

PROFOUND MEDICAL

Incision-free Surgery
Real-Time MR Guided Ultrasound Therapies

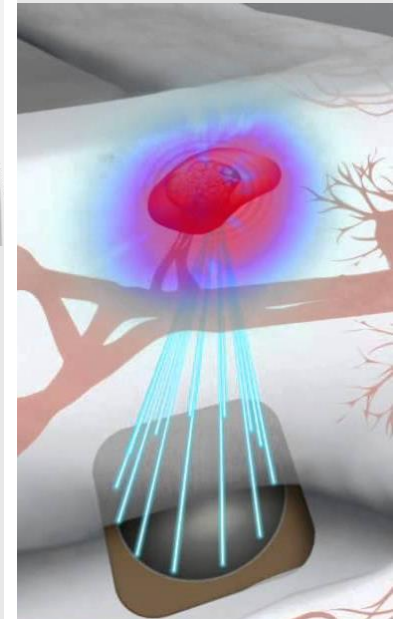


TULSA-PRO®

Prostate Disease

 Sonalleve®

MRgFUS
Uterine Fibroids



CORPORATE PRESENTATION | OCTOBER 2017

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INCISION-FREE PROCEDURES

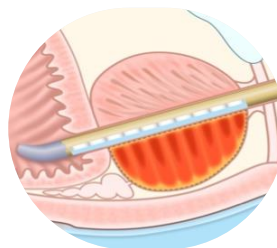
REAL-TIME MR GUIDED TREATMENTS



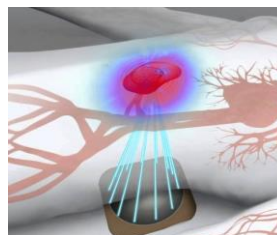
Real-Time
MR Imaging



Energy
Source



Ultrasound 'Inside-Out'

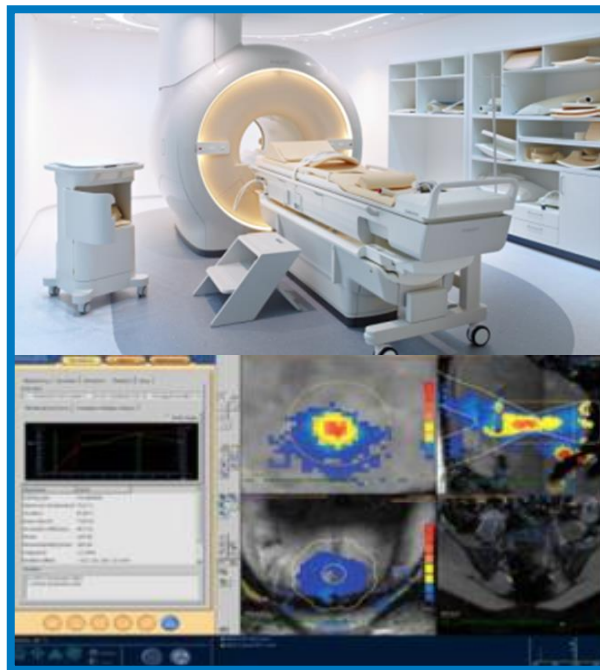
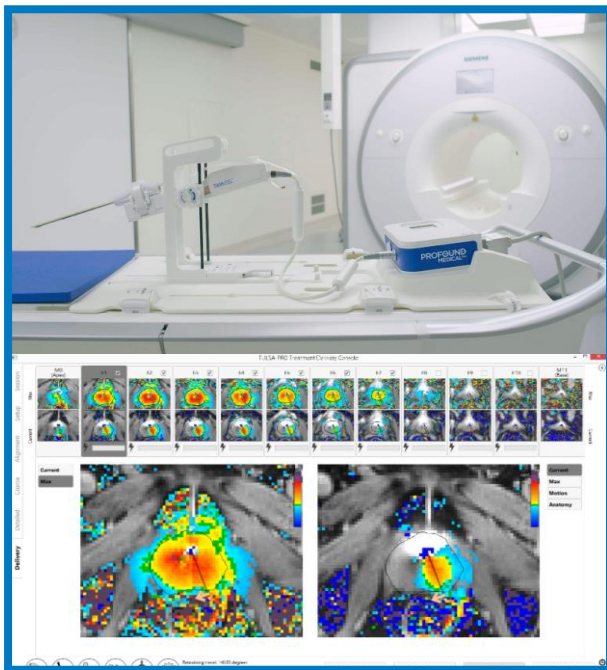


Ultrasound 'Outside-In'

Only company to provide a therapeutics platform that provides the precision of real-time MR imaging combined with the safety and ablation power of directional (inside-out) and focused (outside-in) ultrasound technology for the incision-free ablation of diseased tissue

TULSA-PRO & SONALLEVE

BEST-IN-CLASS PLATFORM: REAL-TIME MR THERMOMETRY AND CLOSED LOOP TEMPERATURE CONTROL



- Current applications – Prostate (TULSA-PRO only), uterine fibroids & bone metastases (Sonalleve only)
- Future potential – Abdominal cancers, hyperthermia for cancer therapy, pediatrics

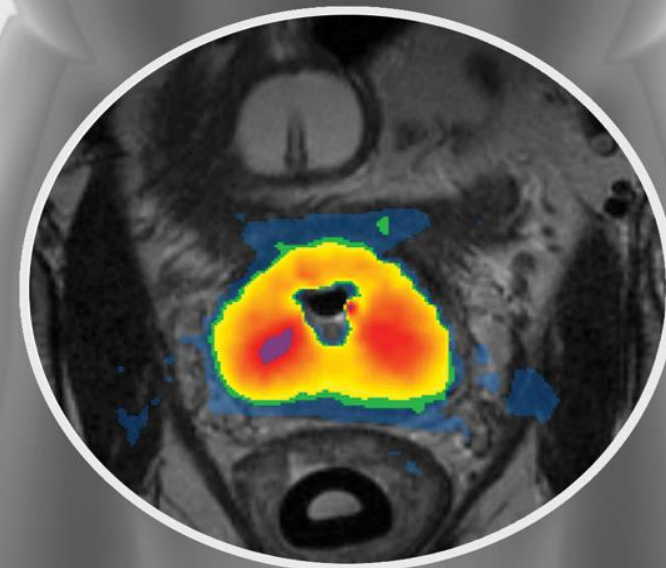
INCISION-FREE PROCEDURES

REAL-TIME MR GUIDED TREATMENTS

Therapeutic solutions that are

- 1 **Precise**
- 2 **Personalized**
- 3 **One and done**

Prostate Treatment



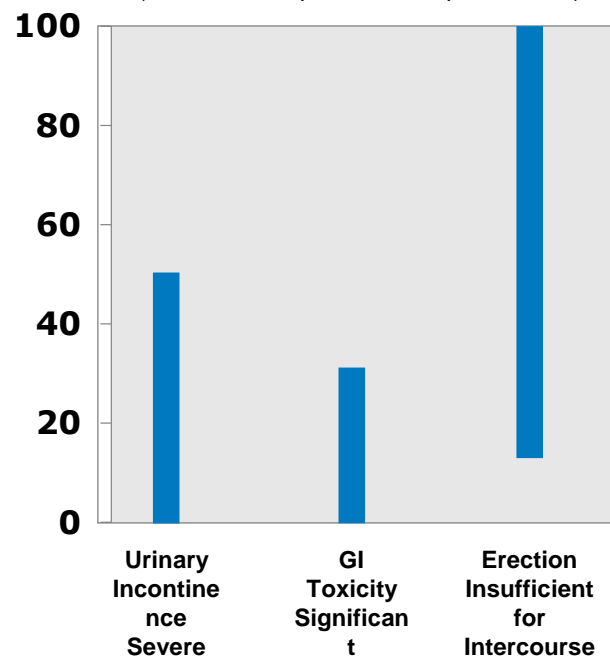
TODAY'S THERAPIES

SIDE EFFECTS

Functional Outcomes at 2 years¹

	PROSTATECTOMY	RADIOTHERAPY
URINARY INCONTINENCE	No control or frequent urinary leakage	
	10%	3%
	Bothered by dripping or leaking urine	
	11%	2%
BOWEL FUNCTION	Bowel urgency	
	14%	34%
	Bothered by frequent bowel movements, pain, or urgency	
	3%	8%
SEXUAL FUNCTION	Erection insufficient for intercourse	
	79%	61%
	Bothered by sexual dysfunction	
	56%	48%

Rate of complications reported with radical prostatectomy & radiotherapy^{2,3}
(Variation as reported in 436 publications)



1. Resnick et al. Long-Term Functional Outcomes after Treatment for Localized Prostate Cancer; New England Journal of Medicine, 2013 (Jan): 368:436-4452.
2. Thompson (Chair) et al AUA prostate cancer clinical guideline update panel, "Guideline for the management of clinically localized prostate cancer: 2007 update," The Journal of Urology, 177: 2106-2331 (2007)3.
3. PMI 12-month Phase 1 Trial, GCP-10102 Table 10

TULSA-PRO EQUIPMENT

Compatible with MR from leading companies – Philips and Siemens



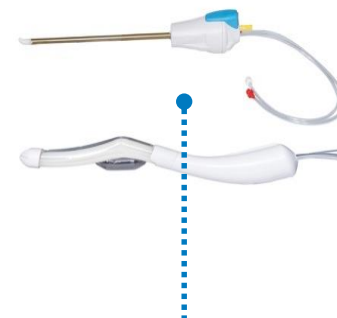
**Robotic Arm,
Computer Hardware**



**Energy
System**



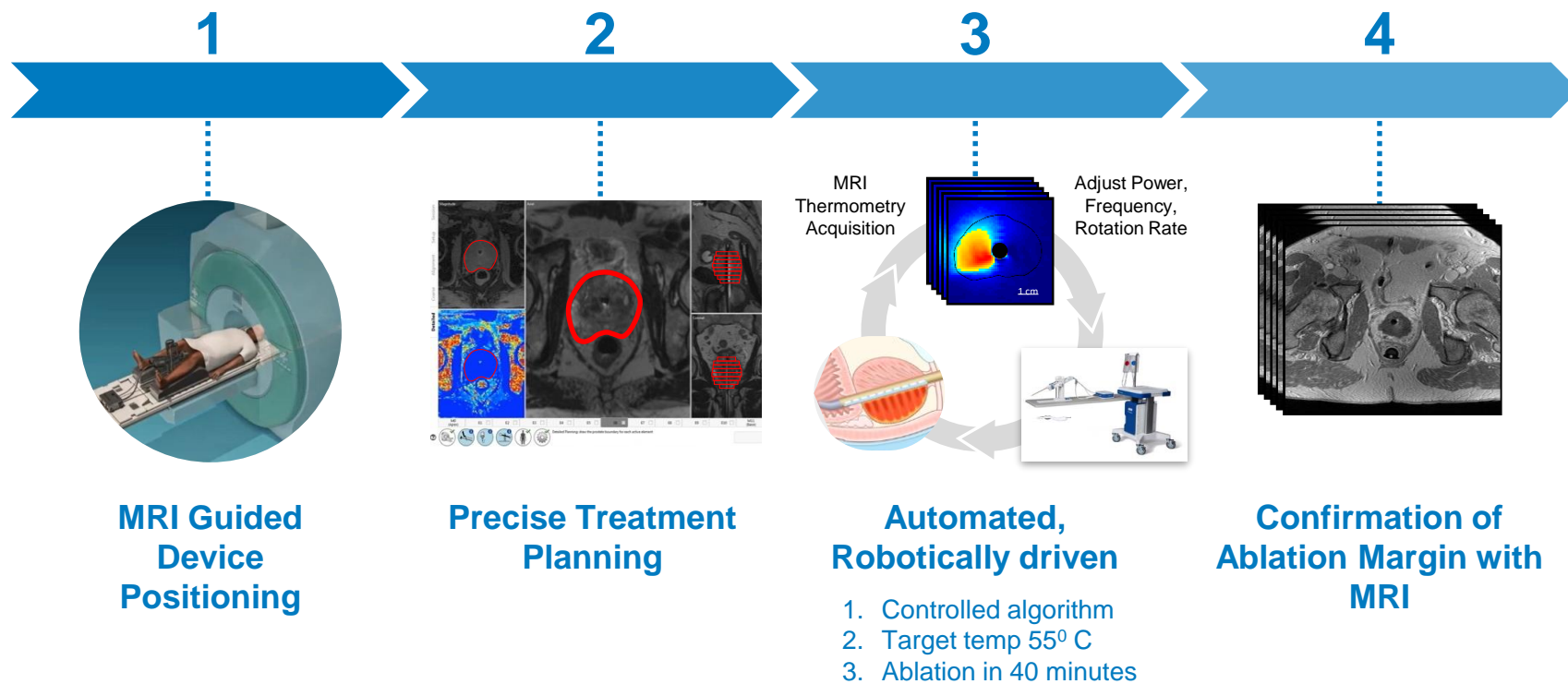
**Surgeon Console
Control Room**



**Disposable
Applicators**

UNIQUE INSIDE-OUT APPROACH

PROSTATE TREATMENT

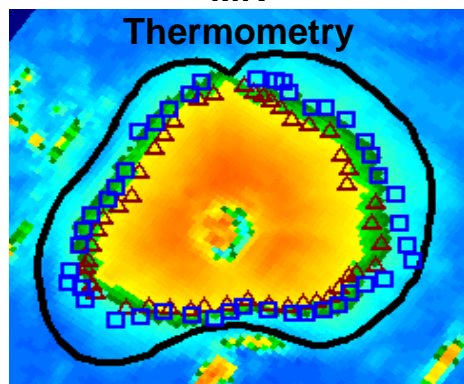


TULSA-PRO'S PRECISION & PERSONALIZATION

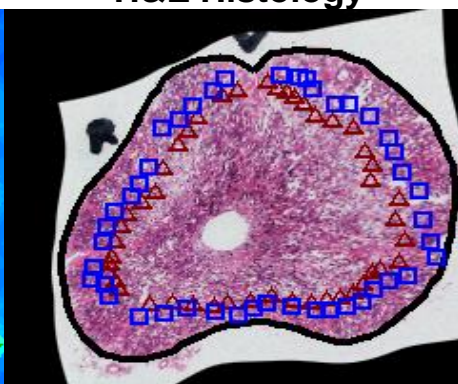
VALIDATED

- Excellent agreement between MR Thermometry and H&E Histology: 1.4 ± 1.0 mm
- Sharp treatment margins: 1.3 ± 0.5 mm (acute), decreases to zero after 48h+

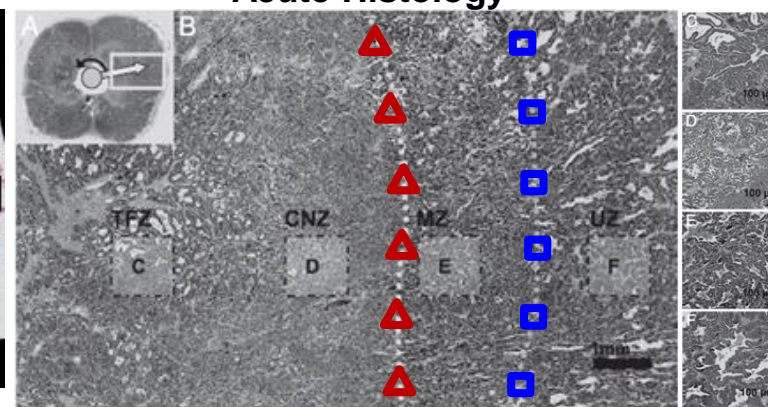
MR



H&E Histology



Acute Histology



Thermally Fixed

Coagulative Necrosis

Margin

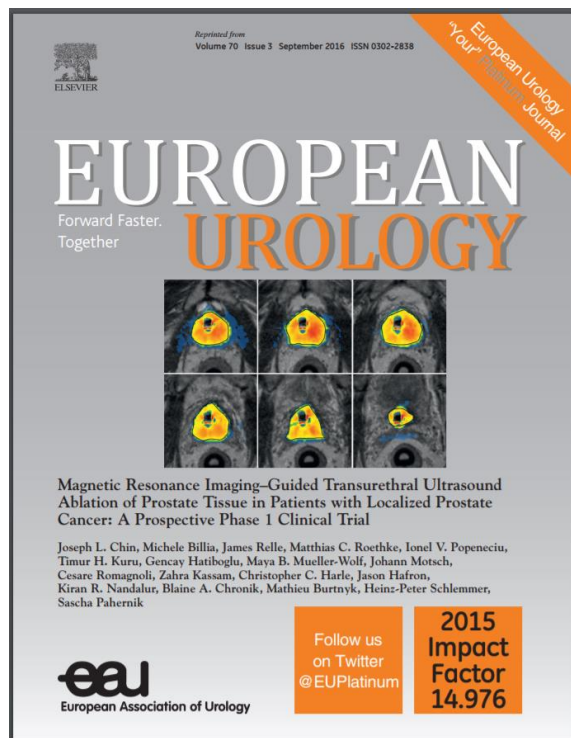
Untreated

- ▲ 100% cell kill: All tissues inside are killed
- 0% cell kill: All tissues outside are untreated/normal

Boyes et al (2007) J Urol 178(3 Pt 1):1080-5; Chopra et al (2009) Phys Med Biol 54(9):2615-33; Siddiqui et al (2010) Urology 76(6):1506-11; Chopra et al (2012) Radiology 265(1):303-13; Burtnyk et al (2015) J Urol 193(5):1669-75; Ramsay et al, (2017) J Urol 197(1):255-261

PHASE I CLINICAL TRIAL COMPLETED

SAFETY & FEASIBILITY



Chin *et al*, European Urology (2016)
Bonekamp *et al*, Radiology (submitted)

Study Population

- Low (80%) & intermediate (20%) risk prostate cancer patients, ≥ 65 years old (n=30)

Treatment Plan

- Imposed treatment margin, with 10% residual viable prostate around gland periphery

Primary Endpoints & Outcomes

- Safety – Frequency and severity of adverse events
 - Erectile function (erection firmness sufficient for penetration, IIEF Item 2 ≥ 2)
21/30 patients potent pre-treatment \rightarrow 20/29 potent at 12 months
 - Urinary incontinence (pads): 0/30 patients at 12 months
 - No rectal fistula or bowel urgency
- Feasibility – Conformal thermal ablation of target prostate volume
 - Median ultrasound treatment time: 36 min for 44 cc prostate volume
 - Median thermal ablation accuracy and precision: 0.1 ± 1.3 mm

Secondary Endpoints & Outcomes

- Quality of life – IPSS, IIEF, UCLA-PCI-SF
 - Well-tolerated favorable safety profile with minor impact on urinary, erectile and bowel function at 12 months
- Prostate volume – 88% reduction at 12 months
- PSA – 87% decrease at 1 month, remained stable to 0.8 ng/ml at 12 months
- Prostate TRUS Biopsy
 - Positive clinically significant cancer: 9/29 patients (31%)
 - Positive any cancer: 16/29 (55%)
 - Positive biopsies had 61% reduction in total cancer length

TACT PIVOTAL STUDY FOR FDA 510(k) REGISTRATION

IN PROGRESS – N=110, Thirteen Sites, Treated 62

Study Population

- Low & intermediate risk prostate cancer patients, 45 – 80 years old

Treatment Plan

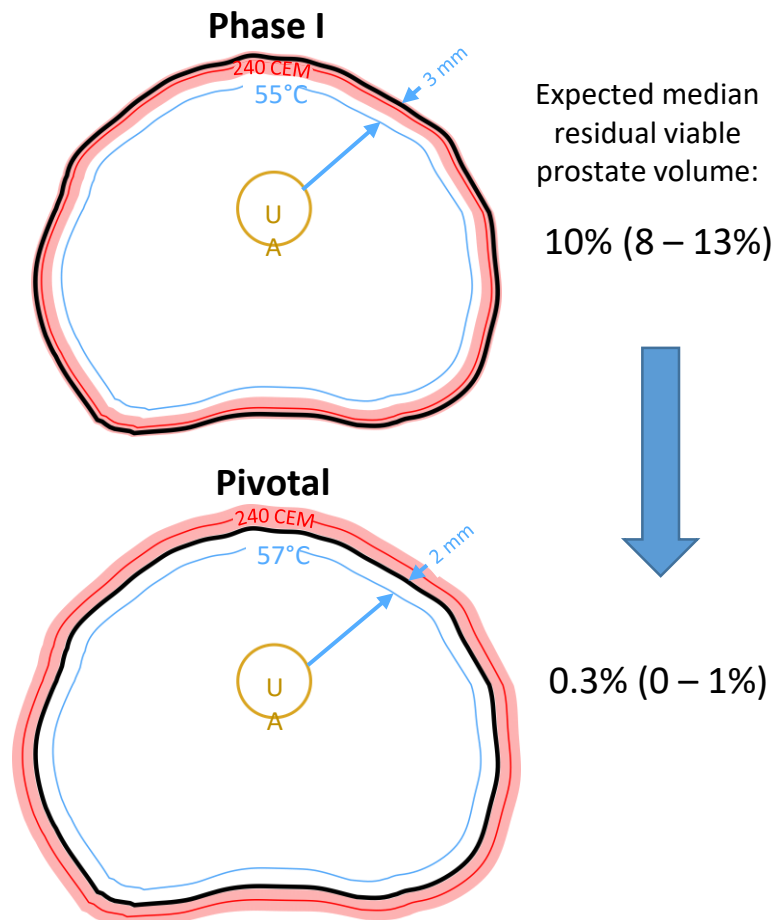
- Reduced margin, with < 1% residual viable prostate around gland periphery

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 & stability – % patients with PSA ≤ 0.5 ng/ml at nadir & 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 item 2 ≥ 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

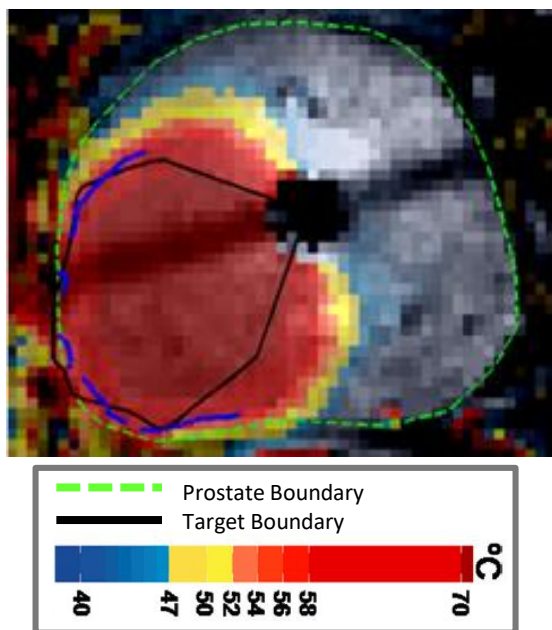


TARGETED ABLATION (FOCAL THERAPY)

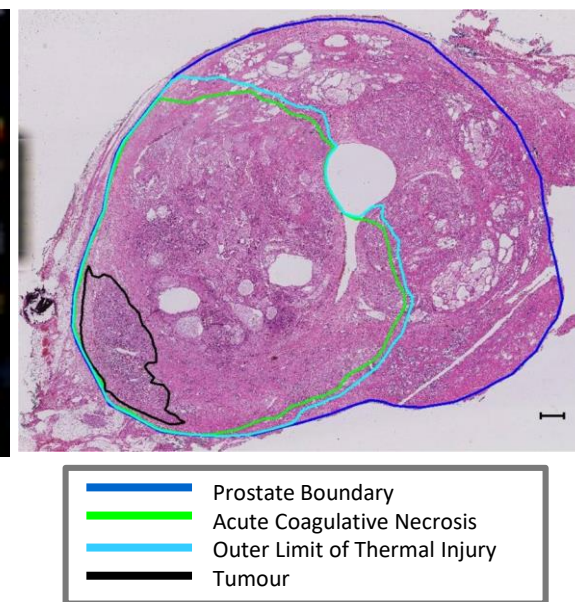
CLINICAL HISTOLOGY

- Treat-and-resect clinical study, targeting MRI-visible lesion with TULSA (n=5)
- TULSA followed by Radical Prostatectomy on same day
- Demonstrated complete ablation of target lesion to prostate capsule on gold-standard whole-mount histology
- Treatment accuracy with respect to histology: -0.4 ± 1.7 mm
- All index tumors were inside the histological outer limit of thermal injury

MRI Thermometry

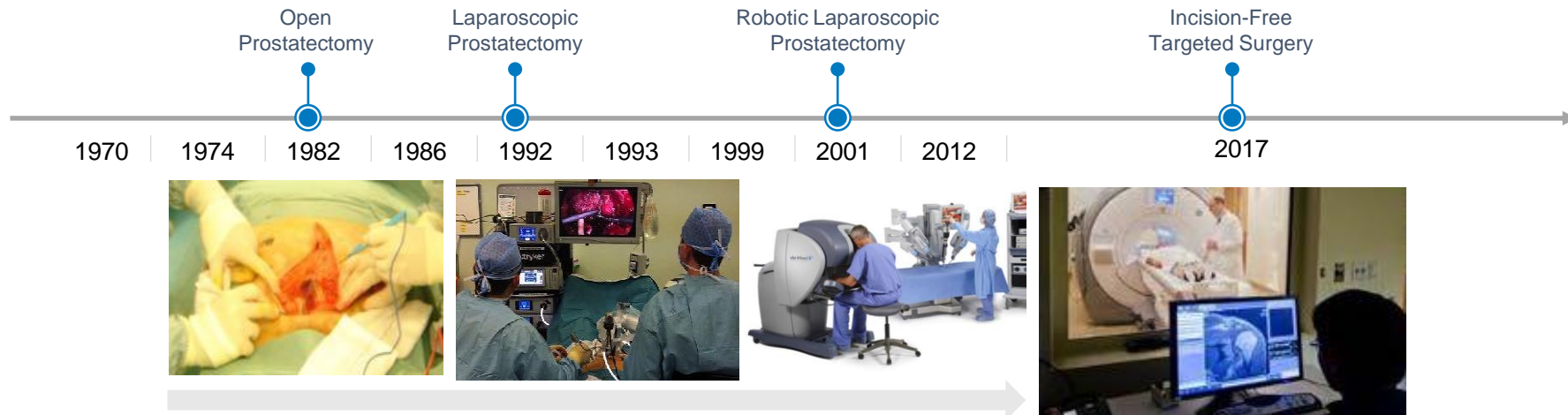


H&E Histology



Ramsay *et al* 2017, The Journal of Urology, 197(1):255-261

FROM OPEN SURGERY TO INCISION-FREE SURGERY



SURGERY TYPE	FULL PROSTATE REMOVAL	FLEXIBLE: FULL PROSTATE OR TARGETED CANCER ABLATION
Invasiveness	Reduced	Incision free
Recovery time	Reduced	Day surgery
Clinical outcome	Unchanged	Superior
Surgeon skill	Dependent	Closed loop process control
Cost of Surgery	Higher	Lower

REIMBURSEMENT ENVIRONMENT FOR PROSTATE

No therapy is considered standard of care

PROCEDURE	APPROXIMATE HOSPITAL PAYMENT	APPROXIMATE SURGEON PAYMENT
Laparoscopic Radical Prostatectomy	\$10,000	\$1,450
Radiation Therapy (IMRT Simple, 40 Sessions)	\$20,000	Fee bundled into primary APC
Brachytherapy	\$8,000	\$2,200
Cryoablation	\$10,000	\$800

MARKET ENTRY STRATEGY

IN US & EUROPE

TULSA-PRO

- Precise
- Safe
- Personalized

PROFOUND SURGERY

- Patients on active surveillance who prefer a safe intervention
- Patients who otherwise might be targets for Radiation

SALES CHANNELS

- Initial equipment sold through distribution partners Philips and Siemens (\$250,000/device)
- Disposable used per patient sold directly to drive utilization (\$2400/patient)



Active Surveillance

5.8 Million patients

- Live with psychological stress for 10-to-15 years
- Monitoring costs up to \$29,000



Radiation

300,000 patients per year

- High rates of side effects
- Multiple treatments over 30-to-60 days
- 30% patients fail treatment



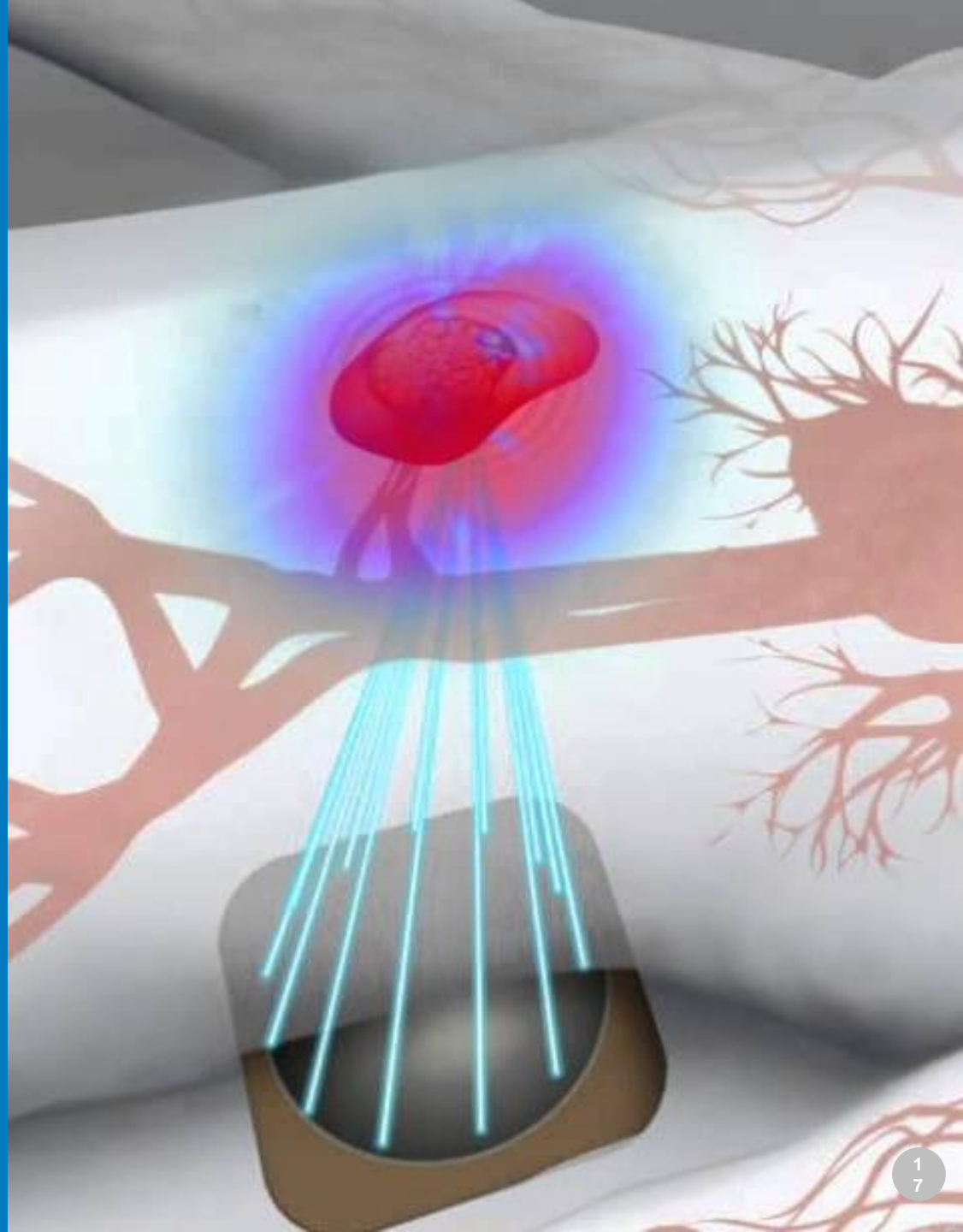
Prostatectomy

200,000 patients per year

- Removal of whole prostate and associated tissue
- Side effects surgeon skill dependent
- Relatively longer recovery time

Less frequent treatments: HIFU, Cryotherapy, Brachytherapy, Hormone Therapy, Laser

Uterine Fibroid Treatment



EXPANDED COLLABORATION WITH PHILIPS

SONALLEVE

CE-Mark approval for:

- Uterine Fibroid Therapy
- Bone Mets Pain Therapy

> 100 peer reviewed publications

Compatible with Philips MRI

- Ingenia 1.5T and 3.0T
- Achieva 1.5T & 3.0T



SONALLEVE

UTERINE FIBROID TREATMENT



CE-Mark approval for:

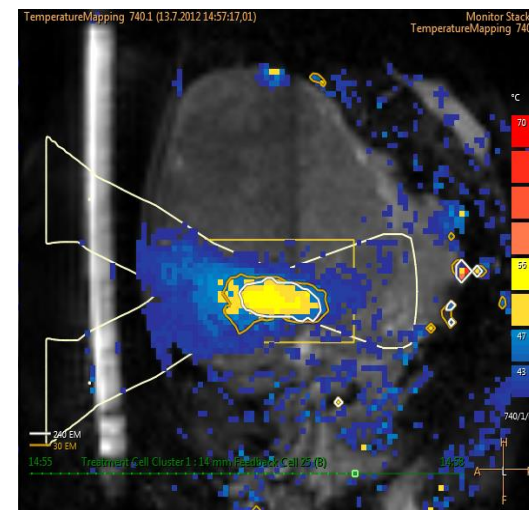
- Uterine Fibroid Therapy
- Bone Mets Pain Therapy

> 100 peer reviewed publications

Compatible with Philips MRI

- Ingenia 1.5T and 3.0T
- Achieva 1.5T & 3.0T

- MR-guided: Treatment planning based on 3D MR images
- Focused ultrasound heats non-invasively through intact skin
- Real-time MR imaging & temperature measurement
 - Verify treatment success
 - Risk mitigation



SYMPTOM RELIEF AND DURABILITY

OVER 85% SUSTAINED SYMPTOM IMPROVEMENT

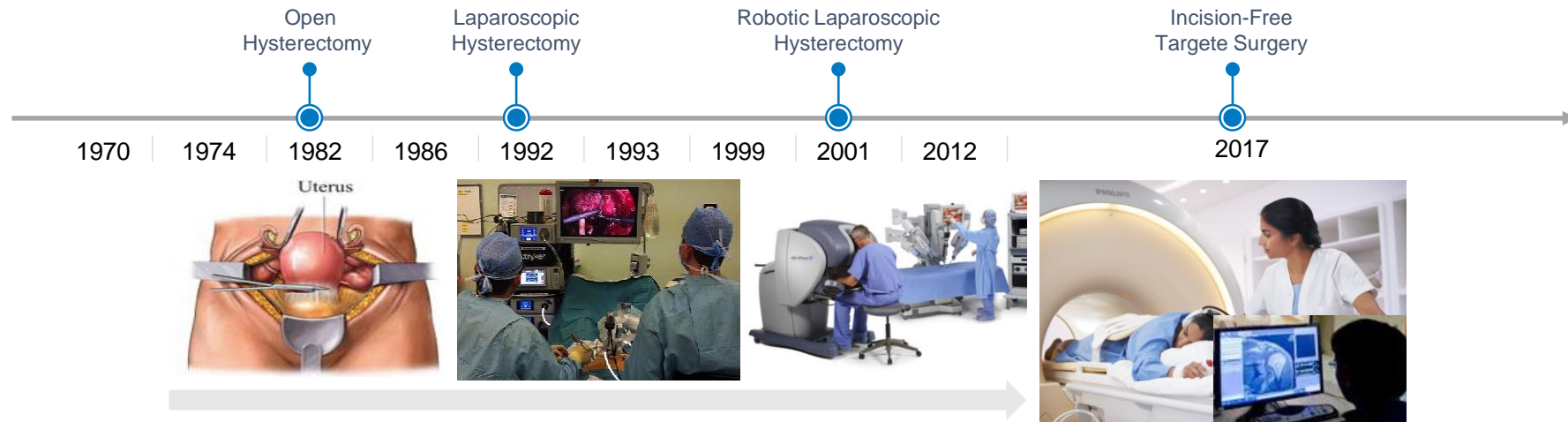
In normal commercial use, over 85% of patients experienced sustained symptom improvement

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

FROM OPEN SURGERY TO INCISION-FREE SURGERY



SURGERY TYPE	FULL UTERUS REMOVAL	TARGETED FIBROID ABLATION
Invasiveness	Reduced	Incision free
Recovery time	Reduced	Day surgery
Clinical outcome	Unchanged	Superior
Surgeon skill	Dependent	Ablation under real time imaging guidance
Cost of Surgery	Higher	Lower

STRONG GLOBAL NETWORK OF SONALLEVE CLINICAL PARTNERS





CE Mark

- Prostate ablation: 2016

FDA clinical trial

- Expected enrollment completion: Year End-2017
- Expected filing for 510(k): Year End-2018

Pilot commercial launch

- Key European and other CE mark jurisdictions
- Revenue ramp: Q1-2017 = \$500,000; Q2-2017 = \$1 million; expect steady increase moving forward

US launch expected H1-2019

Business model

- Capital upfront \$250,000 + disposables \$2,400/patient



CE Mark

- Uterine fibroid treatment: 2009
- Bone metastases treatment: 2011

FDA clinical trial: TBA

Business model

- Currently all capital \$600,000
- Anticipate adding disposable fee in future