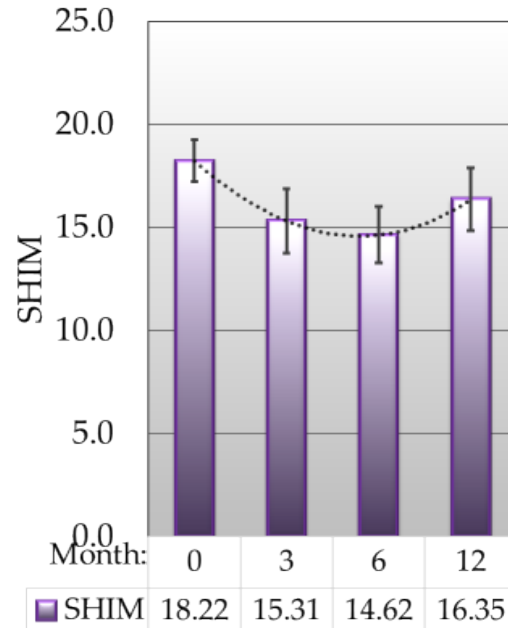


SHIM Results

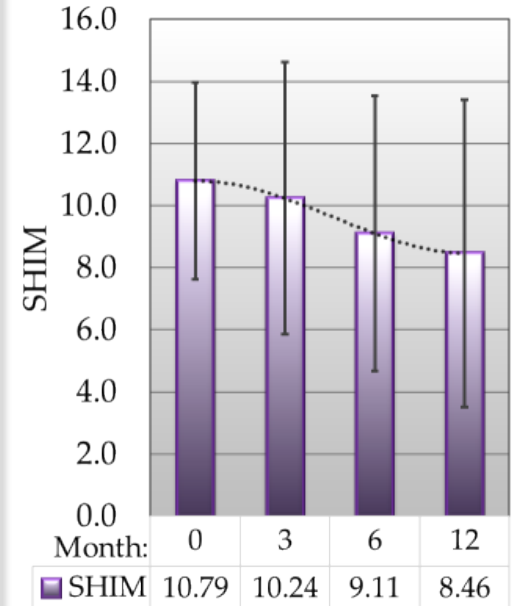
All Patients



Treatment Naïve

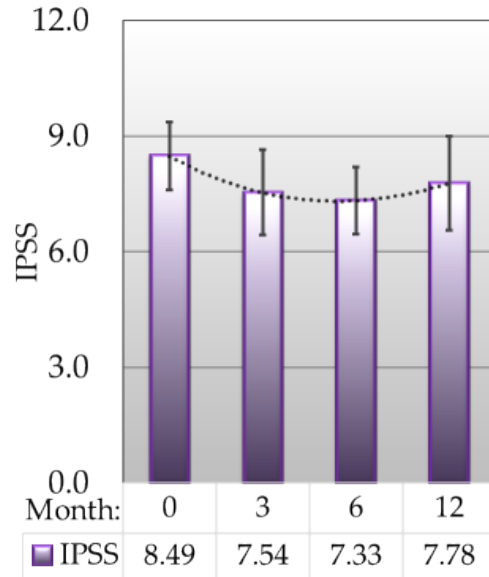


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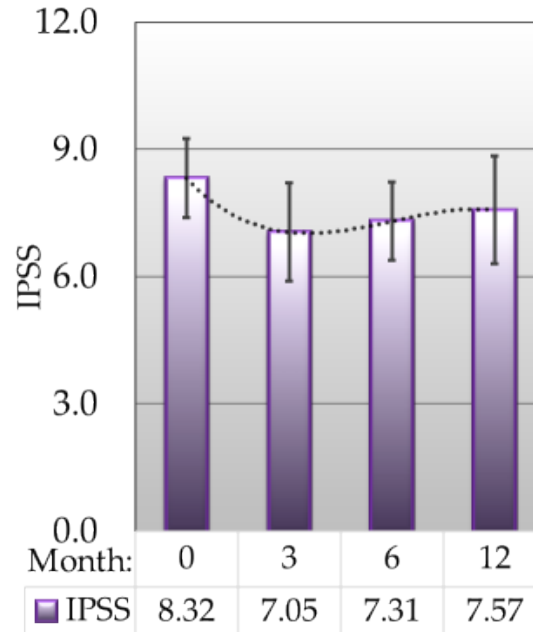


IPSS Results

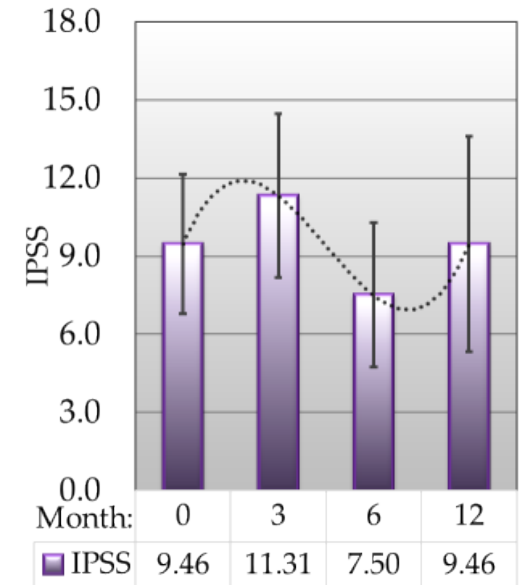
All Patients



Treatment Naïve

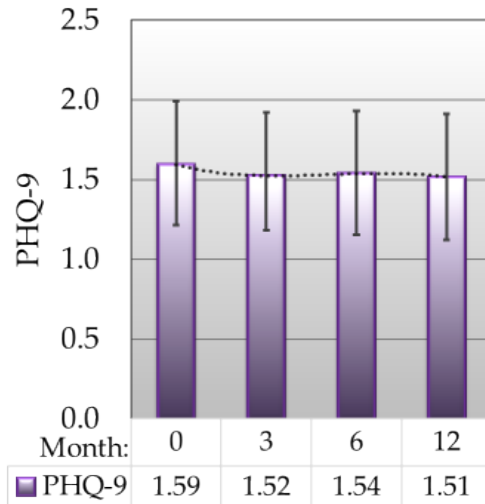


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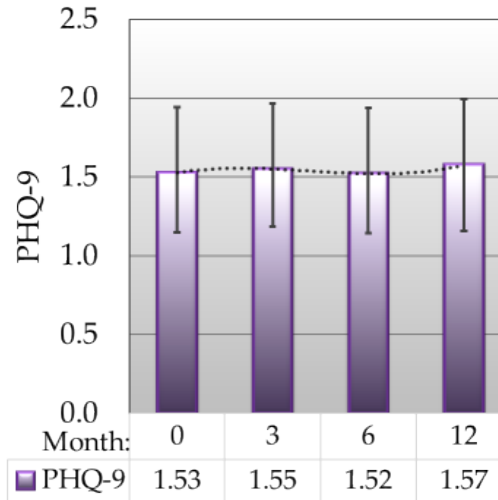


PHQ-9 Results

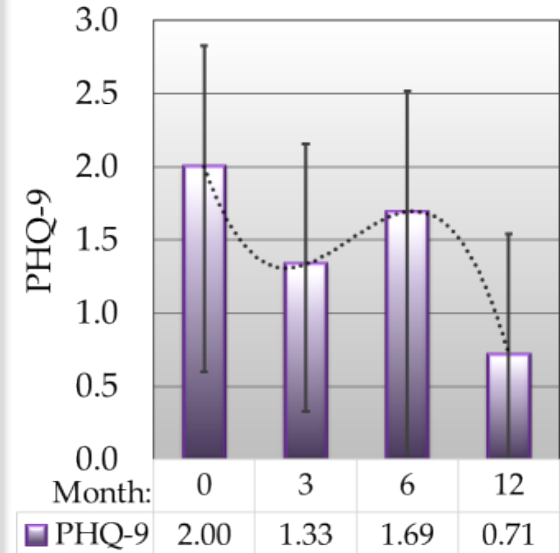
All Patients



Treatment Naïve

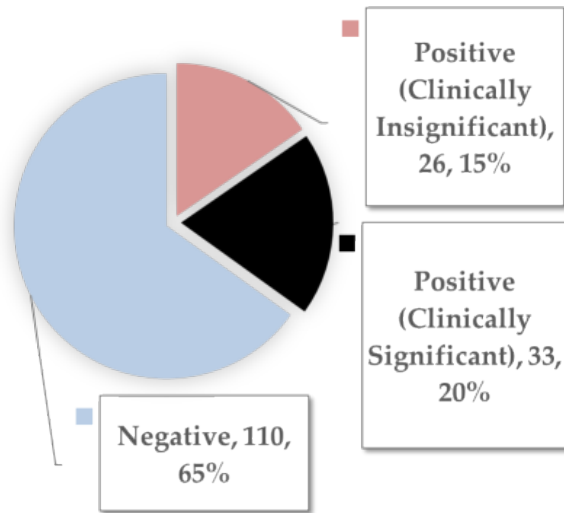


Salvage

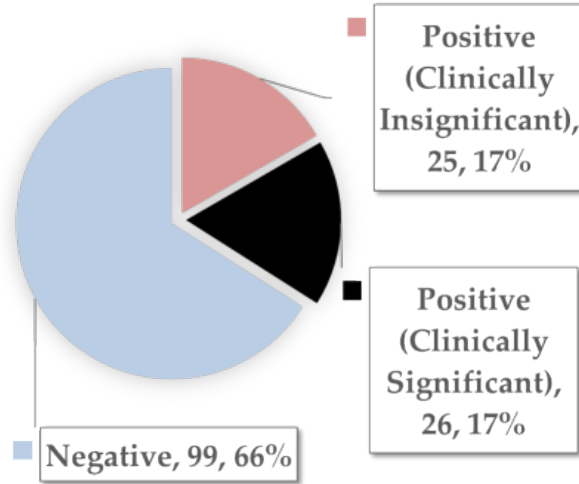


6-Month Biopsy Results

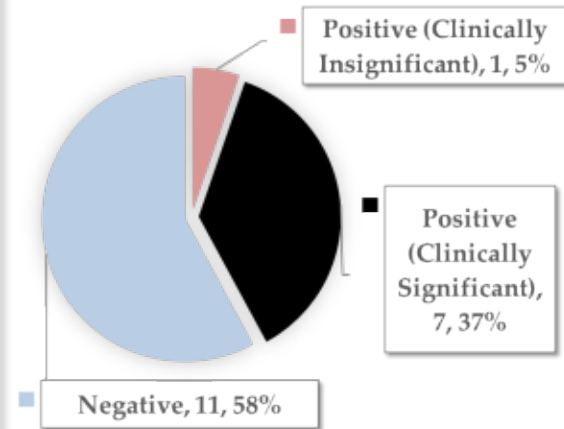
All Patients



Treatment Naïve

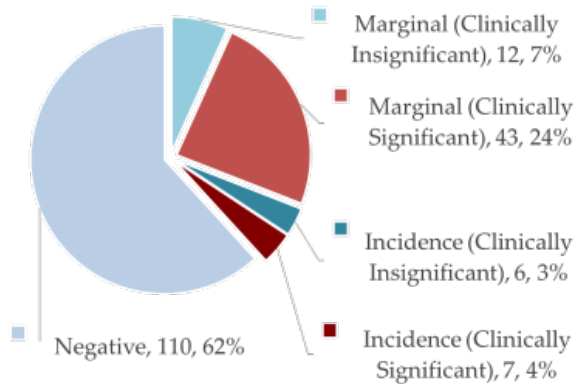


Salvage

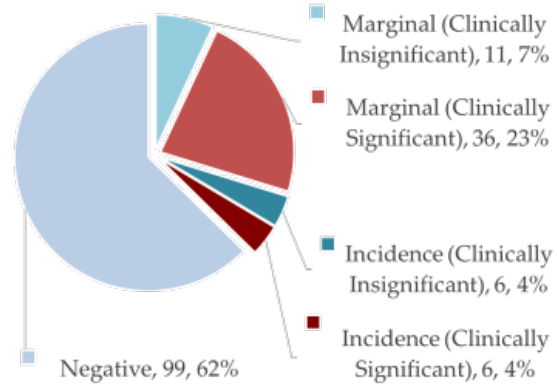


10 Year Biopsy Results

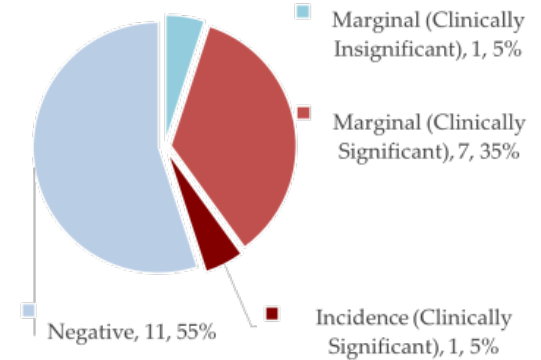
All Patients



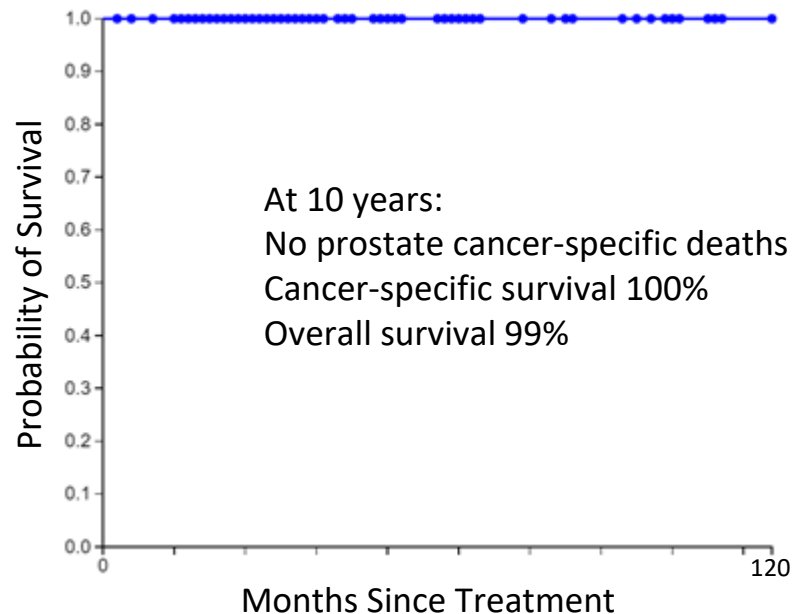
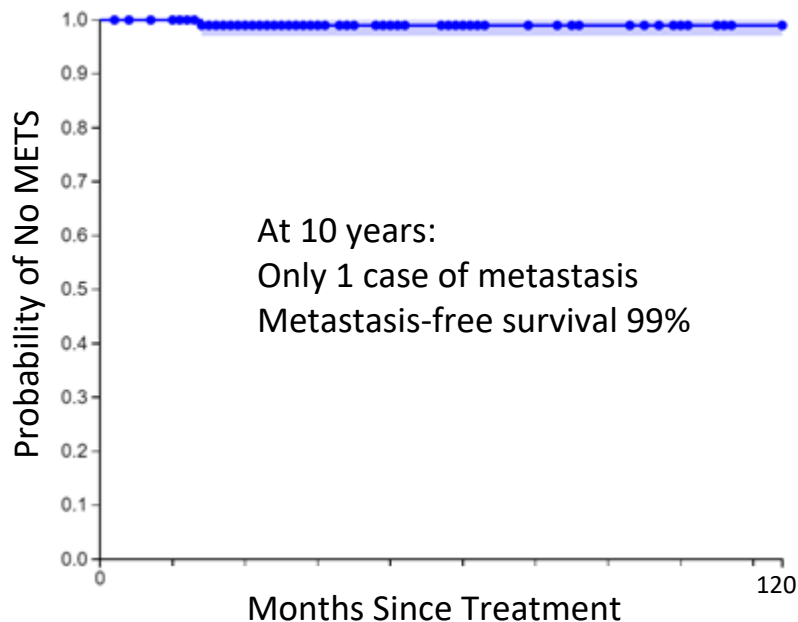
Treatment Naïve



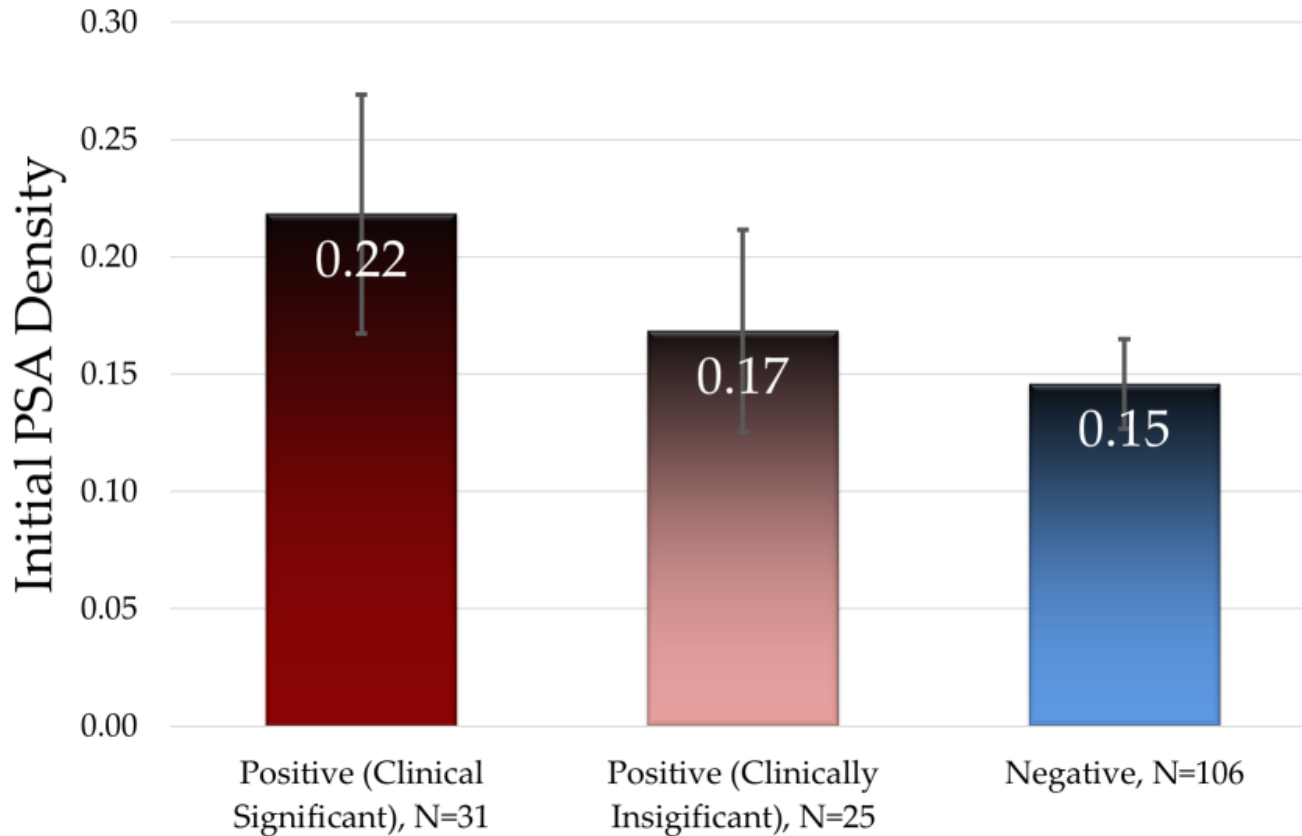
Salvage



Results – Kaplan-Meier Survival Curves



Initial PSA Density vs Treatment Efficacy



Laser Focal Therapy Phase II Clinical Trial Interim 10 Year Results

- 95% biopsy compliance rate at 6 months
- Clinically significant infield recurrence rate = 23%
- Clinically significant outfield cancer rate = 4%
- Conversion rate to whole gland therapy = 6%
- 94% avoided whole gland therapy and associated morbidity
- Rate of prostate cancer specific metastasis = 0.8%
- Short term and intermediate term oncologic control achievable in 77% of patients with initial treatment
- Most recurrence patients elected repeat laser focal therapy

Biochemical Recurrence Rates for RP and XRT for Intermediate Risk Prostate Cancer

>20% at 5 years

> 30% at 10 years

Potential Solutions to Recurrence Rates After Laser Focal Therapy

- Better treatment planning: 3D mapping biopsy, tracking biopsy
- Increasing margin size >>> Increases morbidity
- Better risk stratification
 - PSA Density
 - Tissue-based genomics, Liquid biopsy (CTC's, ctDNA)
 - Molecular imaging; e.g. PSMA PET/CT
 - Combination Rx; e.g. laser focal therapy + IT immunotherapy, oncolytic virus therapy, radiopharmaceutical
- “Haircut” or chronic illness model; retreat prn

Summary: Why Laser?

- Safe, precise and outpatient feasible
- Can “sculpt” a therapy
- Transition zone = 1 mm compared to 5 – 10 mm for HIFU, Cryo, RF and other energy sources
- Biplane real time MR thermometry with safety cursors
- Particularly amenable to treating apex cancers (urethral cooling catheter / CBI) and cancers in large volume prostate glands

HALO Dx Research Team

- Bernadette Greenwood, BSc, PG Cert., RT(R)(MR)(ARRT)
- Steven Gunberg, DO
- Jeffrey Herz, MD
- Wes Jones, RT(MR)
- Rob Toth, PhD