

PROFOUND MEDICAL

Incisionless/Radiation-free Surgery
Real-Time MR Guided Ultrasound Therapies

CORPORATE PRESENTATION | September 2018

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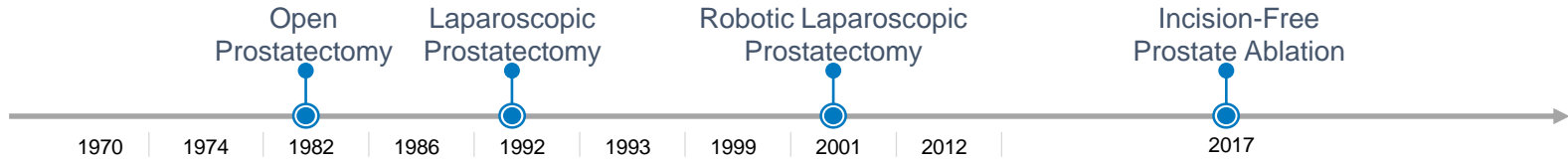
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From open surgery to incisionless/radiation-free surgery



Whole gland removal, reduced hospital stay, faster patient recovery



- Incisionless/radiation-free ablative surgery
- Surgical planning with real time imaging
- Whole gland or disease targeted partial ablation of prostate

TULSA-PRO[®]

Prostate Ablation

- CE Mark
- FDA Registration Study Recruited



Transurethral Ablation Using Thermal Ultrasound with Real-time MR Guided Controlled Dosimetry

TULSA-PRO®

Precise ablation with millimeter accuracy

- Real-Time MR Imaging, thermometry, automated process control

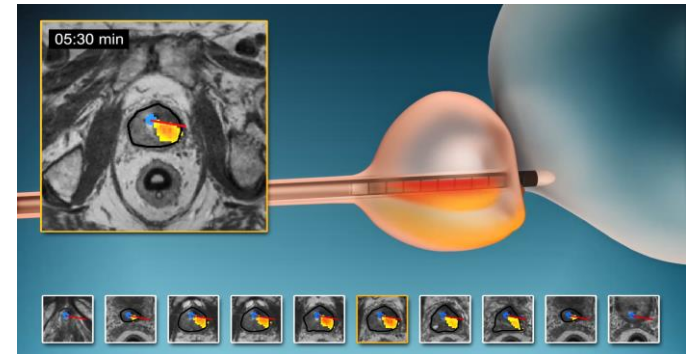
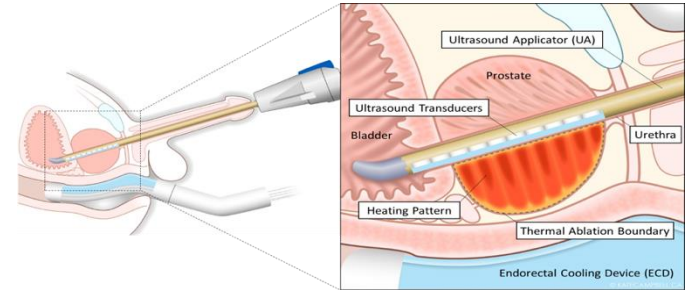
Customized treatment to meet each patients particular need

- Urologist defines region of ablation
- Full gland or targeted therapy for localized cancer
- BPH

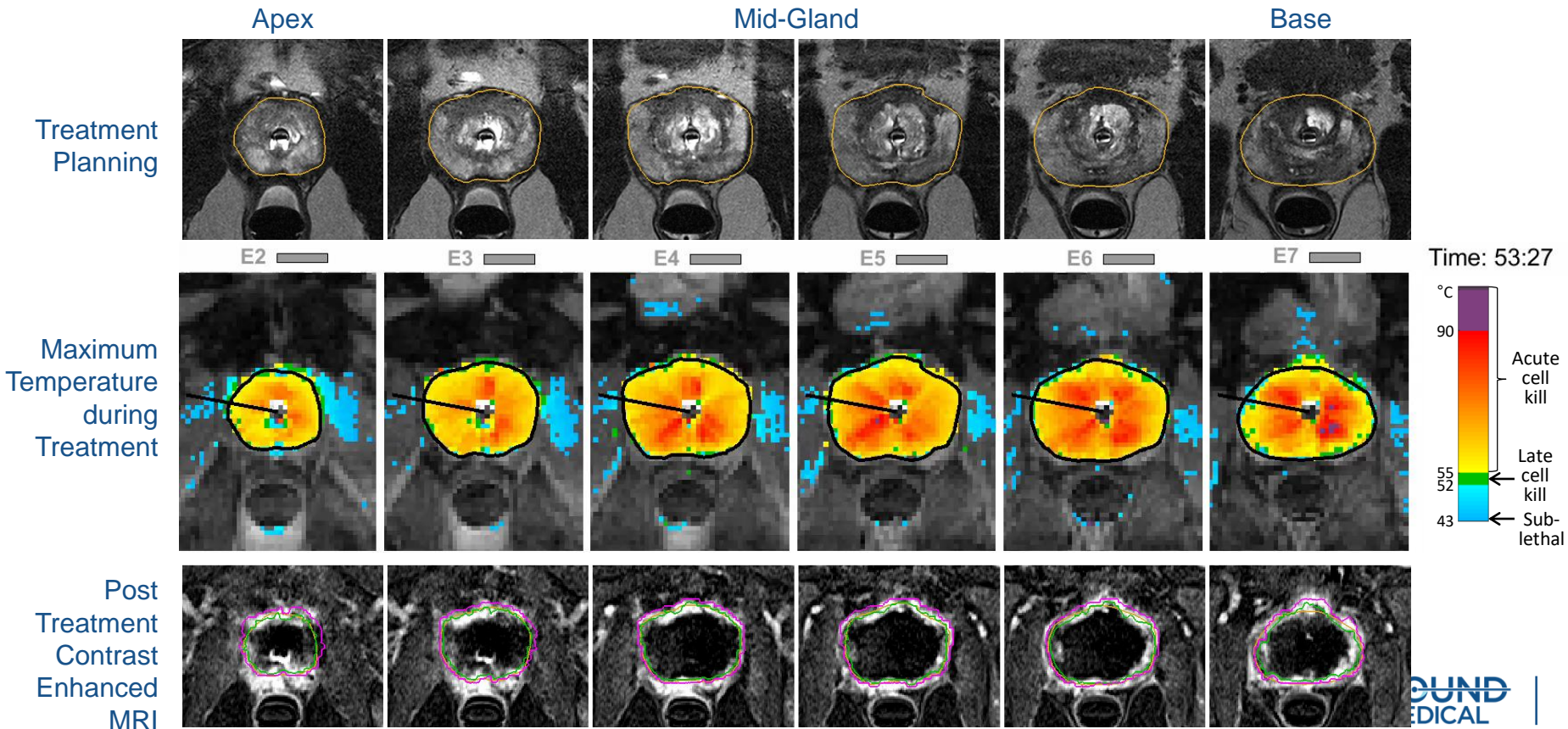
Safety by design

- Ablate from Inside-prostate; safer than outside-through rectum, able to treat prostates >140 cc
- Actively protects urethra and rectum via cooling
- MR and Ultrasound heating are safe modalities

Two hour procedure time



TULSA Procedure Case Example (Axial Images)



Profound Medical: Delivering incision free ablative therapies, customized to each patient, and delivered with precision

Transurethral Thermal Ultrasound

Unobstructed ultrasound from inside the prostate, provides for high speed ablation with minimal impact to outer organs

Real-time MR imaging

Real-time MR Imaging drives accurate treatment planning

Real-time thermometry & Controlled Thermal Dosimetry

Real-time MR thermometry delivers an accurate map of the temperature of the prostate, allow closed loop software controlled heating

Autonomous Robotics

Software guides the robotic arm - automated ablation based on real-time temperature feedback



Precision

Flexibility

Safety by design

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

To support FDA application, enrollment completion Feb 2018

Study Population: Intermediate and low risk patients, 45 – 80 years old, n=115, 13 clinical sites

Primary Endpoints

- Safety – Frequency and severity of adverse events
- Efficacy – PSA reduction $\geq 75\%$
 - Proportion of patients achieving PSA nadir $\leq 25\%$ of the pre-treatment baseline value
 - Performance goal for the success proportion is 50% of patients

Secondary Endpoints

- Prostate volume reduction on MRI at 12 months, PSA nadir – % patients with PSA ≤ 0.5 ng/ml, PSA stability – % patients with PSA ≤ 0.5 ng/ml at 12 months
- Prostate TRUS biopsy – % patients with negative biopsy at 12 months
- Erectile function – Change in % patients with IIEF-5 ≥ 17 , Erection firmness sufficient for penetration – Change in % patients with IIEF Q2 ≥ 2
- Urinary incontinence – Change in % patients using ≥ 1 pad / day
- Quality of life – IPSS, IIEF-15 & EPIC-50
- Targeting accuracy – Accuracy and precision of conformal thermal ablation of target prostate volume

TACT Pivotal Trial – Study Population

Characteristics	Planned	Actual
Enrollment	110	115
Age (years)	45 – 80 y	64 (IQR 59 – 69) y
PSA (ng/ml)	≤ 15	6.4 (IQR 5.0 – 8.3) ng/ml
Gleason Score		
6 (3 + 3)	≤ 3 + 4	45 (39%) 3+3
7 (3 + 4)		70 (61%) 3+4
D'Amico Risk		
Low risk	Low to Intermediate	39 (34%) Low-risk
Intermediate risk		76 (66%) Intermediate-risk
Targeted Prostate Volume		34 (range 15 – 88) cc
Actual Treatment Time		55 (IQR 41 – 70) min

PSA – TACT Primary Efficacy Endpoint **Successful**

Primary Efficacy Endpoint: Proportion of patients achieving PSA nadir $\leq 25\%$ of pre-tx baseline value

Hypothesis: TULSA-PRO would be of clinical interest if $> 50\%$ of patients had a PSA reduction $\geq 75\%$

N=115

- Median PSA reduction to-date is 95%
- Median PSA nadir to-date 0.36 ng/ml
- 95% of pts (109/115) meeting endpoint of $\geq 75\%$ PSA reduction

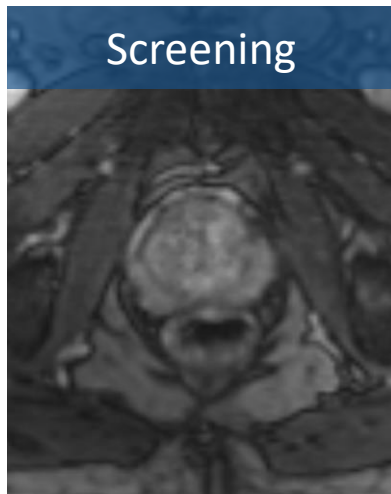
- Number of patients with 12-month QoL data is not yet large enough to assess

Case Study: TACT Pivotal Trial:

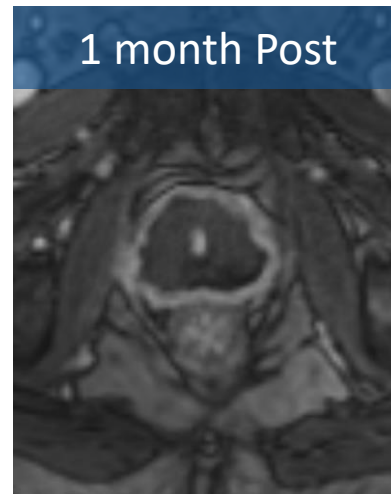
67 year old

Gleason 3+4 (L mid, R apex, R anterior)

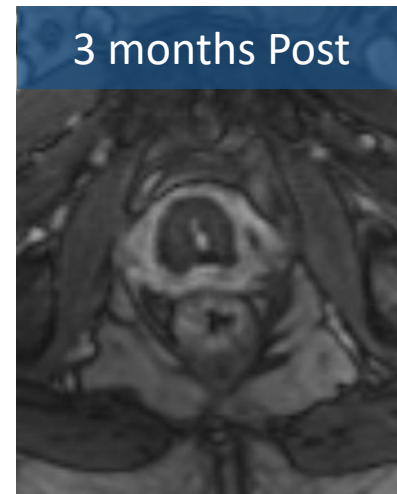
MRI-visible L mid anterior 14mm



PSA 6.0 ng/ml



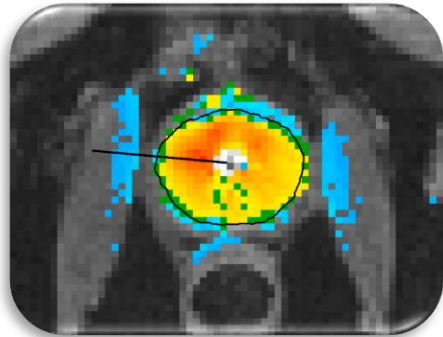
PSA 0.28 ng/ml



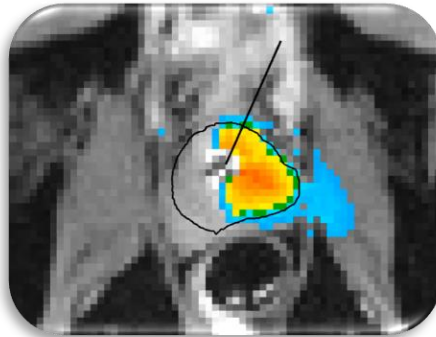
PSA 0.09 ng/ml

TULSA Flexibility – precise whole gland or customized partial gland ablation

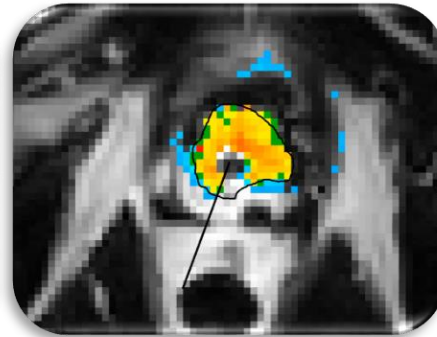
Whole Gland
Ablation



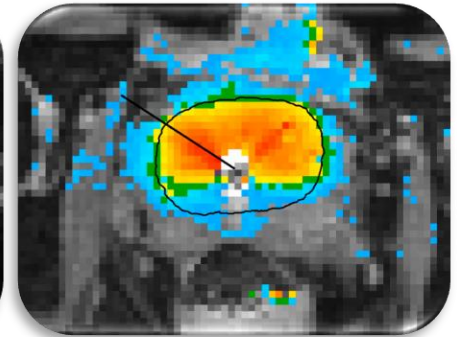
Targeted
Ablation



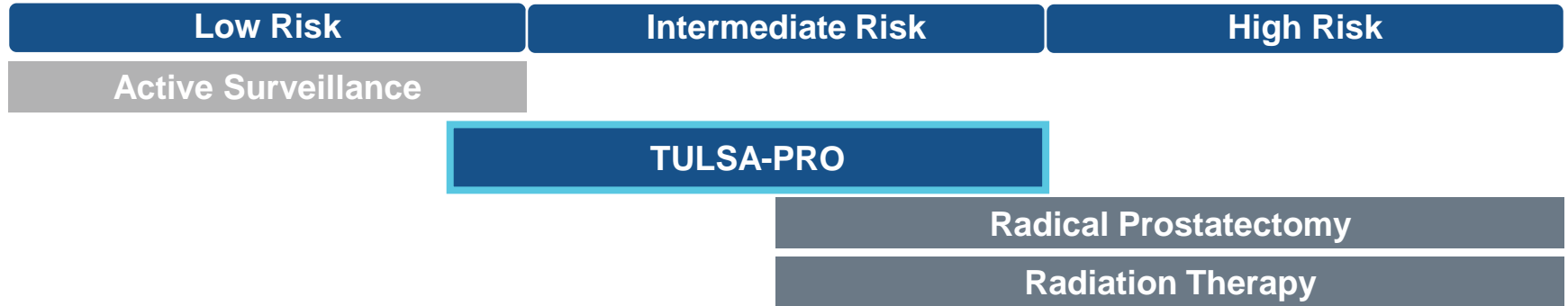
Salvage Therapy
Post Radiation
Therapy Failure



Benign Prostate
Hyperplasia (BPH)



TULSA-PRO Addressing Unmet Need – Cancerous Tissue Ablation



Unmet needs (>200,000 patients, US + EU)

1. Intermediate risk (Gleason 3+4)
2. Comorbid, surgery carries risks
3. Prostate cancer and BPH
4. Failed radiation treatment requiring salvage therapy
5. Genetic testing indicates aggressive disease

TULSA does not preclude any additional intervention if needed in the future

TULSA-PRO Addressing Unmet Need – BPH Tissue Ablation

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

1. Patients with large (>80cc) prostates, 35% of BPH patients
2. Intermediate or late stage disease
3. Patients with both cancerous and BPH tissue

TULSA does not preclude any additional intervention if needed in the future

TULSA-PRO Value Proposition

1. Recurring revenue business model
2. Positioning – Whole gland or customized partial gland treatment
 - Precise
 - Typically day procedures, 2 to 2.5 hours
 - Short recovery, minimal post procedure pain or side effects
3. Market adoption economic plan
 - Robust patient self-pay model, immediately upon receiving 510(K)
 - Regional or patient specific private payor reimbursement
 - National coverage based upon Level 1 study



Sonalleve®

PROFOUND
MEDICAL

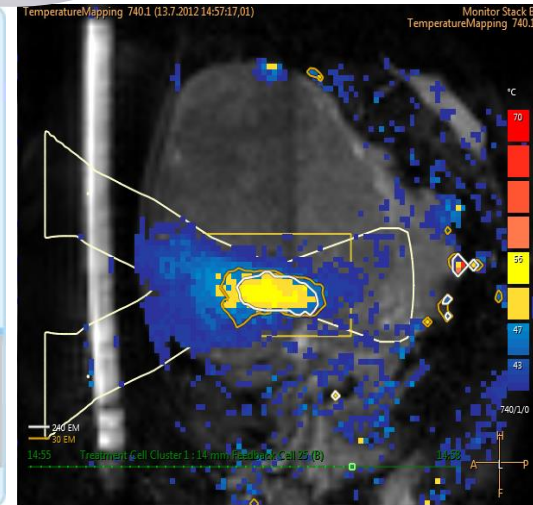
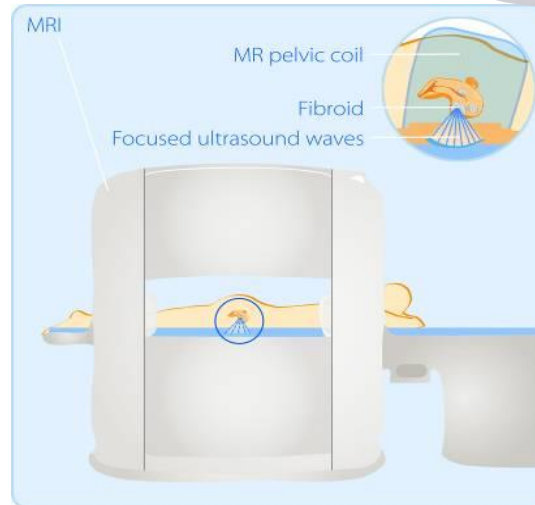
SONALLEVE

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

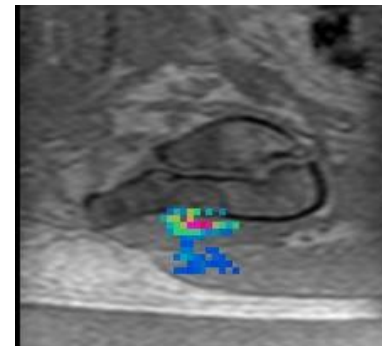
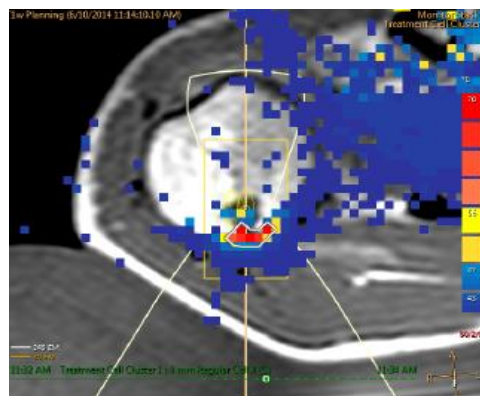
"Volumetric MR-guided high-intensity focused ultrasound ablation of uterine fibroids: treatment speed and factors influencing speed," M. J. Park, Y. S. Kim, B. Keserci, H. Rhim, and H. K. Lim, Eur Radiol, vol. 23, no. 4, pp. 943–950, Apr. 2013. 1. Gorny KR, Woodrum DA et al. Magnetic resonance-guided 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

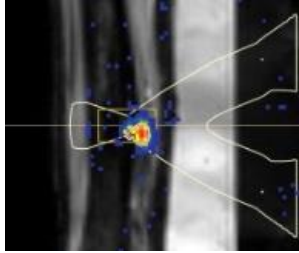
Most patients with slow growing tumors develop bone metastasis in the later stage of the disease. Bone changes and malformations irritate nerve endings creating significant pain for patients.

- 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



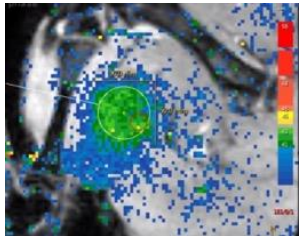
Pediatrics: Osteoid osteoma

- 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

Sonalleve Value Proposition

1. Capital/Recurring revenue business model
2. Positioning
 - Patented technology that enables ablation of large fibroids
 - Typically day procedures, 2.5 to 3.5 hours
 - Short recovery, minimal post procedure pain or side effects
3. Market adoption economic plan
 - Initial focus on China
 - Robust patient self-pay model

Profound Medical

– About disease treatment not organ removal

Incision-free/Radiation-free Procedures

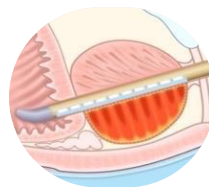
Real-Time MR guided

1 **Precise**

2 **Flexible**

3 **Safe**

TULSA-PRO®

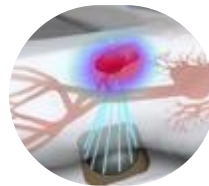


Treatment for prostate disease

- CE marked
- FDA expected H2-2019



Sonalleve

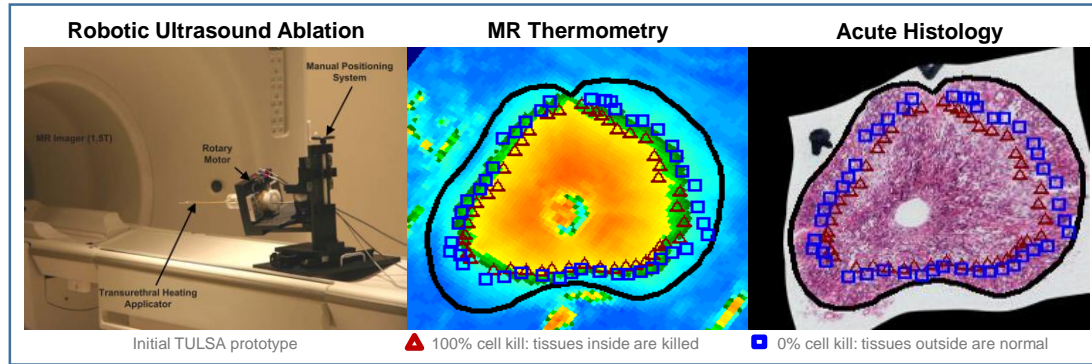


Treatment for uterine fibroids, bone metastasis, pediatric

- CE marked
- China FDA approved for uterine fibroids

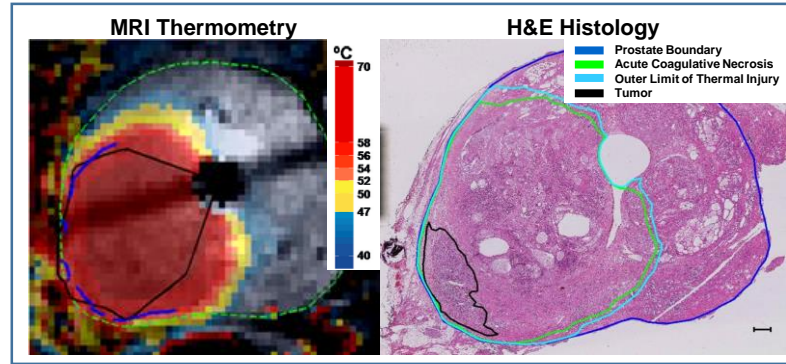
TULSA – Backup Slides

TULSA – Technical & Canine Studies



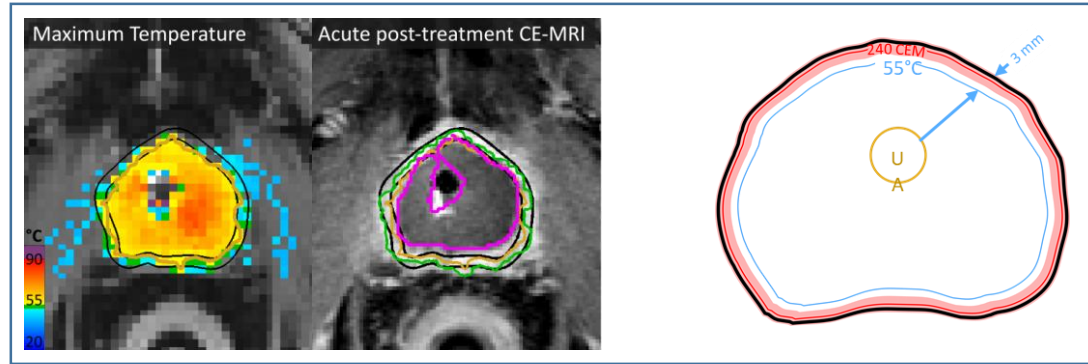
- In vivo evaluation of MRI-compatible robotics, directional US applicators, MRI thermometry, and feedback control algorithm
- Millimeter ablation accuracy on histology
- Urethra spared, no unintended damage on 28d histology

TULSA – Treat & Resect for Targeted Ablation



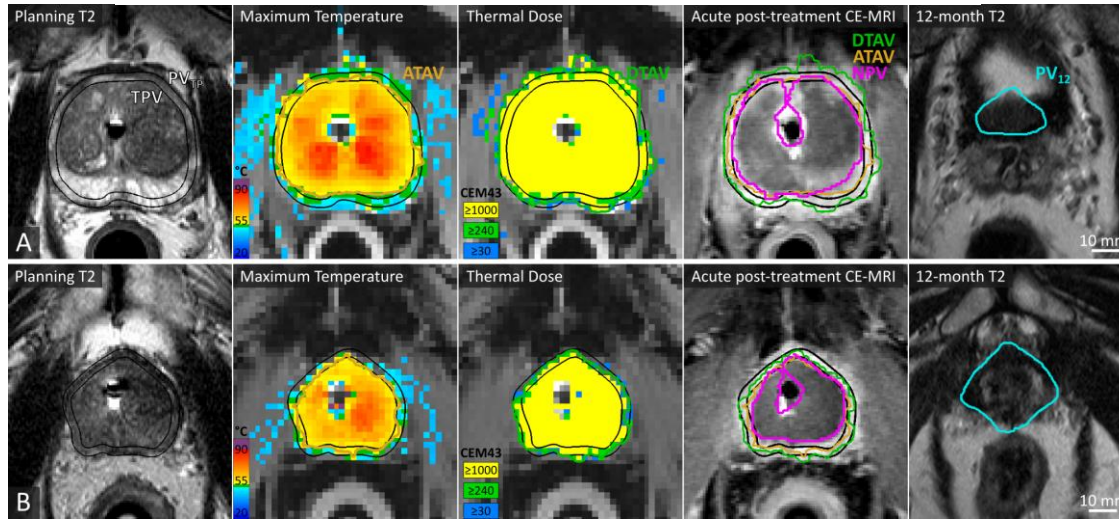
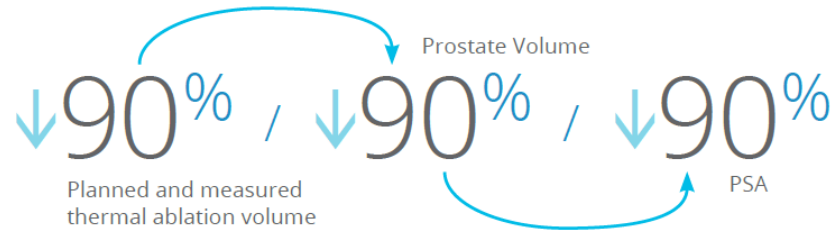
- 5 treat-and-resect patients with whole-mount histology
- Targeting to mpMRI-visible lesion identified during TULSA treatment
- Millimeter ablation precision on histology
- All index tumors within complete tissue ablation zone

Phase I – 90% Ablation for Safety & Precision



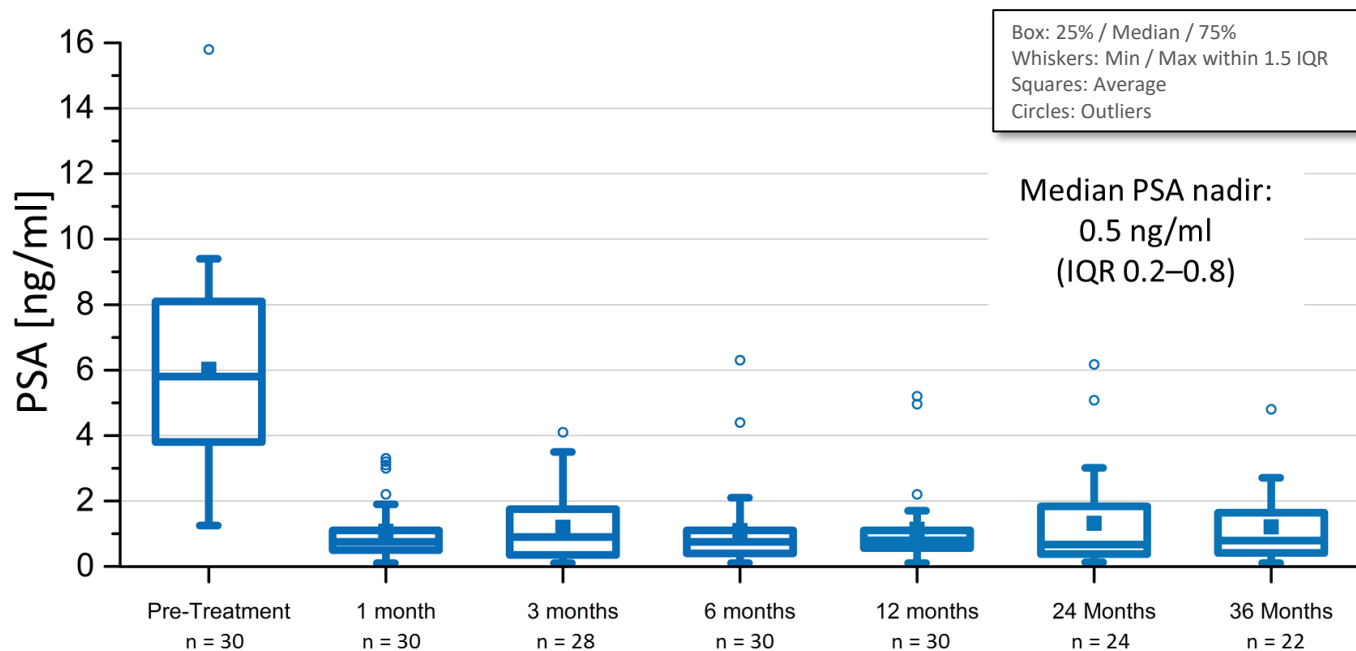
- 30 patients with 3-year follow-up
- 90% ablation with 3 mm margin designed to measure precision
- Demonstrated favorable safety profile with minor impact on QOL
- Millimeter ablation precision on MR thermometry
- **PSA and prostate volume reduction** match **planned** target volume and **measured** thermal ablation volume (90% of the gland)

Phase I: Correlation of Thermal Ablation to Prostate Volume & PSA reduction

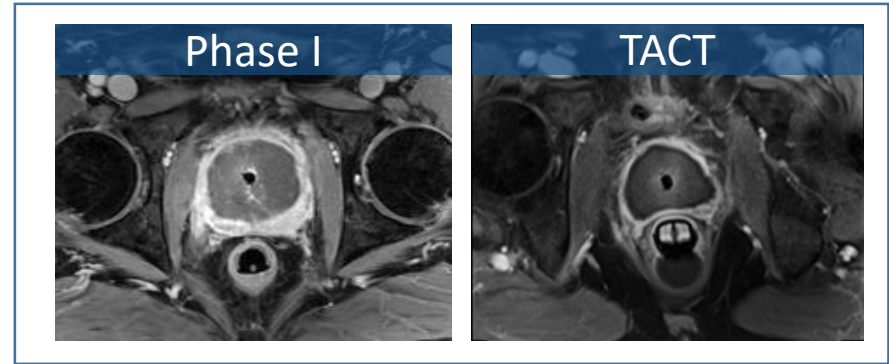


Phase I Ablation Efficacy: PSA

- PSA reduction in agreement with treatment plan
- Decreased 90% to nadir and stable to 36 months



TULSA – TACT – Pivotal Study, Whole Gland Ablation to Capsule



- 115 patients, Gleason 3+3 & 3+4, 45 - 80 years old
- 13 clinical sites
- Millimeter ablation precision on MR thermometry
- Expected 12 month full data release Q1 2019