



Incision & Radiation-Free Surgery
Real-Time MR Guided Ultrasound Therapies

CORPORATE PRESENTATION | November 2018

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Combining Two Powerful Modalities – real time MR and thermal ultrasound to create incision and radiation free interventional procedures

Disease Treatment

Not

Organ Removal

1

Precise

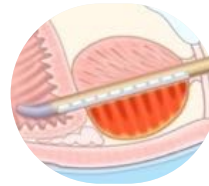
2

Flexible

3

Safe

TULSA-PRO®

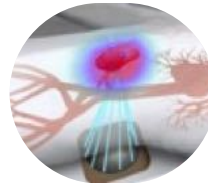


Treatment for prostate disease

- CE marked
- FDA expected H2-2019



Sonalleve



Treatment for uterine fibroids, bone metastasis, pediatric

- CE marked
- China FDA approved for uterine fibroids

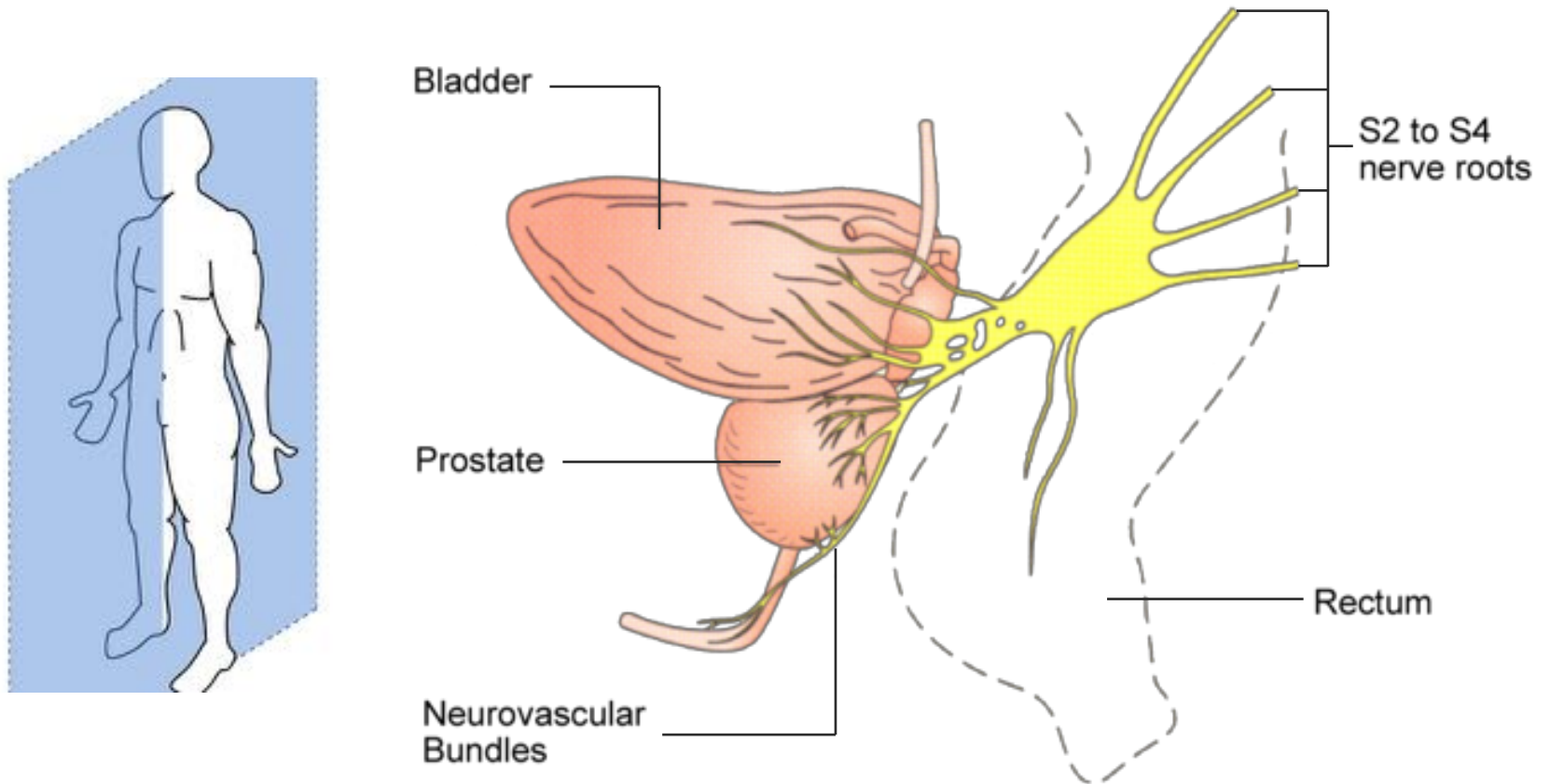
TULSA-PRO

TULSA-PRO MRI-guided robotic ultrasound ablation system for precise treatment of diseased prostate from the inside out

- CE Marked
- FDA Registration Study Recruitment Completed

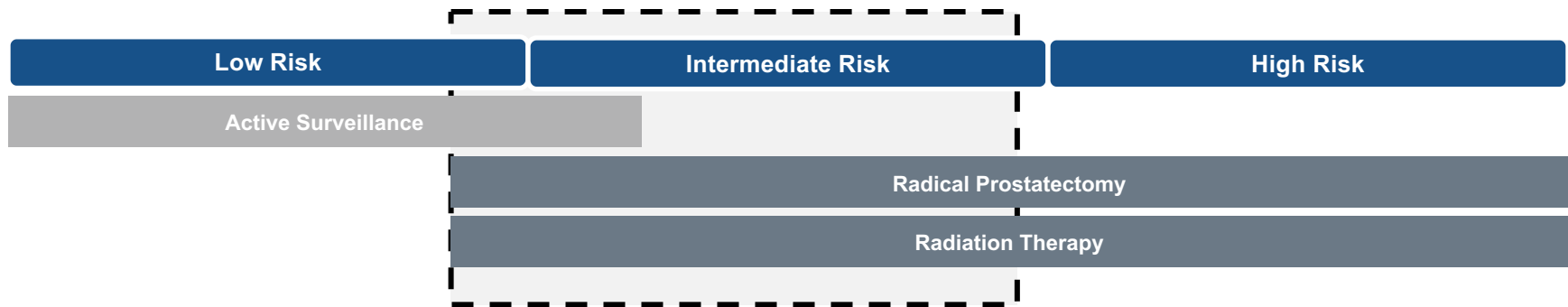


The Prostate



Kirby (1997) An Atlas of Prostatic Diseases, The Encyclopedia of Visual Medicine Series.

Localized Prostate Cancer – Unmet Need



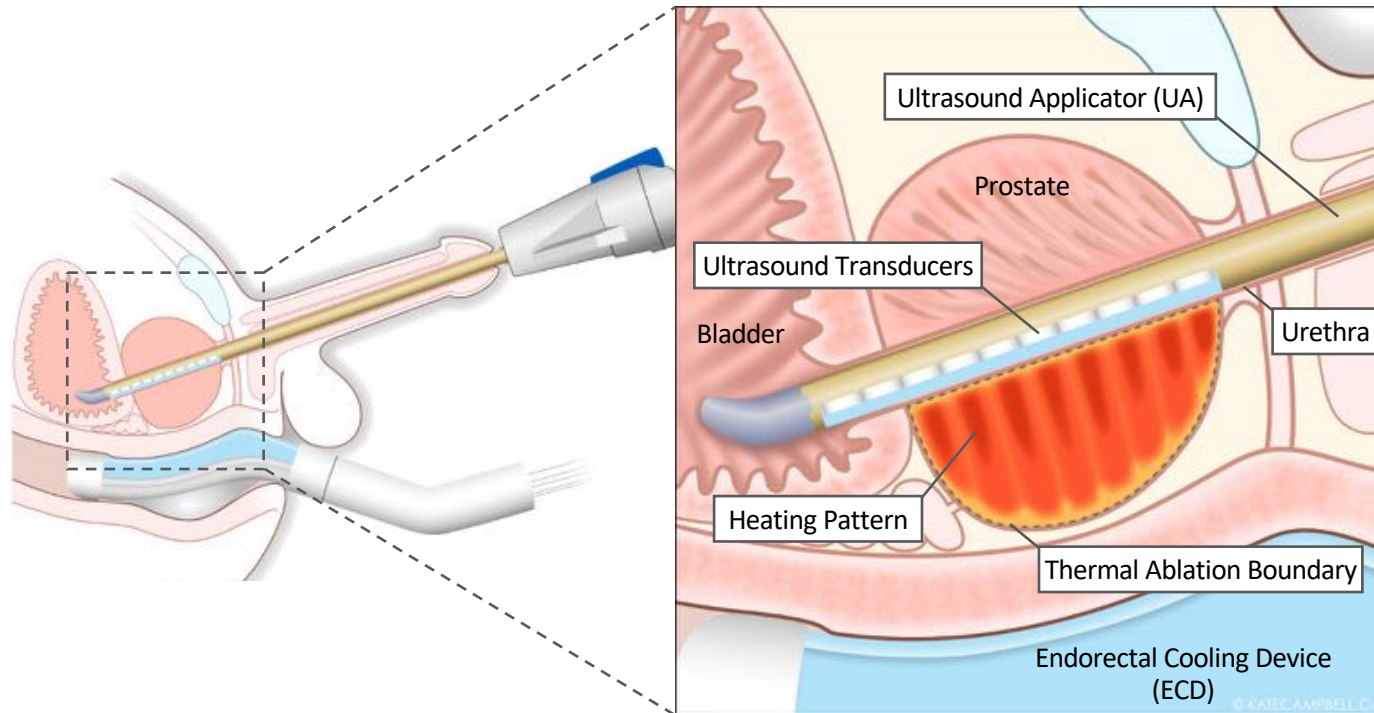
- Radical Prostatectomy & Radiation Therapy effective for clinically significant localized prostate cancer
- Both considered “Radical” (impact on surrounding anatomy) and have limited salvage options
- Both carry significant disability: Incontinence (10-30%), Erectile dysfunction (20-80%), Proctitis (5-25%)
- Acceptable for patients with life threatening disease, but overtreatment for low & intermediate risk



Opportunity for less invasive, function preserving therapies which do not preclude additional intervention if needed in the future

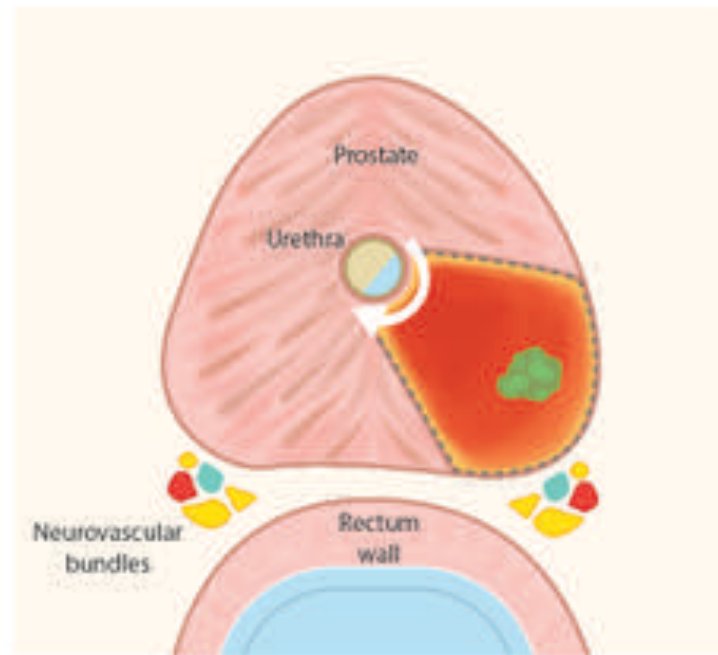
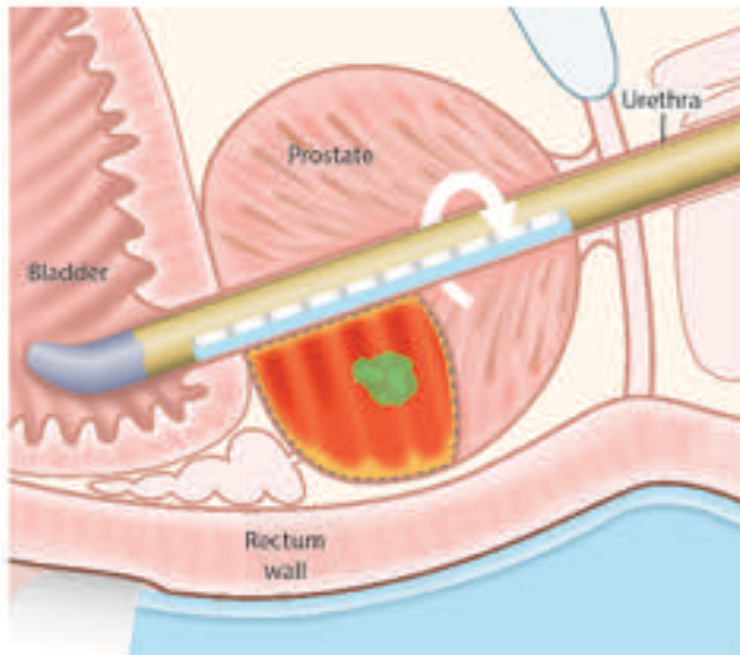
TULSA-PRO – Prostate Ablation From The Inside Out

Whole Gland Ablation



TULSA-PRO Targeted Ablation

Partial Gland Ablation



MR-Guided TULSA – Closed Loop Temperature Control

1. Transurethral directional ultrasound ablation

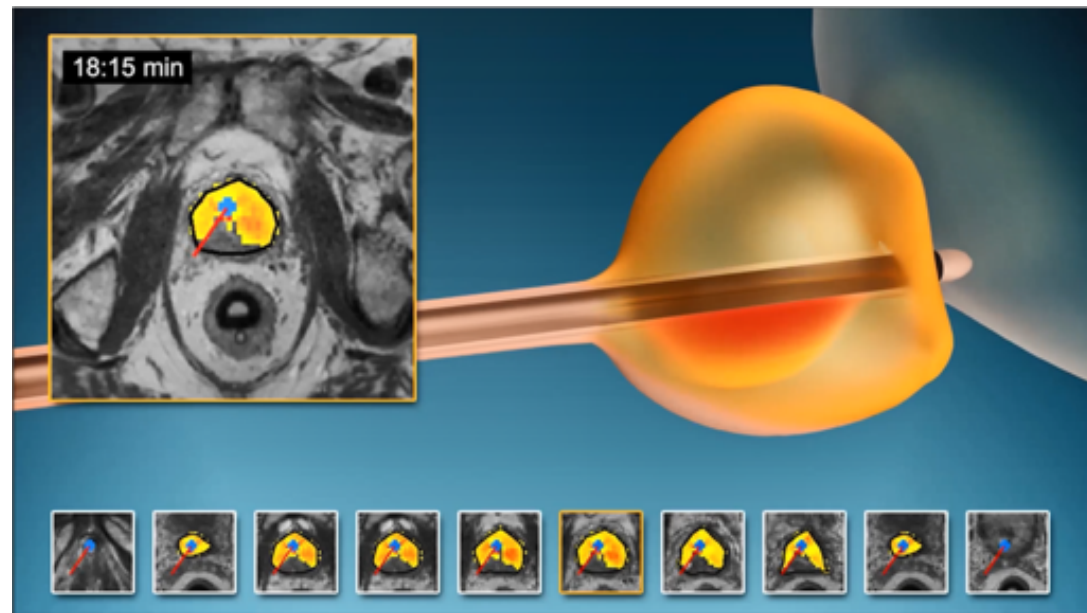
- Incision and radiation free ablation
- No energy through rectum
- Sweeping ultrasound, continuous rotation (no risk of cold spots between discrete sonications)
- Capable of treating large and small prostate volumes

2. Real-time MRI thermal dosimetry & Closed-loop ablation control

- Delivering a thermal therapy, while measuring temperature effect in real time, and automatically adjusting the energy delivered accordingly
- Temperature feedback provides millimeter precision
- Actively compensates for tissue and blood flow changes during treatment

3. Urethra and rectum cooled

- Thermal protection of important anatomy



TULSA-PRO

Equipment

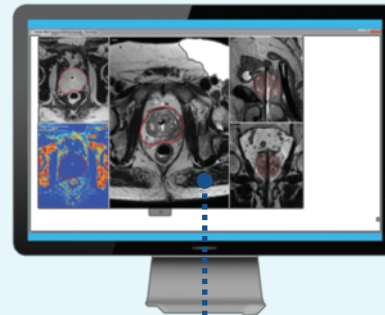
Compatible with MR from leading companies – Philips and Siemens



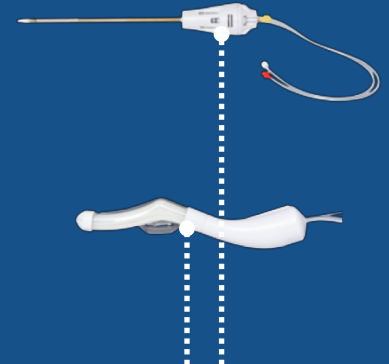
Robotic Arm,
Computer Hardware



Energy System



Surgeon Console
Control Room



Disposable
Applicators

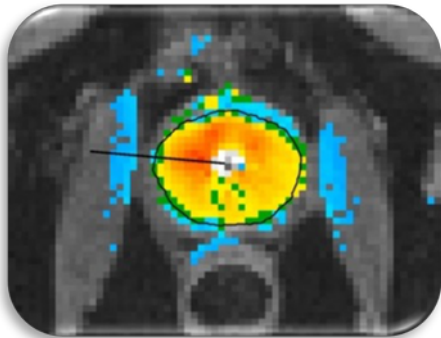
TULSA Unique **Benefits**

- **Single Outpatient Procedure**
Four cases per day
- **Transurethral Ablation From Inside-Out**
Large prostate (no size limit), inherently safer than outside-in, no energy directed through rectal wall
- **Precise Ablation With Millimeter Accuracy**
Robotic applicator, real-time MRI guidance and control, quantitative thermal dosimetry
- **Actively Protect Urethra and Rectum**
Water-cooled Ultrasound Applicator (UA) and Endorectal Cooling Device (ECD), single-use disposable
- **Possibility of Future Treatments**
Repeatable ablation, and does not prevent future treatment with standard of care therapies

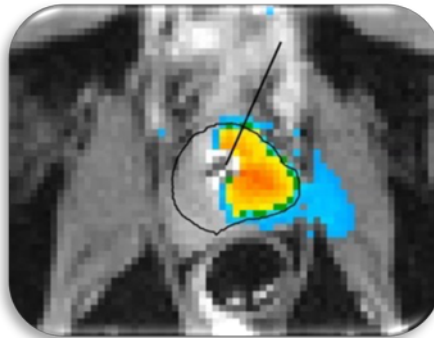
TULSA Flexibility

Precise Whole Gland or Customized Partial Gland Ablation

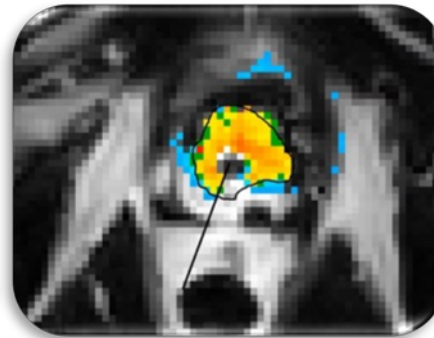
Whole Gland
Ablation



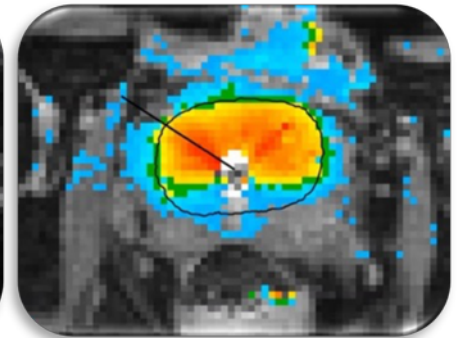
Targeted
Ablation



Salvage Therapy
Post Radiation
Therapy Failure



Benign Prostate
Hyperplasia (BPH)

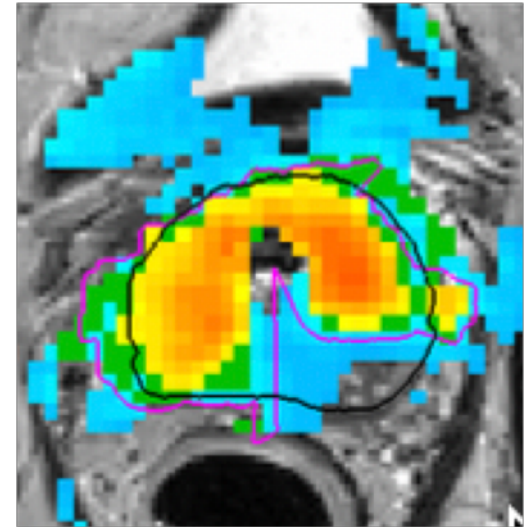


Prostate Tissue Ablation of Transition Zone

TULSA-PRO Addressing Unmet Need

Unmet needs (20% of men over 50, 60% of men over 60 have BPH)

1. Patients with stage IV disease: >80cc prostate
2. Patients with both cancerous and BPH tissue



Patient with BPH and early stage lesion

Example – Ablation & Volume Reduction on MRI

- 67 years old, multi-focal GS 3+4 disease (biopsy), 1x PIRADS 3 Left Mid Anterior (MRI)
- Complete ablation confirmed on CE-MRI immediately after TULSA and during follow-up
- MRI and PSA show ablation of almost entire prostate, with no evidence of complications
- 12-month prostate “size of raisin” and negative for adenocarcinoma on biopsy

Screening

PSA 5.8 ng/ml
58 cc

Immediate Post

1 month Post

PSA 0.3 ng/ml

3 months Post

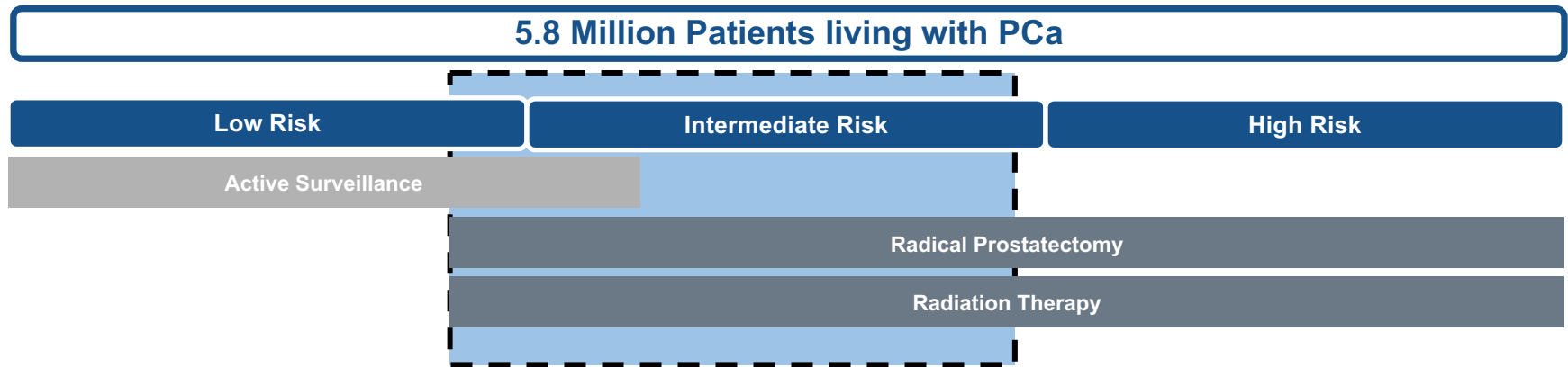
PSA < 0.1 ng/ml

6 months Post

PSA < 0.1 ng/ml
9 cc

Courtesy Dr. Steve Raman, University of California Los Angeles (UCLA)

Localized Prostate Cancer – Target Intermediate Risk



Intermediate risk patients (200,000 patients in US +EU)

1. Patients with active lives
2. Patients under active surveillance but don't want to wait, or also have BPH
3. Patients with co-morbidities preventing surgical intervention
4. Salvage patients who failed radiation treatment
5. Patients with early stage disease, Gleason Score (GS) = 3+3 but genetic testing indicates aggressive disease
6. Patients with mid stage disease with MRI visible disease pattern
7. BPH patients who value erectile and ejaculatory functions

Positive Reimbursement Environment

For Prostate

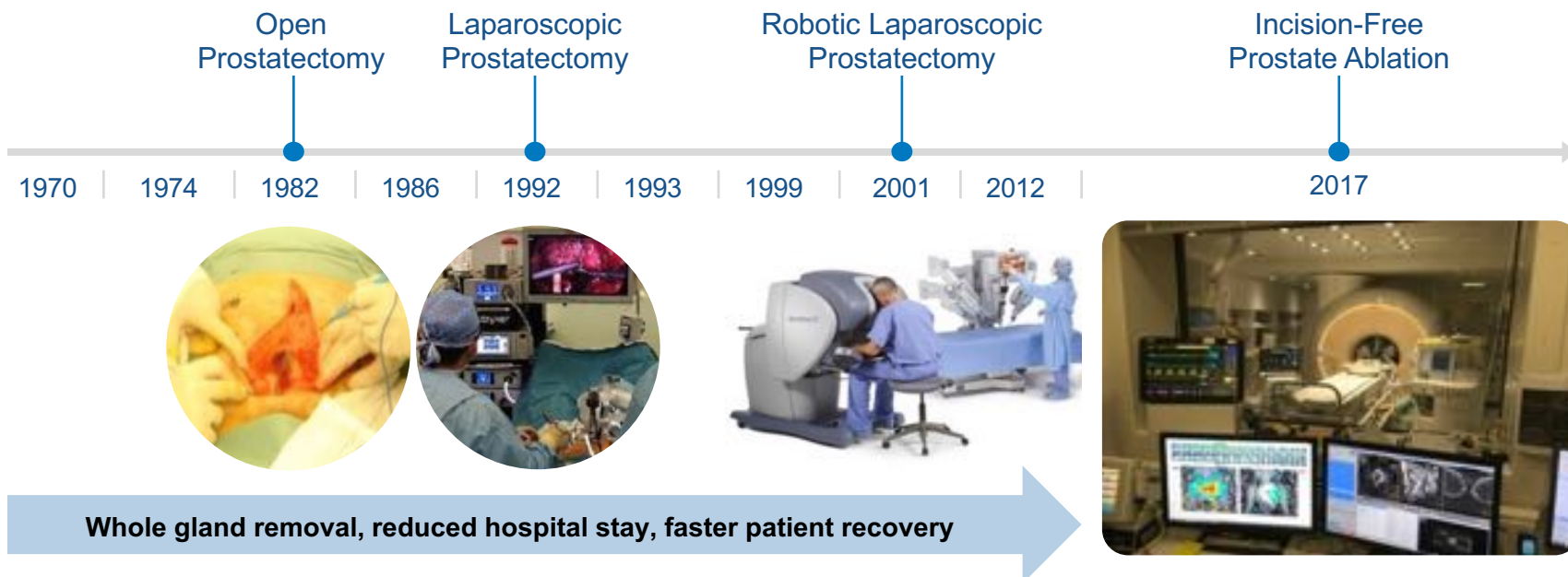
Procedure	Approximate Hospital Payment	Approximate Surgeon Payment
Laparoscopic Radical Prostatectomy	\$15,692*	\$1,450
Radiation Therapy (IMRT Simple, 40 Sessions)	\$27,564**	Fee bundled into primary APC

No therapy is considered standard of care

* Lowrance WT, Eastham JA, Yee DS, Laudone VP, Denton B, Scardino PT, et al. Costs of medical care after open or minimally invasive prostate cancer surgery: a population-based analysis. Cancer. 2012;118(12):3079-86.

** Sher DJ, Parikh RB, Mays-Jackson S, Punglia RS. Cost-effectiveness analysis of SBRT versus IMRT for low-risk prostate cancer. American journal of clinical oncology. 2014;37(3):215-21.

Adding Incision & Radiation-Free Intervention – A New Paradigm To Treat The Disease



Potential to Expand Urologist's Practice

- Potential to keep radiation candidates “in practice”
 - Partnering, not competing with radiology
 - TULSA-PRO takes significantly less time to perform than prostatectomy
 - Frees up valuable surgery suite capacity
- Surgical planning with real time imaging
 - Whole gland or disease targeted partial ablation of prostate

TACT Pivotal Trial: Full Prostate Volume Ablation (99%)

To support FDA application, enrollment completion Feb 2018

Study population (2/3 Intermediate Risk)

- Low and intermediate risk PCa, 45-80 y, PSA \leq 15, GS \leq 3+4
- n = 115, 13 clinical sites, 5 countries

Treatment plan

- Reduced margins for complete ablation

Primary endpoints (12 months)

- Efficacy: PSA reduction \geq 75%
- Safety: Frequency & severity of adverse events

Secondary endpoints

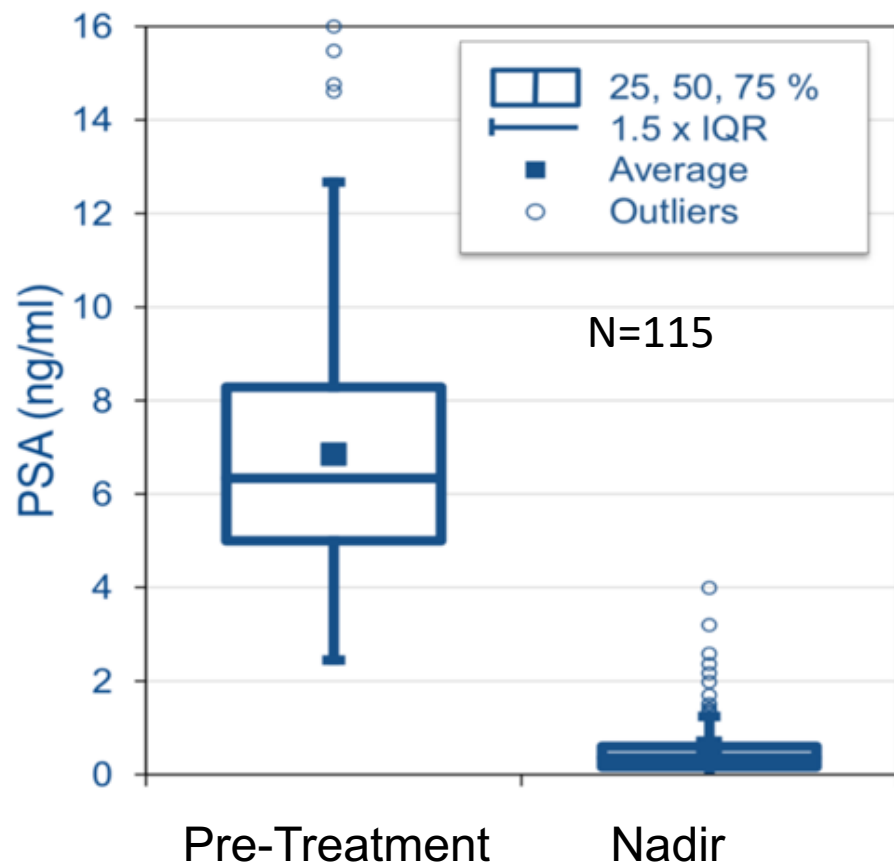
- 12 month MRI and biopsy in all patients
- QoL: EPIC, IIEF, IPSS



TACT Pivotal Trial

Safety and PSA Outcomes

Full data expected in Spring 2019



Primary efficacy endpoint

- PSA nadir $\leq 25\%$ of pre-tx baseline

Results to-date

- 95% of patients met PSA endpoint
- PSA reduction 95% (91 – 97%)
- PSA nadir 0.36 (0.16 – 0.60) ng/ml

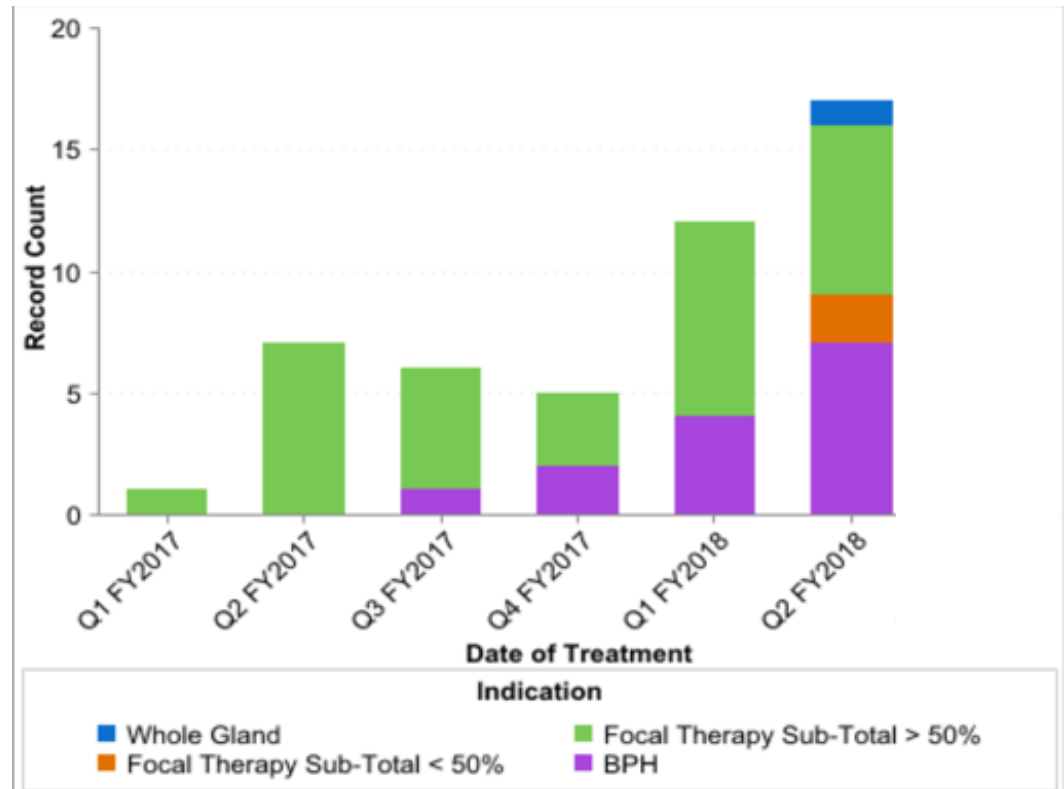
Safety

- No rectal injury, No Grade ≥ 4 AE, No incontinence $>$ Grade 1
- Attributable Serious AE in 7% of patients, all resolved: 3 G2 retention, 3 GS infection, 1 urinoma, 1 ileus, 1 DVT

Expanded Use: Prostate Cancer ► BPH

Pilot Launch In Europe: Case Study

- Initiated use of TULSA-PRO for targeted/focal therapy – Q1-2017
- Monitored treated patients methodically for six months
- Increased usage to BPH patients – Q3-2017
- Further added full gland higher grade cancer patients, and <50% focal ablation – Q2-2018
- Routine – 4 cases /day

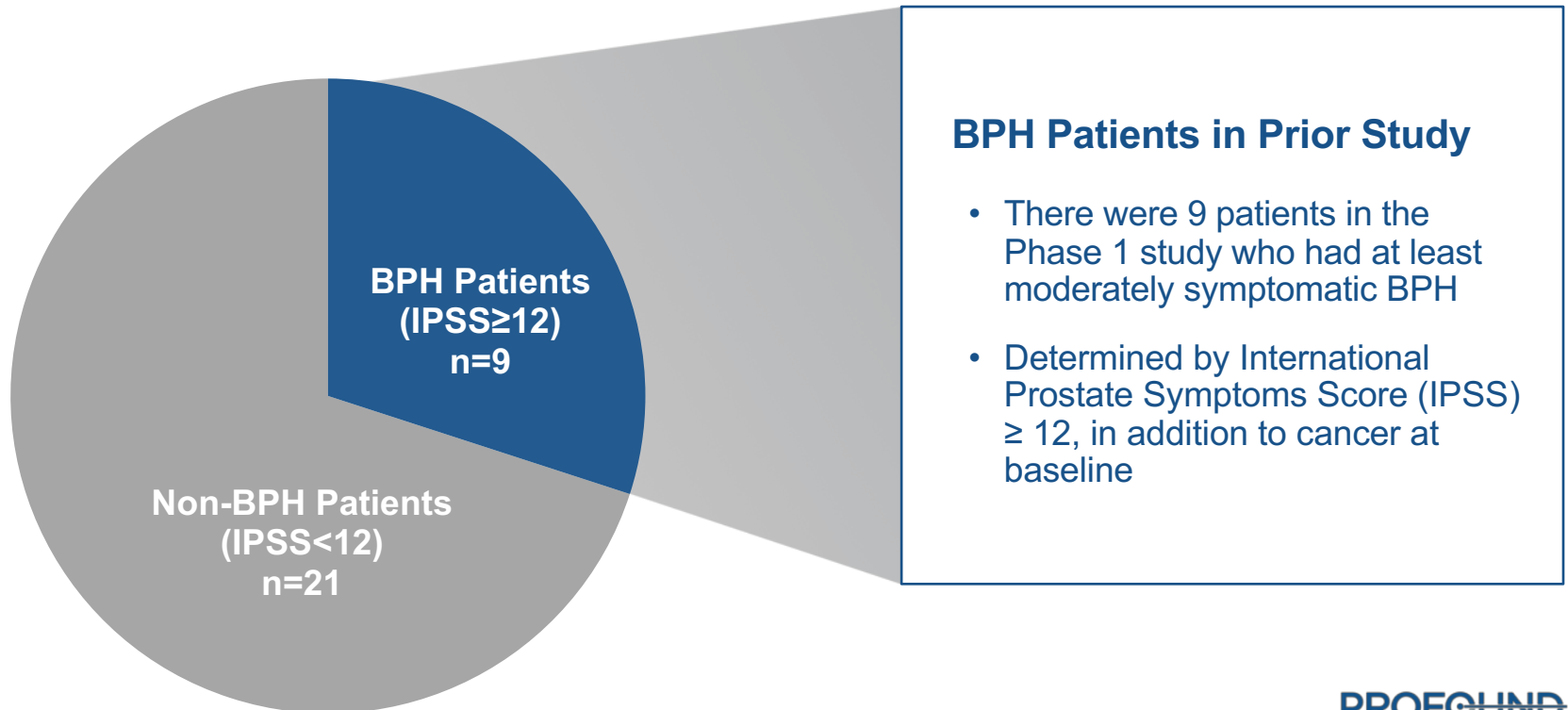


Retrospective Analysis

of TULSA-PRO in Patients with BPH

- Physicians involved in the TULSA trial observed strong anecdotal results in patients with BPH
- A retrospective examination of the quantitative results has shown a consistent trend

TULSA Phase 1 Study (n=30)



Feasibility

of TULSA-PRO for BPH

Retrospective subgroup analysis of 9/30 Phase I patients with IPSS ≥ 12 suggests similar urinary symptom relief as other surgical techniques

Characteristics	Baseline	12 months	Change (%)
IPSS	16.1 ± 3.8	6.3 ± 5.0	-9.8 ± 5.0 ($58 \pm 34\%$)
IPSS QoL	2.8 ± 1.1	0.8 ± 1.0	-2.0 ± 1.7 ($66 \pm 48\%$)
Prostate Volume (cc)	54 ± 23	14 ± 5	-40 ± 24 ($70 \pm 19\%$)
Peak flow (Qmax, ml/s)	14.5 ± 4.1	21.9 ± 12.7	$+7.4 \pm 13$ ($60 \pm 93\%$)

No Grade 3 adverse events, erectile function (IIEF) stable from 15 ± 9 to 16 ± 9 ,
% Patients with erections sufficient for penetration (IIEF Q2 ≥ 2): from 7/9 to 8/9 men

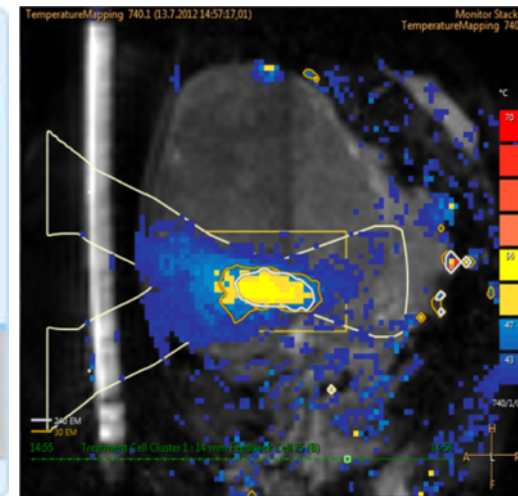
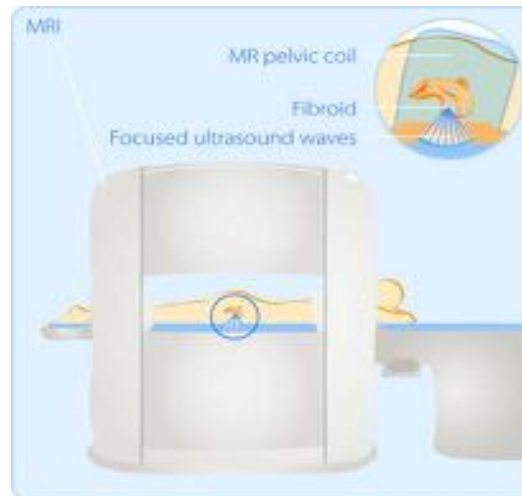
SONALLEVE

Technology platform for:

- Uterine Fibroid Treatment
- Bone Metastasis Pain
- Pediatric bone
- Hyperthermia

Over 200 publications from leading US and European clinicians and hospitals

CE Marked
CFDA Approved



Uterine Fibroid

Symptom Relief & Durability

In normal commercial use, over 85% of patients experienced sustained symptom improvement

Months post-procedure	Patients available for follow-up	Symptom improvement		
		Improved	No relief	Worse
3 months	105	90 (85.7%)	14 (13.3%)	1 (1%)
6 months	99	92 (92.9%)	7 (7.1%)	0
12 months	89	78 (87.6%)	11 (12.4%)	0

Durability of the therapeutic effect compared to other uterine preserving treatments

Need for alternative treatment	@ 12 month	@ 24 month	References
Myomectomy	10.6 %	13-16.5 %	1,2,3,4
UAE (Uterine Artery Embolization)	7-10 %	12.7-23.7 %	5,6,7
MR-HIFU/MRgFUSNPV >60%	6 %	13 %	8

"Volumetric MR-guided high-intensity focused ultrasound ablation of uterine fibroids: treatment speed and factors influencing speed," M. J. Park, Y. S. Kim, B. Keserci, H. Rhim, and H. K. Lim, Eur Radiol, vol. 23, no. 4, pp. 943-950, Apr. 2013. 1. Gorny KR, Woodrum DA et al. Magnetic resonance-guided focused ultrasound of uterine leiomyomas: review of a 12-month outcome of 130 clinical patients. J Vasc Interv Radiol 2011 2. Subramanian S, Clark MA, Isaacson K. Outcome and resource use associated with myomectomy. Obs & Gyn.2001; 98: 583-587 3. Nezhat FR, Roemisch M, et al. Recurrence rate after laparoscopic myomectomy. Am Assoc Gynecol Laparosc. 1998;5: 237-240 4. Rossetti et al. Long term results of laparoscopic myomectomy: recurrence rate in comparison with abdominal myomectomy. Hum Reprod. 2001;16:770-774 5. Doridot et al. Recurrence of leiomyomata after laparoscopic myomectomy. J Am Assoc Gynecol Laparosc. 2001;8: 495-500 6. Spies JB, Bruno J, et al. Long-term outcome of uterine artery embolization of leiomyomata. Obstet Gynecol. 2005; 106: 933-939 7. Goodwin SC, Spies JB, et al. Uterine artery embolization for treatment of leiomyomata: long-term outcomes from FIBROID registry. Obstet & Gynecol. 2008; 111: 22-32 8. Sharp HT. Assessment of new technology in the treatment of idiopathic menorrhagia and uterine leiomyomata. Obstet Gynecol. 2006;108: 990-1003

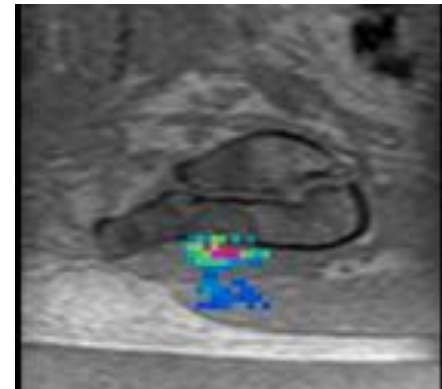
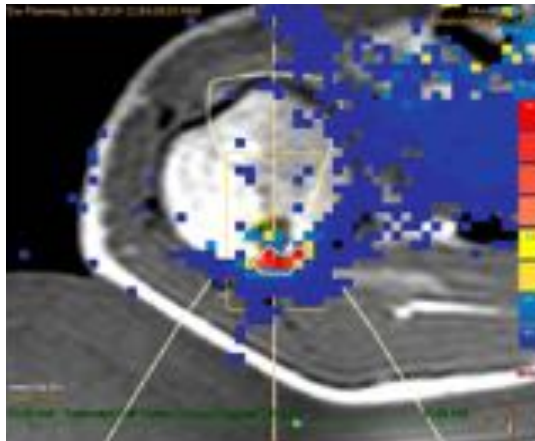
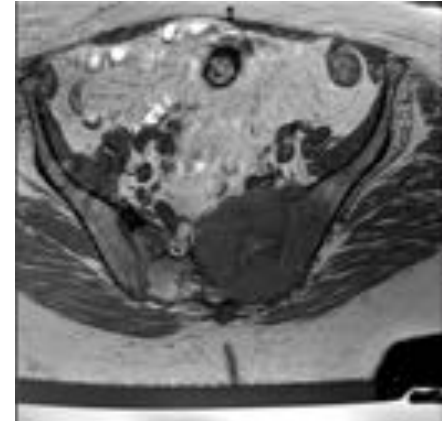
Sonalleve: Bone Metastasis Pain Therapy

Non-invasive alternative to radiotherapy

Most patients with slow growing tumors develop bone metastasis in the later stage of the disease.

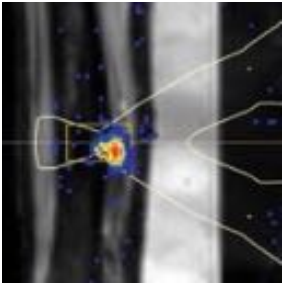
Bone changes and malformations irritate nerve endings creating significant pain for patients.

- Radiotherapy standard of care for bone mets, but 20-30% of patients do not respond
- Sonalleve as non-invasive alternative to radiotherapy
- Heating of bone surface, ablation of periosteal nerves
- Quick pain relieve in 2-3 days, vs. radiotherapy typical 3 weeks



Exploring Further Indications on Current Platform

Pediatrics, Hyperthermia



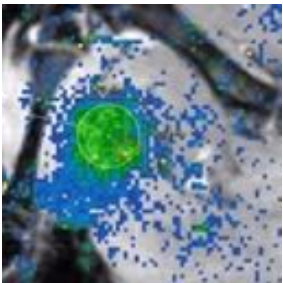
Pediatrics: Osteoid osteoma

- Very painful, benign bone tumor in children and young adults
- MR-HIFU very effective, immediate pain relief and bone restructuring
- Standard of care is radiofrequency ablation (RFA, invasive)



Pediatrics: Desmoid tumors (Fibromatosis)

- Benign aggressively growing tumors, everywhere in the body
- Can cause severe (bulk) symptoms
- Surgery (+/- radiotherapy) is standard of care, but high risk of recurrence
- Successful MR-HIFU treatments presented as individual case studies



Hyperthermia

- Increase tumor sensitivity to Radiation and Chemo Therapy
- Local heating to 40 – 43°C, precise control of temperature and lesion size
- Adjuvant therapy to chemotherapy or radiation therapy
- Enabling technology for Local Drug Delivery

Adoption Strategy

Profound Platform

TULSA-PRO

1. Pilot launch in Europe
 - Further clinical data generation
 - Confirmation of business model and value proposition
2. Complete TACT (pivotal study) clinical data set available in spring 2019
3. Full launch in US and Europe – H2, 2019
 - Submission to FDA for 510(k) – late spring 2019
 - Leverage existing agreements with Philips and Siemens for capital or new device installs
 - Build sales team to drive utilization as installed base grows

Sonalleva

1. Pilot launch in China
 - CFDA approved in May 2018
 - Leverage distribution agreement with Philips and its installed base of MR's in China
 - Initial focus – key opinion leading reference sites

Combining Two Powerful Modalities – real time MR and thermal ultrasound to create incision and radiation free interventional procedures

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Organ Removal

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Precise

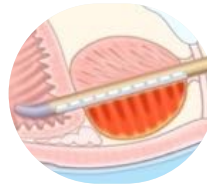
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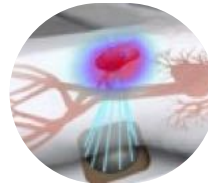


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Sonalleve



Treatment for uterine fibroids, bone metastasis, pediatric

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