

PROFOUND MEDICAL

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

CORPORATE PRESENTATION | October 2018

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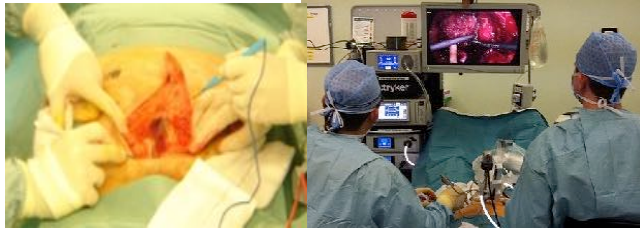
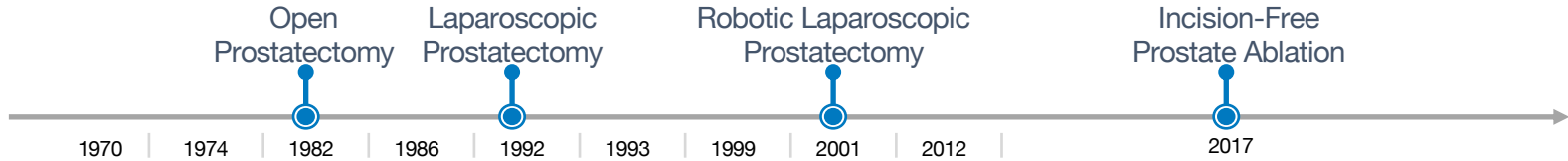
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From open surgery to incisionless/radiation-free surgery



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

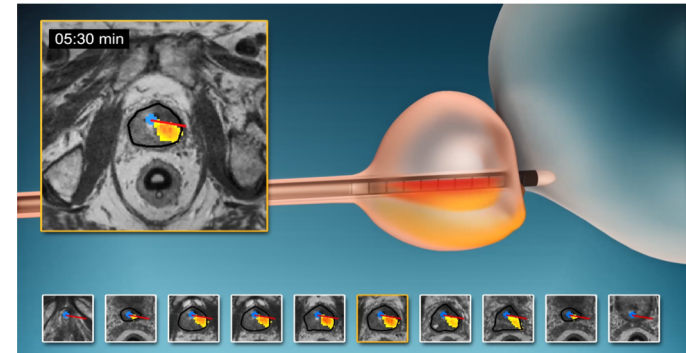
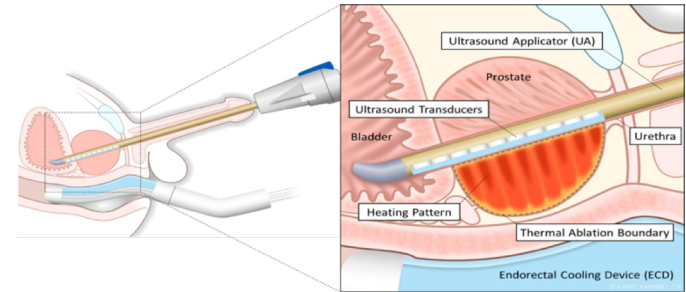
Customized treatment to meet each patients particular need

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

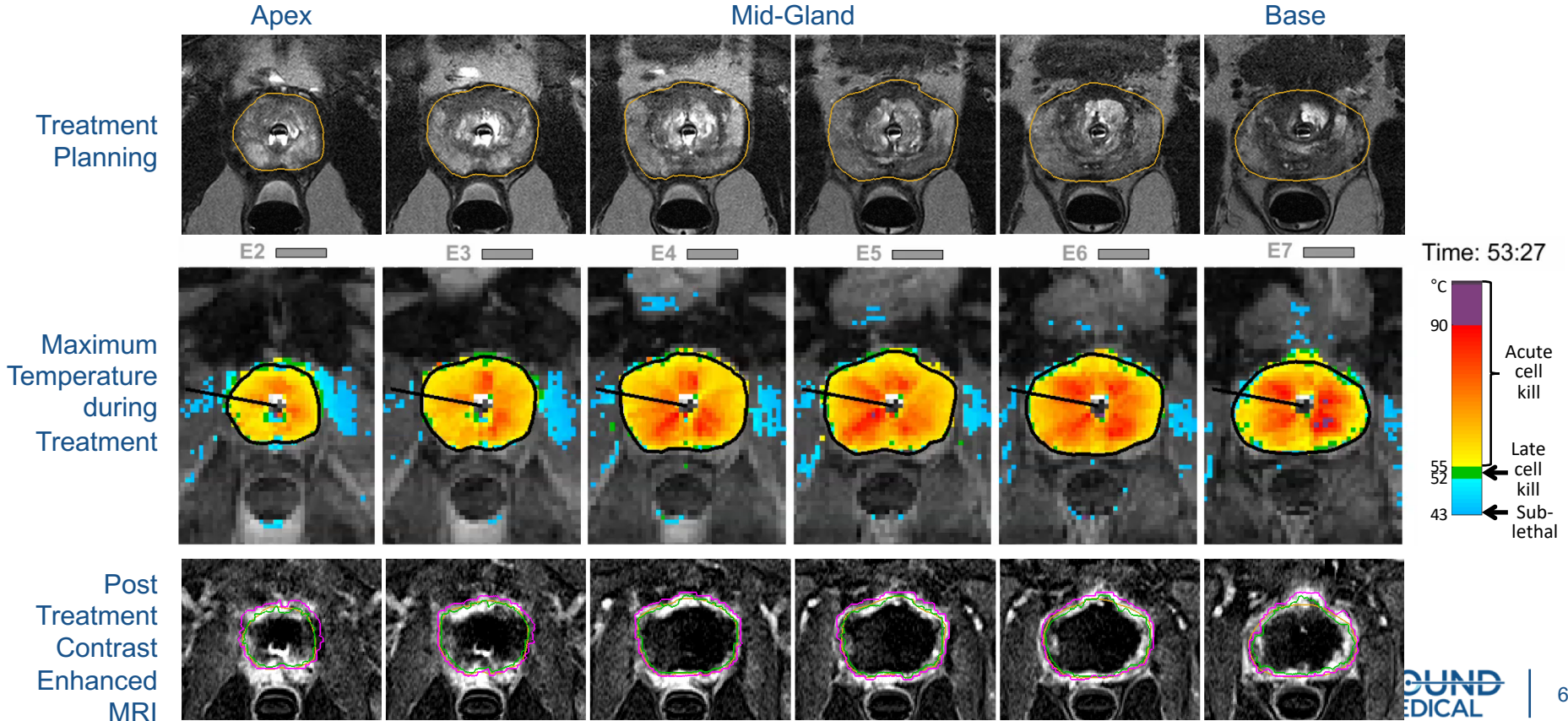
Safety by design

- 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

- 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

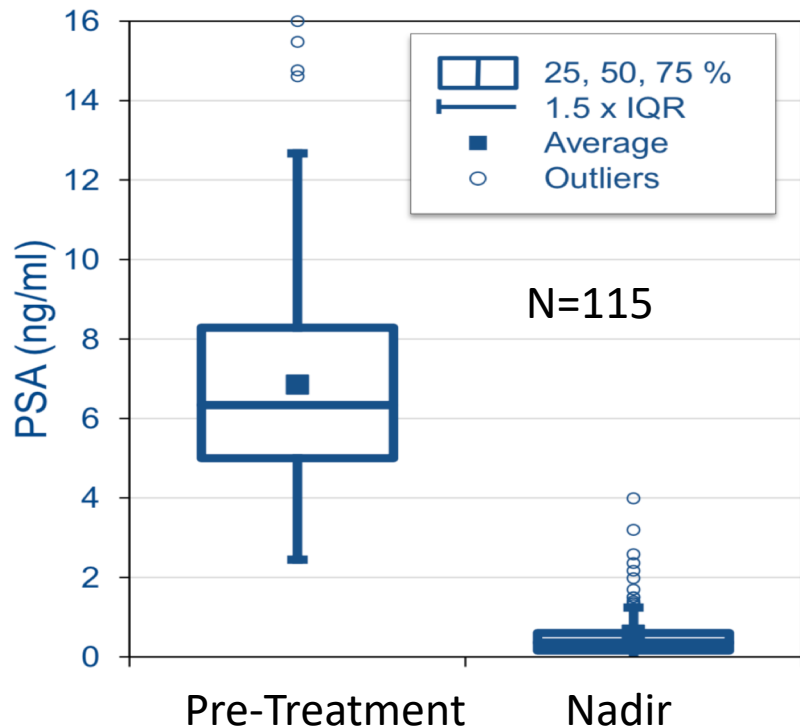


TACT Pivotal Trial – Study Population

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

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:

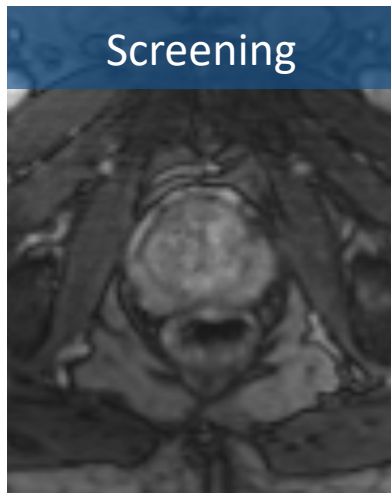
- No rectal injury, No Grade \geq 4 AE, No incontinence > Grade 1
- Attributable Serious AE in 7% of patients, all resolved: 3 G2 retention, 3 G3 infection, 1 urinoma, 1 ileus, 1 DVT

Case Study: TACT Pivotal Trial:

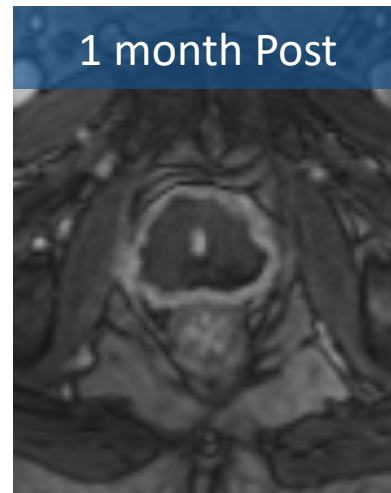
67 year old

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

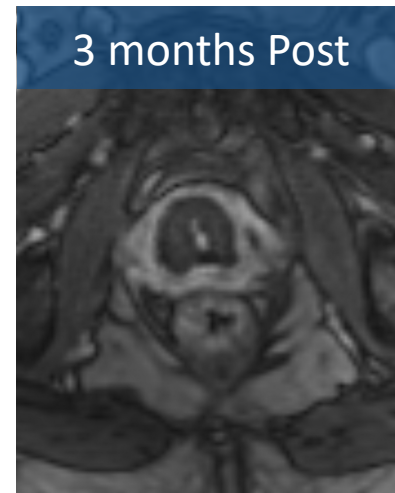
MRI-visible L mid anterior 14mm



PSA 6.0 ng/ml



PSA 0.28 ng/ml

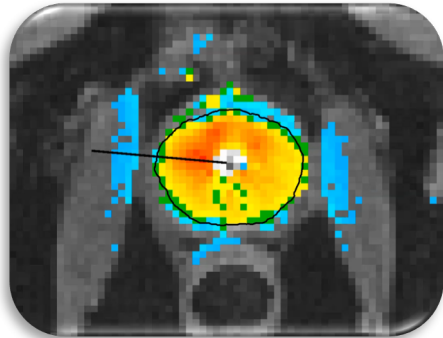


PSA 0.09 ng/ml

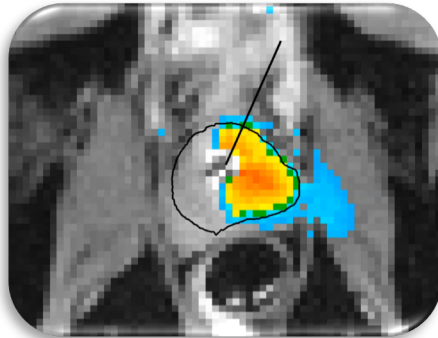
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TULSA Flexibility – precise whole gland or customized partial gland ablation

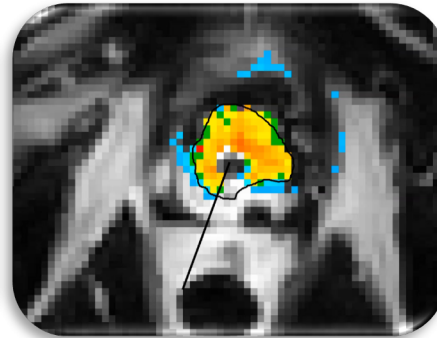
Whole Gland
Ablation



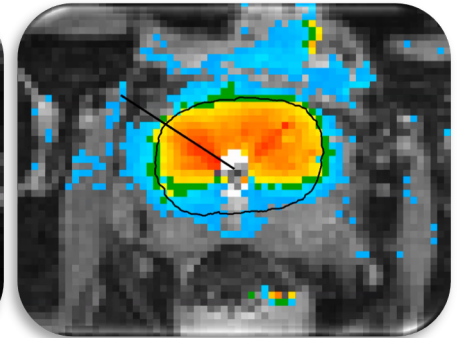
Targeted
Ablation



Salvage Therapy
Post Radiation
Therapy Failure



Benign Prostate
Hyperplasia (BPH)



TULSA-PRO Addressing Unmet Need – Cancerous Tissue Ablation

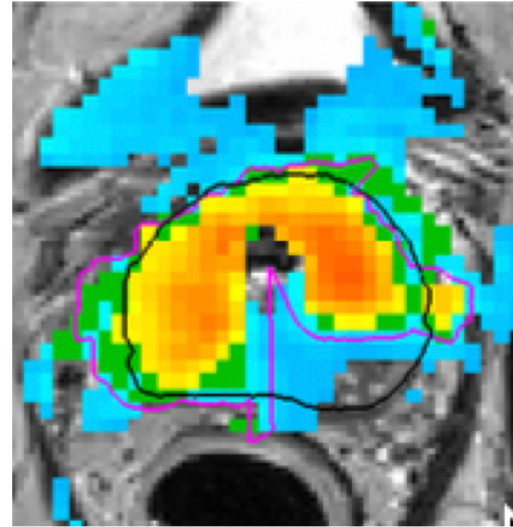
1. Organ confined disease, intermediate stage (200,000 patients in US+EU)
 - Full prostate ablation
 - Partial prostate ablation
2. Failed radiation patients requiring salvage therapy (10,000 patients in US+EU)
Potential best in class option
3. Palliative care patients (20,000 patients in US+EU)
Eliminate symptoms such as blood loss and enable of natural urination

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



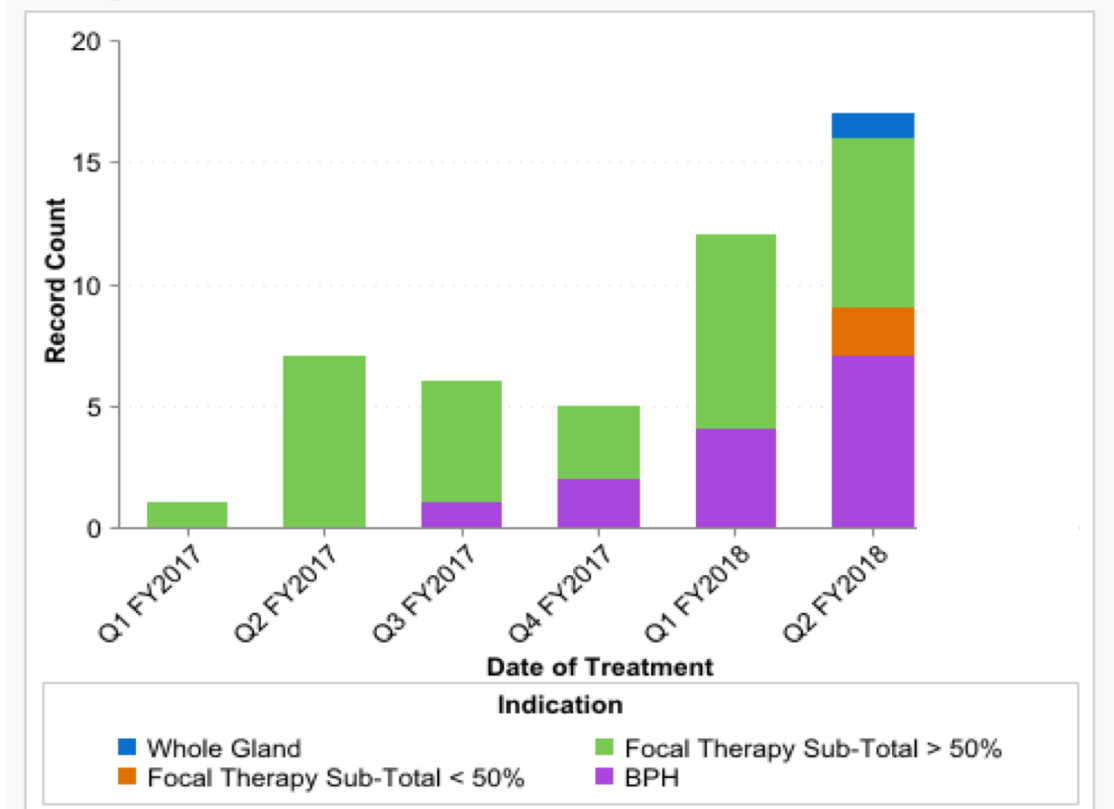
Patient with BPH and early stage lesion

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

TULSA-PRO Case Study – Pilot Launch In Europe

- 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 – 3 cases /day



A photograph of a family in a nursery. A man and a woman are sitting on a grey shag rug, holding a baby who is playing with colorful rings. The man is holding a ring, and the woman is holding the baby. The nursery has white furniture, a white crib, and colorful wall decals of a tree, owls, and birds. A blue semi-transparent banner is overlaid on the left side of the image.

Sonalleve®

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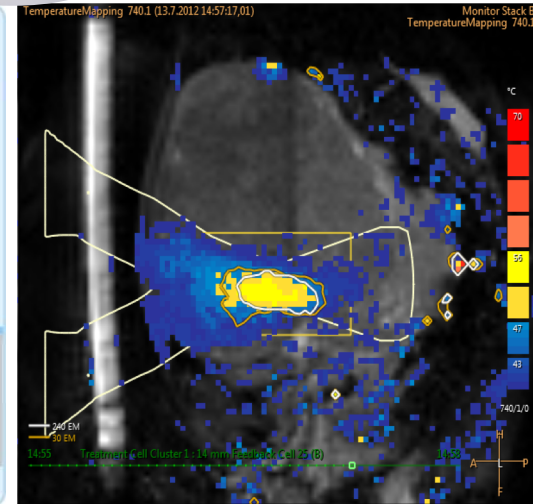
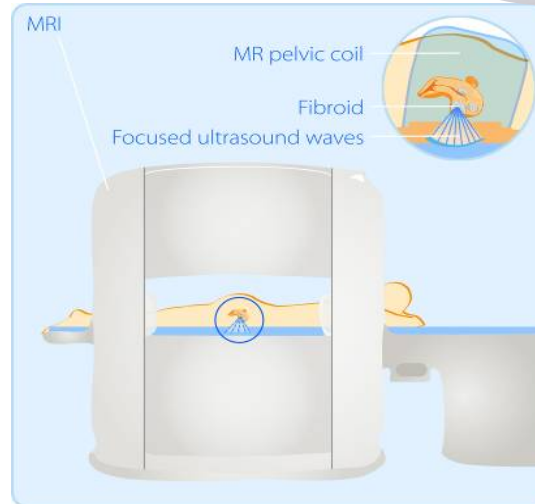
SONALLEVE

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

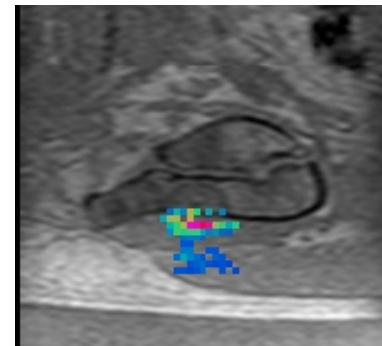
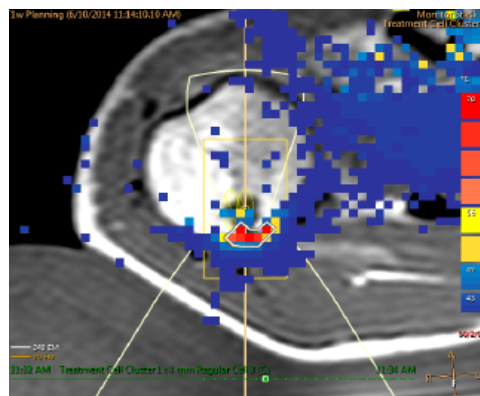
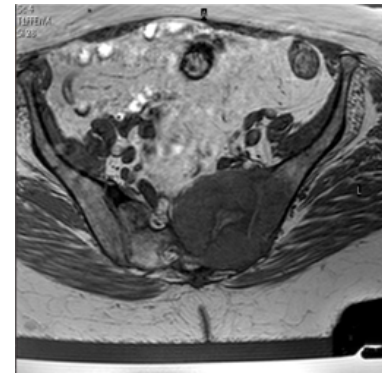
"Volumetric MR-guided high-intensity focused ultrasound ablation of uterine fibroids: treatment speed and factors influencing speed," M. J. Park, Y. S. Kim, B. Keserci, H. Rhim, and H. K. Lim, Eur Radiol, vol. 23, no. 4, pp. 943–950, Apr. 2013. 1. Gorny KR, Woodrum DA et al. Magnetic resonance-guided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

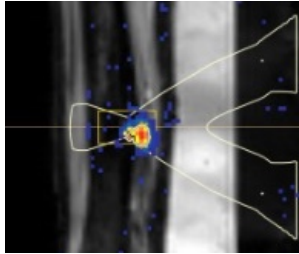
Most patients with slow growing tumors develop bone metastasis in the later stage of the disease. Bone changes and malformations irritate nerve endings creating significant pain for patients.

- 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



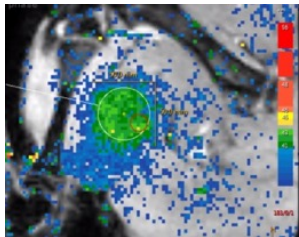
Pediatrics: Osteoid osteoma

- 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

Product Adoption Strategy

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

Profound Medical

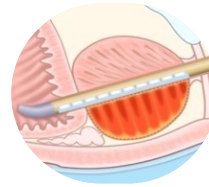
– About disease treatment not organ removal

Incision-free/Radiation-free Procedures

Real-Time MR guided

- 1 **Precise**
- 2 **Flexible**
- 3 **Safe**

TULSA-PRO®

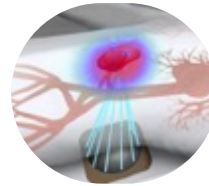


Treatment for prostate disease

- CE marked
- FDA expected H2-2019



Sonalleve



Treatment for uterine fibroids, bone metastasis, pediatric

- CE marked
- China FDA approved for uterine fibroids