PROFCUND MEDICAL

Incision-free Surgery Real-Time MR Guided Ultrasound Therapies

TULSA-PRO°

Prostate Disease



MRgFUS Uterine Fibroids



CORPORATE PRESENTATION | OCTOBER 2017

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PROFOUND PLATFORM INCISION-FREE TREATMENTS WITH INHEREHTLY SAFE TECHNOLOGIES



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



Prostate Treatment



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TODAY'S THERAPIES SIDE EFFECTS

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	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%	

Functional Outcomes at 2 years¹

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



Computer Hardware







UNIQUE INSIDE-OUT APPROACH PROSTATE TREATMENT



Device Positioning

Precise Treatment Planning

Automated, Robotically driven

- 1. Controlled algorithm
- 2. Target temp 55° C
- 3. Ablation in 40 minutes

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Margin with MRI

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+



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 CLINCIAL TRIAL COMPLETED SAFETY & FEASBILITY



Magnetic Resonance Imaging–Guided Transurethral Ultrasound Ablation of Prostate Tissue in Patients with Localized Prostate Cancer: A Prospective Phase 1 Clinical Trial

Joseph L. Chin, Michele Billia, James Relle, Matthias C. Roethke, Ionel V. Popeneciu, Timur H. Kuru, Gencay Hatiboglu, Maya B. Mueller-Wolf, Johann Motsch, Cesare Romagnoli, Zahra Kassam, Christopher C. Harle, Jason Hafron, Kiran R. Nandalur, Blaine A. Chronik, Mathieu Burtnyk, Heinz-Peter Schlemmer, Sascha Pahernik



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

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Study Population

• Low (80%) & intermediate (20%) risk prostate cancer patients, \geq 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 $2 \ge 2$) 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 \geq 17
- Erection firmness sufficient for penetration Change in % patients with IIEF item $2 \ge 2$
- Urinary incontinence Change in % patients using \geq 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 wholemount 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

Prostate Boundary Prostate Boundary Target Boundary Acute Coagulative Necrosis Outer Limit of Thermal Injury Õ Tumour 4 555558 2

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

H&E Histology

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

* Payment is the sum of the indicated APC/CPT codes

** Payments are for Medicare patients. Private payer payments for these procedures will vary and may result in higher payments than published Medicare rates.

MARKET ENTRY STRATEGY IN US & EUROPE



- 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

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Uterine Fibroid Treatment



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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



- MR-guided: Treatment planning based on 3D MR images
- Focused ultrasound heats noninvasively 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 Patients a	Patients available	Sym	ptom improvement	
post-procedure	for follow-up	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,

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

UTERINE FIBROID TREATMENT SONALLEVE CREATES CLINICAL AND ECONOMIC VALUE



Targeted/Precise

Typically best for fibroids on the outer side of uterus



Uterus Preserving Therapy

No negative impact on future pregnancy



Incision Free

Low pain alternative to invasive procedures



Out-Patient Procedure Go home same day



Quick Recovery Return to normal

activity in 2 days

STRONG GLOBAL NETWORK OF SONALLEVE CLINICAL PARTNERS



IN SUMMARY INVESTMENT HIGHLIGHTS

TULSA-PRO®

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