PROFOUND

Customizable, Incision-Free Ablation Therapies

PROFOUND

CORPORATE PRESENTATION | SEPTEMBER 2019

 TSX: PRN | OTCQX: PRFMF

Forward-Looking Statements

Certain statements in this presentation and oral statements made during this meeting may contain “forward-looking statements” within the meaning of applicable securities laws, including the “safe harbour provisions” of the Securities Act (Ontario), with respect to Profound Medical Corporation (“Profound” or the “Company”). Such statements include all statements other than statements of historical fact contained in this presentation, such as statements that relate to the Company’s current expectations and views of future events. Often, but not always, forward-looking statements can be identified by the use of words such as “may”, “will”, “expect”, “anticipate”, “predict”, “aim”, “estimate”, “intend”, “plan”, “seek”, “believe”, “potential”, “continue”, “is/are likely to”, “is/are projected to” or the negative of these terms, or other similar expressions, as well as future or conditional verbs such as “will”, “should”, “would”, and “could” intended to identify forward-looking statements. These forward-looking statements include, among other things, statements relating to expectations regarding future clinical trials, expectations regarding regulatory approvals, expectations regarding the safety and efficacy of its products, expectations regarding the use of its products and its revenue, expenses and operations, plans for and timing of expansion of its product and service offerings, future growth plans, ability to attract and develop and maintain relationships with suppliers, manufacturers, physicians/clinicians, etc., ability to attract and retain personnel, expectations regarding growth in its product markets, competitive position and its expectations regarding competition, ability to raise debt and equity capital to fund future product development, and anticipated trends and challenges in Profound’s business and the markets in which it operates.

Forward-looking statements involve known and unknown risks, uncertainties and other factors which may cause the actual results, performance or achievements of the Company to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. The results, performance and achievements of the Company will be affected by, among other things, the risks and uncertainties discussed in the “Risk Factors” section in the Company’s Annual Information Form dated March 7, 2019, such as successful completion of clinical trial phases with respect to Profound’s device, obtaining regulatory approvals in relevant jurisdictions to market Profound’s device, risks related to the regulation of Profound (including the healthcare markets, lack of funding may limit the ability to commercialize and market Profound’s products, fluctuating input prices, international trade and political uncertainty, healthcare regulatory regime in relevant jurisdictions may affect the Company’s financial viability, reimbursement models in relevant jurisdictions may not be advantageous), competition may limit the growth of Profound, if the Company breaches any of the agreements under which it licenses rights from third parties, Profound could lose license rights that are key to its business, loss of key personnel may significantly harm Profound’s business and past performance is not indicative of future performance, and such other risks detailed from time to time in the other publicly filed disclosure documents of the Company which are available at www.sedar.com. The Company’s forward-looking statements are made only as of the date of this presentation and, except as required by applicable law, Profound disclaims any obligation to update any forward-looking statements, whether as a result of new information, future events or results or otherwise, unless required by applicable law. There can be no assurance that forward-looking statements will prove to be accurate, as actual results and future events could differ materially from those anticipated in such statements. Accordingly, and because of the above-noted risks, uncertainties and assumptions, readers should not place undue reliance on forward-looking statements due to the inherent uncertainty in them.

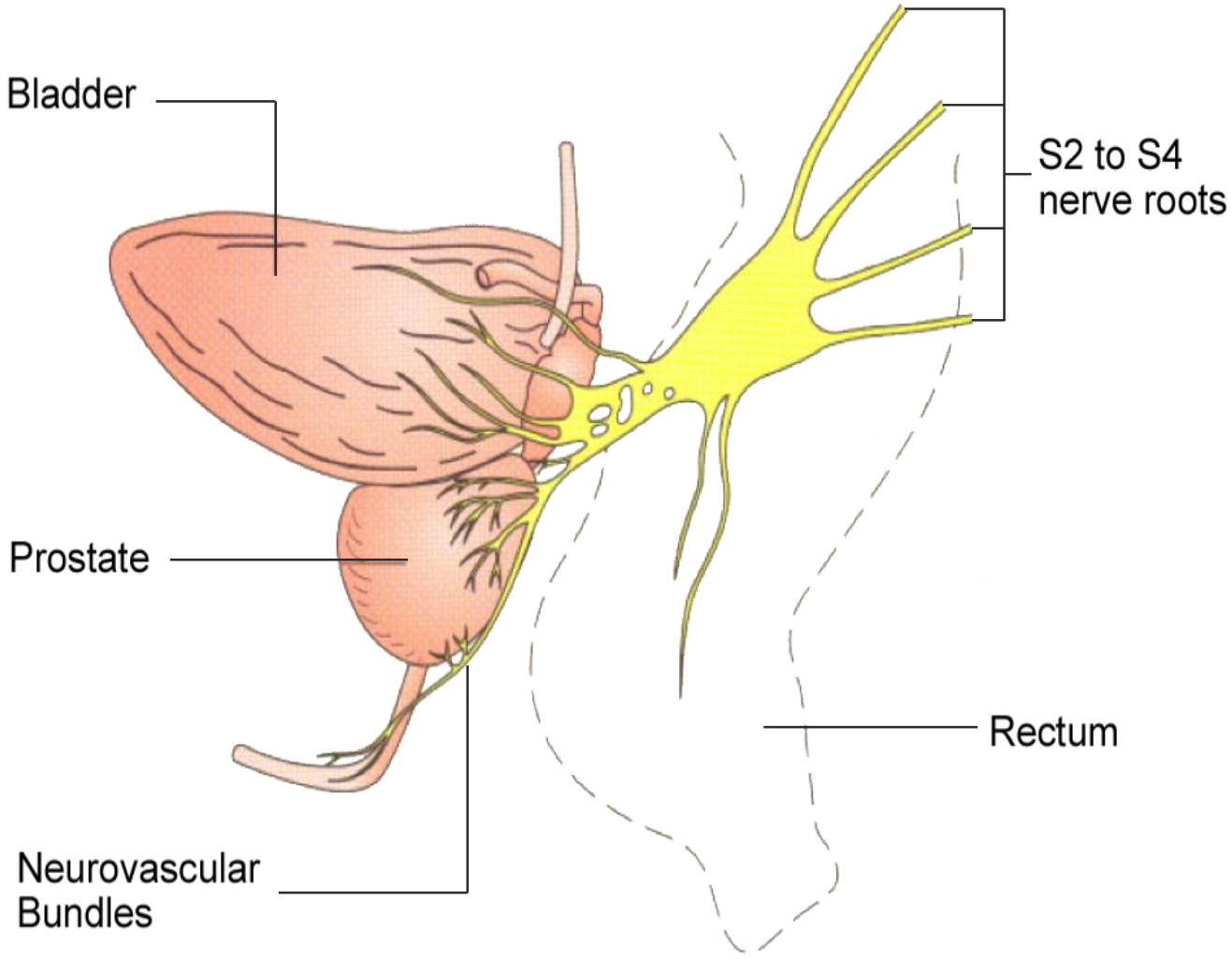
“My life should not have to change”

TULSA-PRO®

U.S. FDA Cleared, August 2019
Ablation of Prostate Tissue

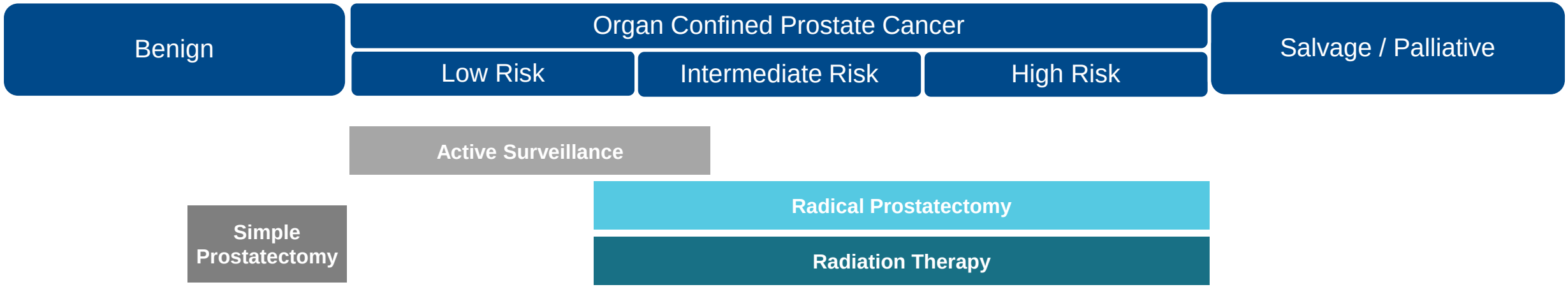
PROFOUND

Prostate Anatomy



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

Current Approaches to Prostate Disease



- 175,000 new prostate cancer patients diagnosed each year according to the American Cancer Society, 2.9 million patients living with prostate cancer on active surveillance (US)
- 300,000 BPH surgeries based upon CMS data
  10 million patients living with BPH
- Radiation failure and palliative patients have limited treatment options
- Approx 10% of prostate cancer patients undergo other treatments such as HIFU, Laser and Cryo

TULSA-PRO

Customizable, Predictable, Incision-Free

1. Real-time MR imaging

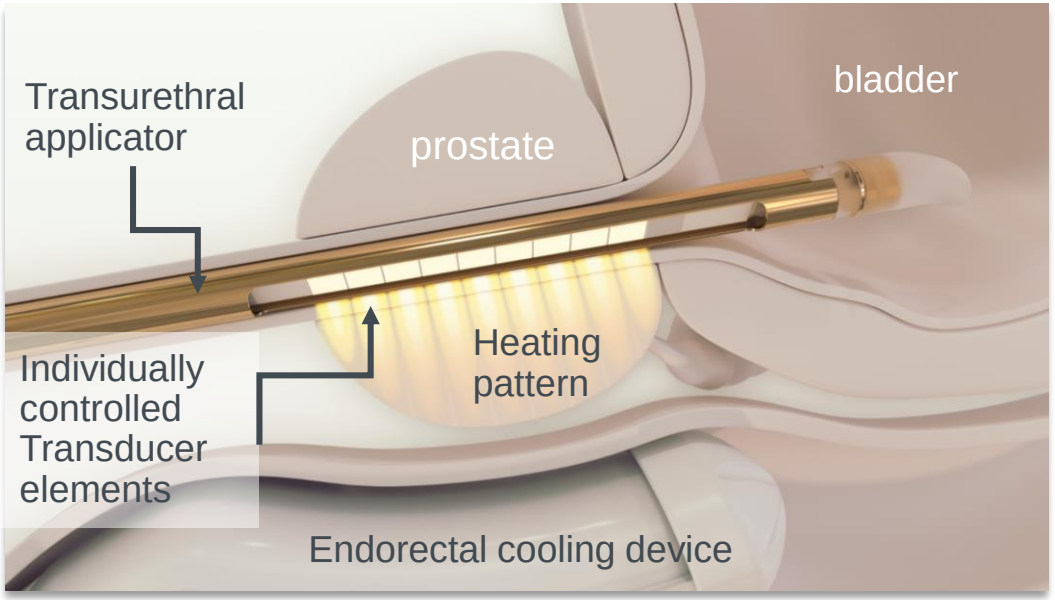
- Customized treatment plan

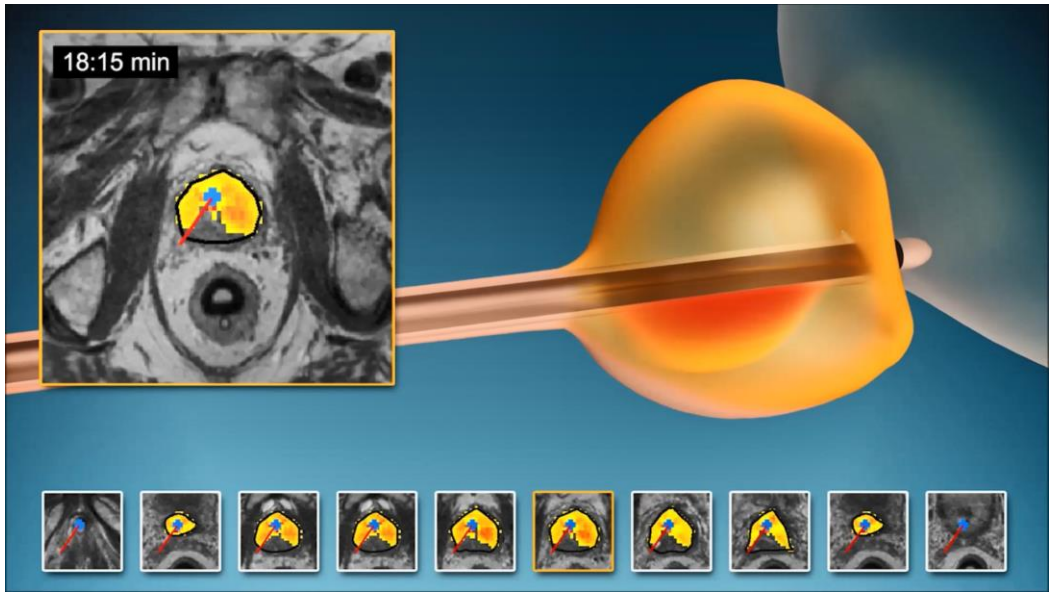
2. Transurethral directional ultrasound for thermal ablation; water cooling of urethra and rectum

- Sweeping ultrasound, continuous rotation (no risk of cold spots between discrete sonications)
- Capable of treating both large and small prostate volumes
- Thermal protection of important anatomy

3. Closed-loop process control software

- Real-time temperature feedback provides for gentle and precise ablation

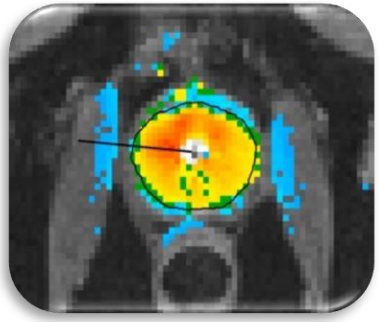




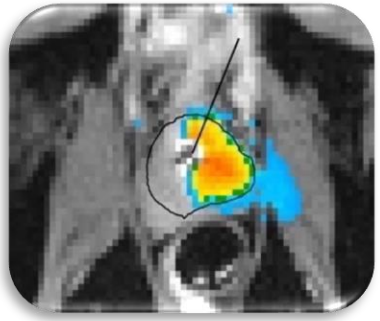
TULSA **Flexibility**

Customizable, Predictable, Incision-Free

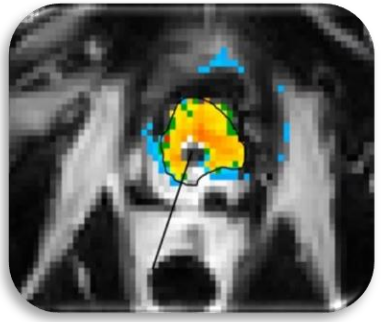
Whole gland ablation



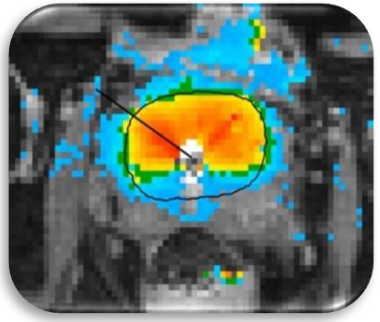
Targeted ablation



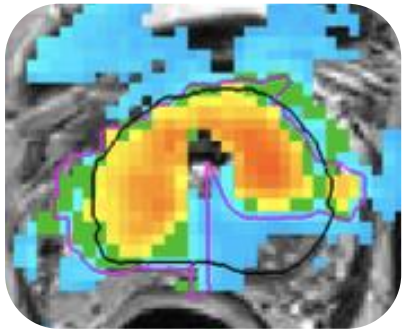
Post radiation failure ablative therapy



Targeted ablation of a benign large prostate



Targeted ablation of a benign large prostate with malignant lesion



TACT: Clinical Trial Design

Pivotal study of whole-gland ablation in a clinically-significant patient population

Study Population

- n = 115, 13 clinical sites, 5 countries
- 45 – 80 years old
- Low (33%) & intermediate risk (67%) prostate cancer

Ablation Treatment Plan

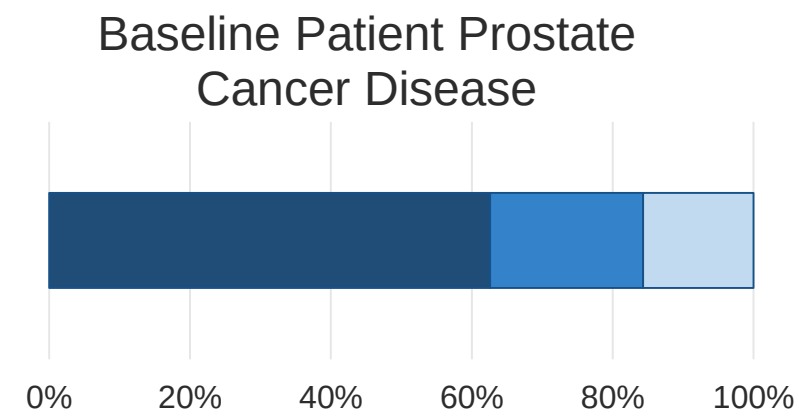
- Treatment intent was whole-gland ablation with sparing of the urethra and urinary sphincter
- Recommended by FDA to determine substantial equivalence with predicate devices and comparison with standard of care

Primary Endpoints (12 months)

- Safety: Frequency and severity of adverse events
- Efficacy: PSA reduction ≥ 75% (in > 50% of patients)

Secondary Endpoints (to 5 years)

- Prostate volume reduction at 1 year
- Prostate biopsy at 1 year in all patients
- Multi-parametric MRI at 1 year (Central Radiology Lab, Cleveland Clinic)
- Functional Disability: EPIC, IIEF, IPSS



TACT: **Prostate Ablation Efficacy**

PSA primary efficacy endpoint resolutely met:

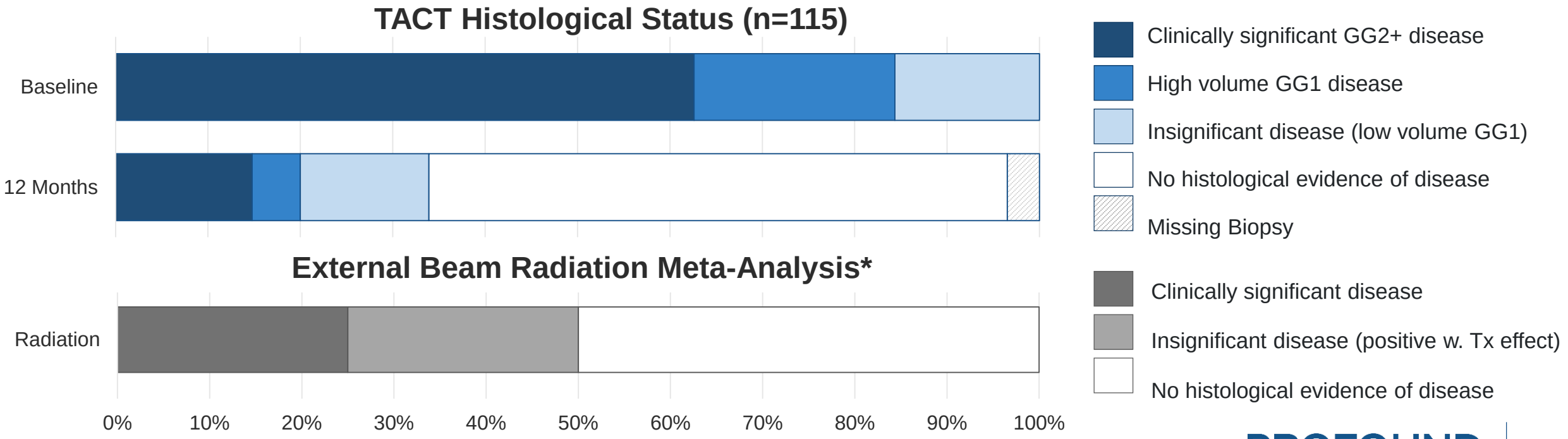
- Primary endpoint of PSA reduction ≥75% was achieved in 110 of 115 (96%)
- Median (IQR) PSA reduction was 95% (91-98%)
- Median PSA nadir was 0.34 (0.12-0.56) ng/ml

	Pre-Treatment	12 Month	PSA Nadir
N	115	115	115
Median	**6.26**	**0.53**	**0.34**
IQR	4.65 – 7.95	0.28 – 1.25	0.12 – 0.56
Average	**6.72**	**0.93**	**0.51**
T-Test against baseline		<0.001	<0.001

TACT: **Histological Response**

Biopsy Outcomes (1-year, 10-core TRUS, High Sampling Density 0.4 cc / core)

- Only 4 of 115 follow-up biopsies are missing, all due to patient refusal
- Among men with pre-treatment intermediate-risk GG2 disease, **54 of 68 (79%)** were free of GG2 disease
- Of men with one-year biopsy data, 72 of 111 (65%) had complete histological response and were free of any disease
- 41% (16 of 39) of positive biopsies were clinically insignificant (Very Low Risk)
- Multivariate Analysis: Among men w. pre-Tx GG2 disease and w/o calcifications at screening, **51 of 60 (85%)** were free of GG2 disease



*GCP-10102 available upon request

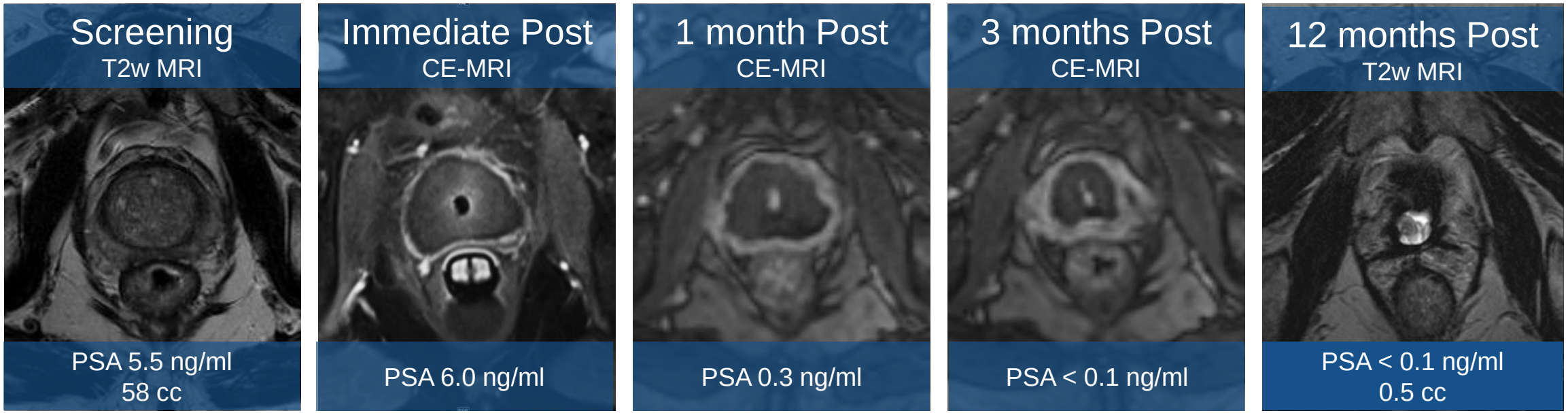
TACT: **Prostate Volume Reduction**

Prostate volume significantly reduced demonstrating effective prostate ablation

- Median perfused prostate volume decreased 91% from 37 cc to 3 cc, on MRI at 1 year (central radiology)
- Prostate ablation confirmed on Contrast Enhanced MRI immediately after TULSA and during follow-up

Follow-up prostate MRI predicts clinically significant disease on biopsy

- Multivariate Analysis: Absence of PIRADS ≥ 3 lesion at 1-year multi-parametric MRI has 92% Negative Predictive Value for absence of GG2 disease on 1-year biopsy (local radiologists, same as diagnostic PIRADS)
- Ongoing work: Adjusting PIRARDS for post-ablation setting, MRI has **96% Negative Predictive Value** for absence of GG2 disease on 1-year biopsy (central radiology)

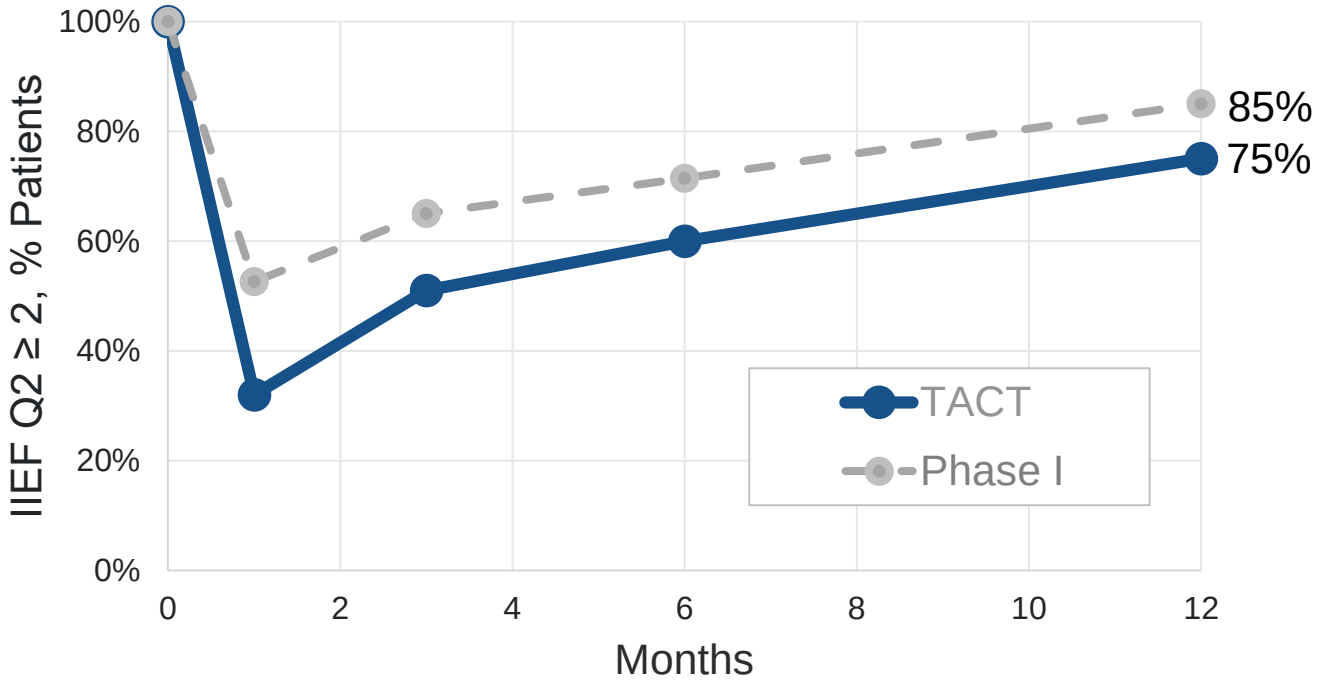


TACT: **Erectile Function**

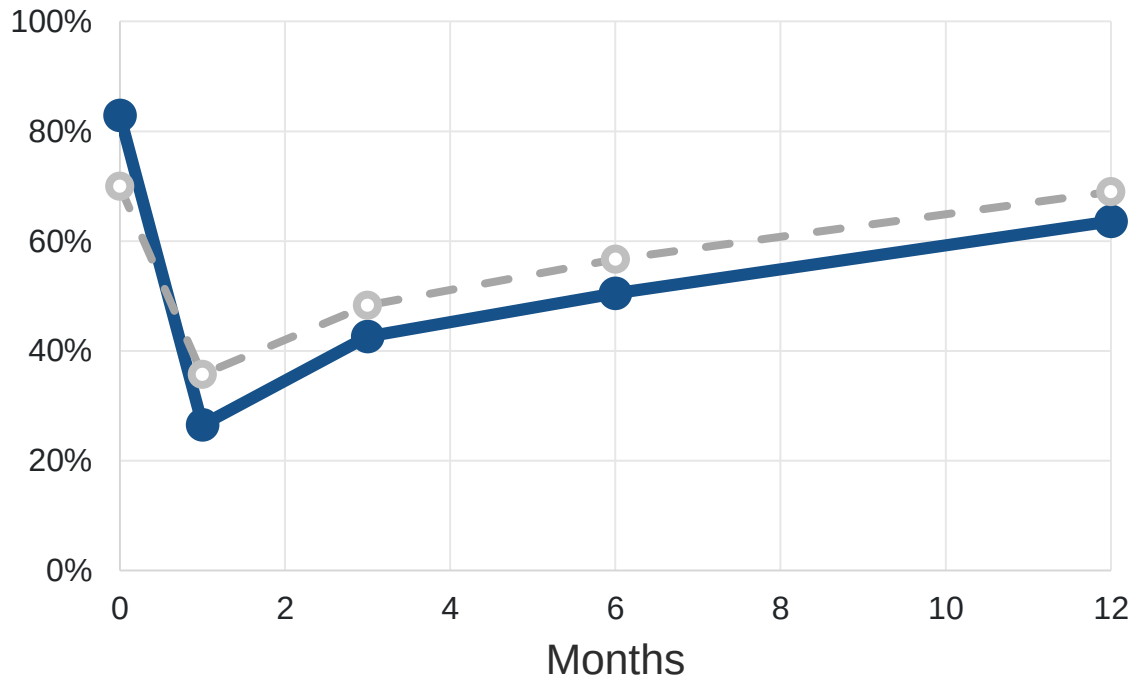
Erectile Function, at one year:

- 23% surgeon-assessed moderate erectile dysfunction (CTCAE Grade 2, intervention such as medication indicated)
- 0% any occurrence of severe erectile dysfunction (CTCAE Grade 3, intervention such as medication not helpful)
- 75% (69/92) of previously potent patients maintained erections sufficient for penetration
- Phase I 90% ablation, TACT whole gland ablation

Patients Potent at Baseline (n=92)



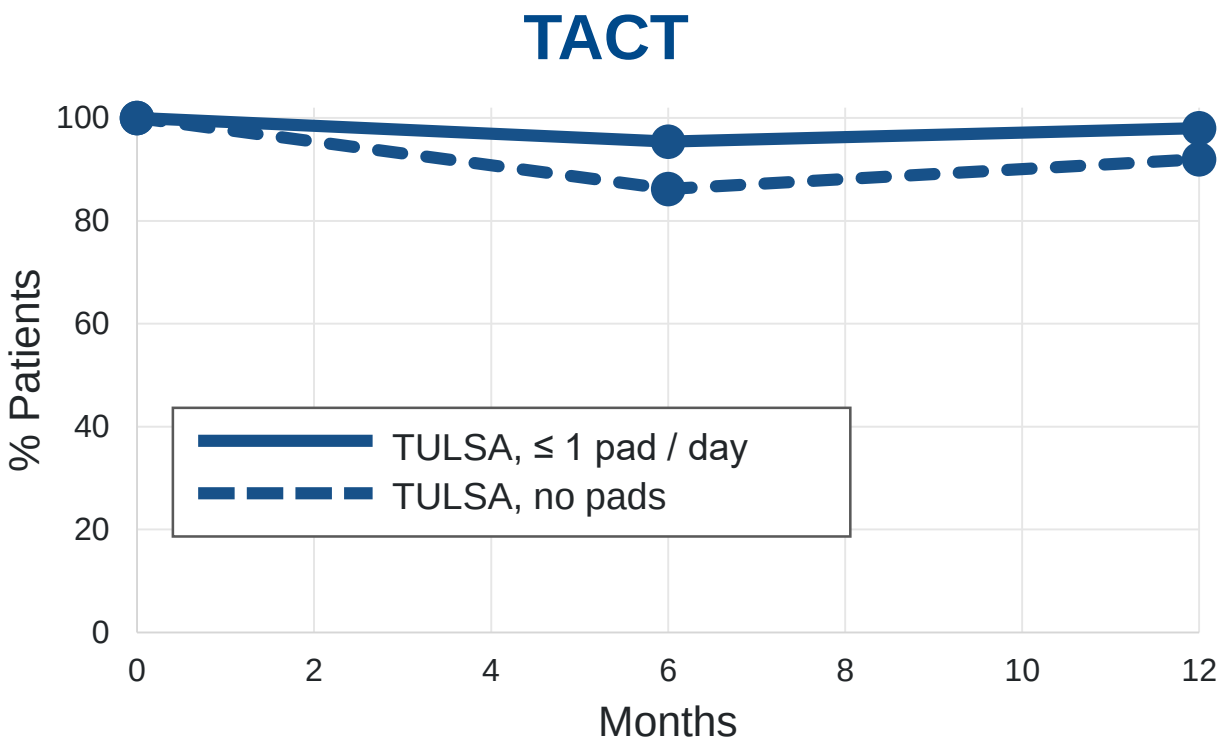
All Patients (n=110)

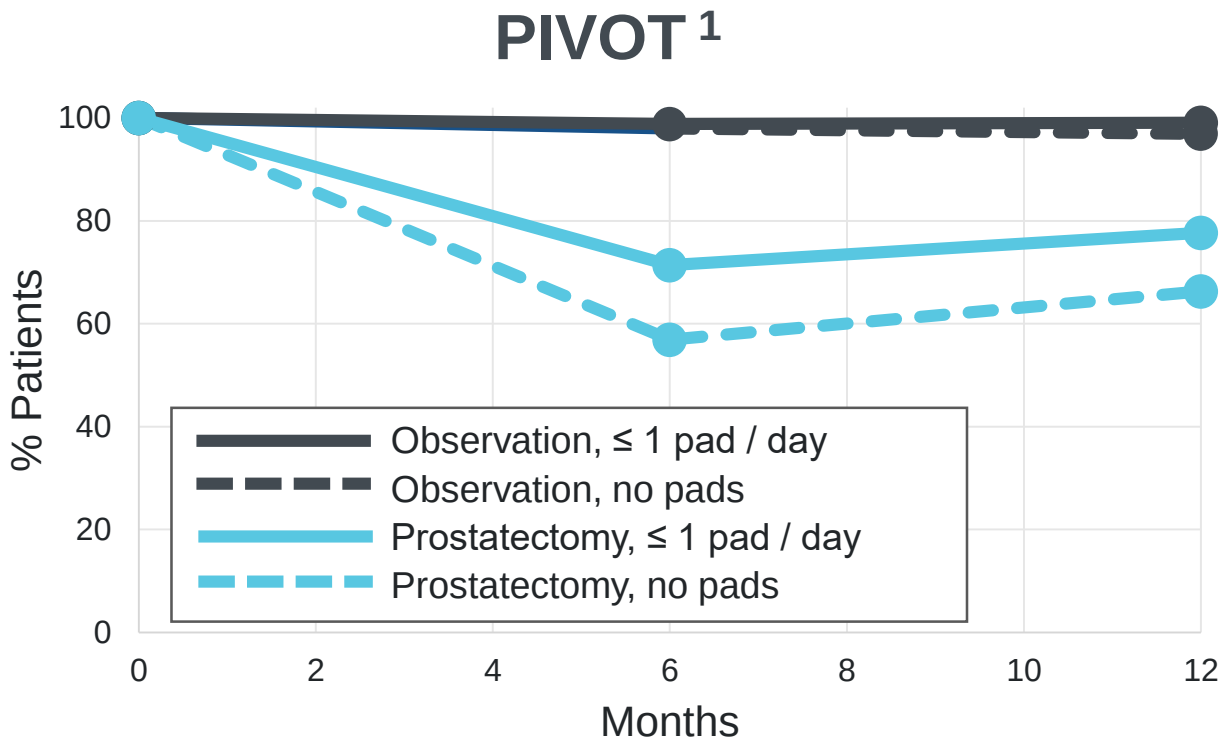


TACT: **Urinary Incontinence**

Urinary Incontinence, at one year:

- 2.6% surgeon-assessed moderate urinary incontinence (CTCAE Grade 2, pads indicated)
- 0% any occurrence of severe urinary incontinence (CTCAE Grade 3, operative intervention indicated)
- TACT Urinary Continence (pad use) similar to Observation arm of PIVOT study





1. Wilt *et al*, The New England Journal of Medicine, 2017

TACT summary, **Literature review** of other trials provided for context

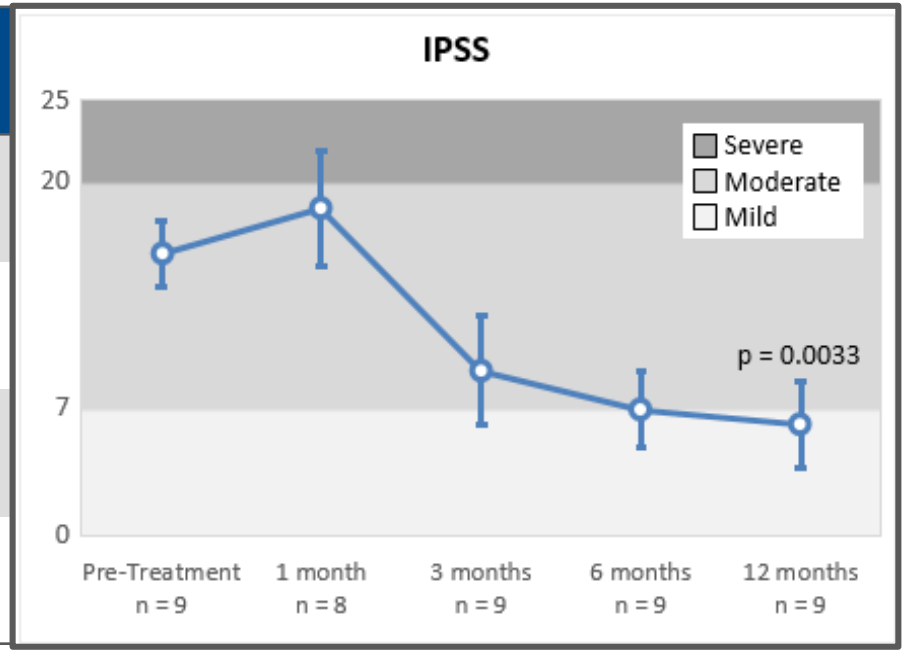
	TACT Study	Literature Review		
	TULSA	**Prostatectomy**	**Radiation**	**HIFU**
Biopsy / Histology	**21% Clinically significant** **14% Insignificant disease** (GG1, ≤2 cores, < 50% CCL) **65% Negative**	**16 – 24% +Margin** [1] (Meta-Analysis) **10 – 15% +Margin** [2] (RCT) **24% +Margin** [3] (ProtecT)	**28% Clinically significant** [4] **20% Insignificant disease** [4] (Positive w. treatment effect) **52% Negative** [4]	**59 – 61% Negative** [5-6] (Intent to treat) **63% Negative, after 40% having repeat HIFU and 39% ADT** [7]
Erectile Dysfunction erections insufficient for penetration	**23%** Grade 2 medication indicated. No Grade 3 ED	**79%** [9] *(Range: 25 – 100%)* [1-4]	**63%** [9] *(Range: 7 – 85%)* [1-5]	**58%** [7] *(Range: 44 – 67%)* [6-8]
Urinary Incontinence moderate to severe	**2.6%** Grade 2 pads indicated. No Grade 3 Incontinence	**15%** [9] *(Range: 0 – 50%)* [1-4]	**4%** [9] *(Range: 2 – 15%)* [1-5]	**3%** [5] *(Range: 3 – 22%)* [6-8]
Urethral Stricture moderate to severe	**2.6%**	**9%** [11] *(Range: 3 – 26%)* [1-4]	**2%** [11] *(Range: 1 – 9%)* [1-5]	**35%** [5] *(Range: 9 – 35%)* [6-8]
GI Toxicity, moderate to severe diarrhea, urgency, incontinence, fistula	**No GI Toxicity**	**15%** [9] *(Range: 0 – 24%)* [1-4]	**25%** [9, 12] *(Range: 0 – 40%)* [1-5]	**7%** [5] *(Range: 1 – 21%)* [6-8]

1. 1. Tewari et al 2012 (Meta-Analysis)
2. Yaxley et al 2016 (RCT)
3. Hamdy et al 2016 (ProtecT)
4. Radiation Meta-Analysis (publication pending)
5. FDA IDE Study K153023
6. FDA IDE Study DEN150011
7. Crouzet *et al*, Eur Urol 2014 (1000+ patients, Whole-gland HIFU)
8. Thompson (Chair) *et al,* AUA prostate cancer clinical guideline update panel, J Urol 2007
9. Resnick et al, Prostate Cancer Outcomes Study (PCOS), NEJM 2013
10. Potosky *et al*, Prostate Cancer Outcomes Study (PCOS), J NCI 2004
11. Elliott *et al*, CaPSURE database, J Urol 2007
12. Budaus *et al*, Review, Eur Urol 20012

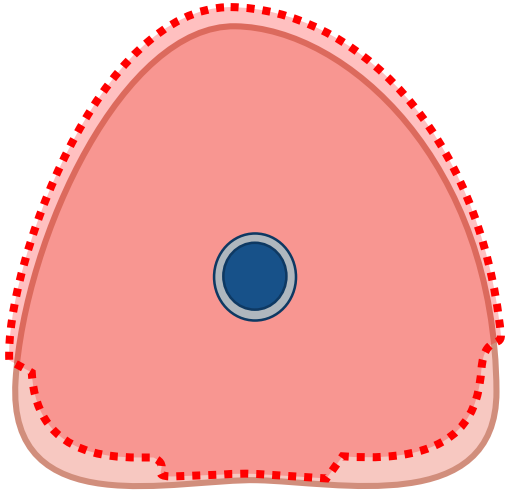
BPH Subgroup Analysis of Phase I Study

- Subgroup analysis of Phase I patients with baseline IPSS ≥ 12 (n = 9/30)
- No Grade 3 adverse events, erectile function (IIEF) stable from 15±9 to 16±9
- Elterman *et al*, Prostate Cancer and Prostate Diseases, 2019 *(Under Review)*

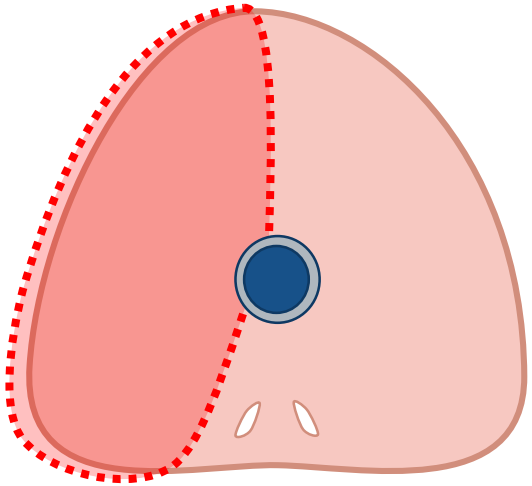
Characteristics (n=9)	Baseline	12 months	Change (%)
IPSS	16.1 ± 3.8	6.3 ± 5.0	Δ -9.8 ± 7.1 (-58%)
IPSS QoL	2.8 ± 1.1	0.8 ± 1.0	Δ -2.0 ± 1.7 (-66%)
Prostate Volume (cc)	54 ± 23	14 ± 5	Δ -40 ± 24 (-70%)
Peak flow (Qmax, ml/s)	14.5 ± 4.1	21.9 ± 12.7	Δ +7.4 ± 13 (+60%)



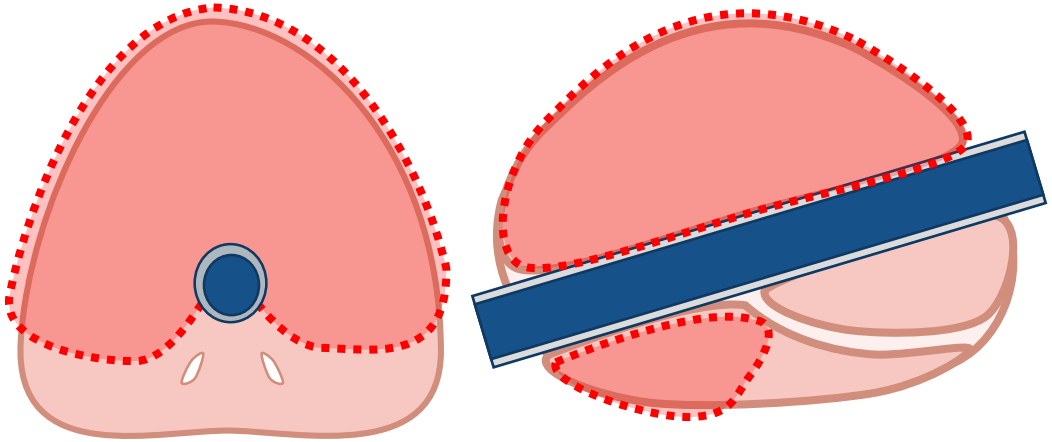
Predictable and Targeted Ablation



Bilateral sparing ablation of cancerous prostate tissue



Targeted & customized ablation of diseased prostate tissue



Ablation of benign tissue

Clinical Experience with TULSA

Benign	Organ Confined Prostate Cancer			Salvage / Palliative
	Low Risk	Intermediate Risk	High Risk	

Large prostate BPH [1]

- Preservation of ejaculatory function
- Combined with targeted cancer ablation
- Prophylactic ablation of suspicious MRI lesion

Prophylactic ablation of male BRAC2 [10]

Customized ablation [2-7]

- Targeted ablation (focal)
- Large ablation (wide margins)
- Whole gland ablation (with urethral sparing)

Recurrence after radiation [8]

- Localized recurrences have limited options, and morbidity is high

Palliative locally advanced [9]

- Severe urinary symptoms including BOO with retention and/or intractable hematuria

Oligometastatic [10]

- Benefit to locally treat prostate
- Often radio-recurrent

1. Elterman *et al*, Prostate Cancer and Prostate Diseases, 2019 *(Under Review)*
2. Ramsey *et al*, The Journal of Urology, 2017
3. Chin *et al*, European Urology, 2016
4. Bonekamp *et al*, European Radiology, 2018
5. Eggener *et al*, The Journal of Urology, 2019 *(AUA Abstract)*
6. Anttinen *et al*, International Journal of Hyperthermia, 2019
7. Anttinen *et al*, Scandinavian Journal of Urology, 2019 *(Under Review)*
8. Suomi *et al*, ISTU Barcelona, Spain, 2019 *(Conference)*
9. Sainio *et al*, ISTU Barcelona, Spain, 2019 *(Conference)*
10. *Physician interest*

Commercial Experience with TULSA

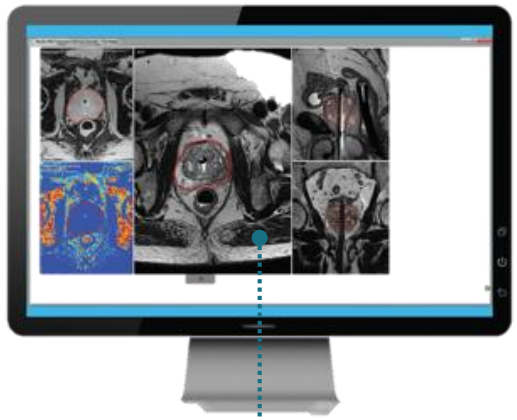
	Prostatectomy	Radiation	TULSA
Throughput, Procedures/Day	2 typically, 3 on a longer day	Multiple sessions: 5 to 40, 4 - 8 weeks	• 4 in a routine day • Consistent treatment times
Patient Recovery	Weeks	Deterioration over time	• 2 days • Minimal need for pain management

TULSA-PRO **System Components**

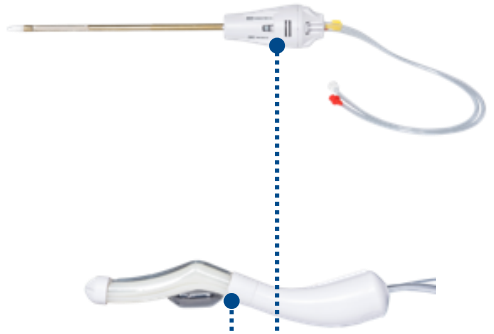
Compatible with MR from leading companies, Philips and Siemens

Robotic Arm, Computer Hardware

Energy System



Surgeon Console Control Room



Disposable Applicators

Capital Equipment

One-Time Consumables

TULSA-PRO Total Annual Addressable Market in the U.S.

Total Annual Addressable Market	
400,000 BPH Patients In Need of Intervention[1]	**175,000** Patients Diagnosed with Prostate Cancer[2]
$4,000 / patient average selling price of Profound's procedure kit Additional **$2,000 / patient** for device usage and services	
$2.3 - 3.45 Billion Total annual addressable market in the U.S.	
Upside potential: 2.9 Million patients currently diagnosed with prostate cancer that remain on Active Surveillance (US). The low side-effect profile of the TULSA treatment may prompt this patient population to opt for TULSA instead of waiting	

TULSA-PRO Addressable Patient Population

Immediate

28,750 – 57,500 Patients
5% – 10% of the total addressable U.S. patient population (cash pay)

Gather extensive clinical efficacy data for TULSA-PRO in the U.S.

Establish broad reimbursement for TULSA-PRO in the U.S.

Longer-Term

575,000 Patients
100% of the total addressable U.S. patient population

References:
1. BPH: 300,000 surgeries based upon CMS data plus 1% of 10M BPH patients in the U.S.
2. Prostate cancer: 175,000 new prostate cancer diagnoses each year in the U.S. according to the American Cancer Society.

U.S. Market Entrance Strategy

1. **Increasing awareness of TULSA-PRO technology and the TACT clinical data**
   - TACT clinical data presented at >8 conferences (AUA, EAU, RSNA)
   - TULSA-PRO and TACT clinical data presented to >50 institutions
2. **Early adopter pipeline developed through interest from clinical presentations**
3. **Potential delivery channels for TULSA-PRO**
   - Imaging centers
   - Urology practice co-ops who focus on new technologies
   - Large opinion leading hospital-based practices
4. **Recurring revenue business model**
5. **‘Profound Genius Services’ launched to support early adopters**

Building Our Brand: **Low-Cost / High-Impact Patient Awareness Initiatives**

Profound Branded Patient Marketing

A. TULSA Patient Website
- EU/APEC site launched
- U.S. site in development
- Global TULSA-PRO site locator

B. Corporate Website enhancement
- Language accessibility
- Blog development with patient-focused material
- TULSA clinical data webpage

C. Video Patient & Physician Testimonials
- Cross platform promotion across
  - YouTube channel
  - Patient resources
  - Social media

Customer Branded Patient Marketing

A. TULSA Patient Marketing
- Patient brochure
- Patient procedure pamphlet

B. TULSA Digital Marketing
- Site branded testimonials
- Digital marketing collateral as required
  - Ad campaigns
  - Social media collateral

Reimbursement: **AMA Requirements for Category I CPT Code**

- FDA cleared
- Performed widely by many physicians across United States (warrants new CPT code)
- Frequency consistent with intended clinical use (common conditions have higher volume)
- Consistent with current medical practice (mentioned in guidelines/policies)
- Clinical Efficacy (documented in “top 5” peer-reviewed publications, judged by CPT Panel)
  - 1+ reference in a majority US patient population
  - 2+ references with no overlapping patients or authors
  - 1+ reference with Level of Evidence IIa (review of large long-term cohort studies) or Level I (randomized controlled trials)

SourceL https://www.ama-assn.org/practice-management/cpt/criteria-cpt-category-i-and-category-iii-codes

Reimbursement: **Clinical Evidence Plan**

Publication Package

		Rationale	Level	N	US %	Start
1.	TACT 2.0 5-year	TULSA US Momentum at key teaching sites Increase US patient % Re-treat TACT 1.0 patients	2b	115 (+35=150)	48% (60%)	Started
2.	BPH RCT 6-month	Anchor study for Level 1 data Backup plan (next slide)	1b	144 in 2:1 96 TULSA	~100%	2020
3.	Salvage 1-year	Strong clinical value & entry into guidelines Need to sponsor or too slow with patient pay	2b	68	~100%	2020
4.	Primary Cancer Meta-Analysis (Phase I, EU, Registry)	% Ablation vs. Outcomes	2a			
5.	Single/Small-center Cancer RCT TULSA vs. Radiation (Turku, UWO, US?)	Small RCT, 50+ pts, good chance to randomize Level 1 data in cancer, even if not traditional Offloads sponsor requirements from Profound	1b	50 minimum	0% (more)	2020

Why This is a **Good Plan**

- Unify device indication with coding and TULSA value proposition (1 CPT for multiple prostate diseases)
- Level 1b data in both BPH and Cancer
- Meet CPT & payer requirements (level of evidence, US patients, exclusive authors, exclusive patients)
- Sponsor: TACT 2.0 (n=35), BPH (n=96), Salvage (n=68) = 199 TULSA-PRO Treatments
- Registry: FLEX protocol (and/or SPARED) to get more data at low cost to Profound
- Minimize company-paid procedures, while also providing runway for teaching sites as we motivate them to perform patient pay

Longer Term

Building an Incision- and Radiation-free Ablative Therapeutic Platform

Oncology, Highly Symptomatic Chronic Diseases

PROFOUND

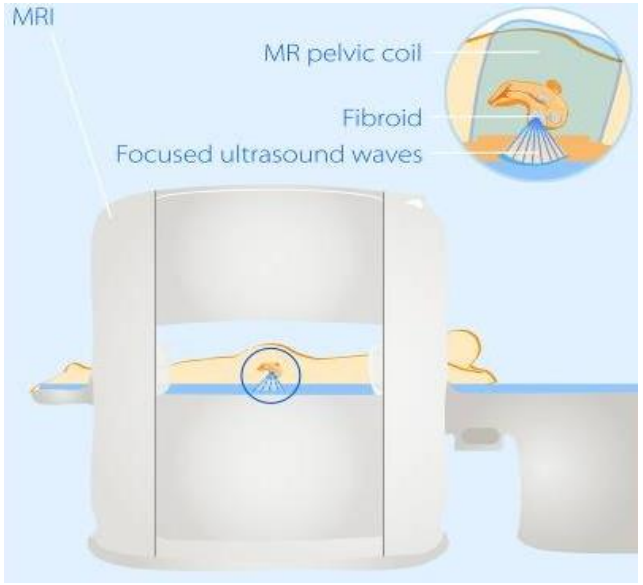
SONALLEVE

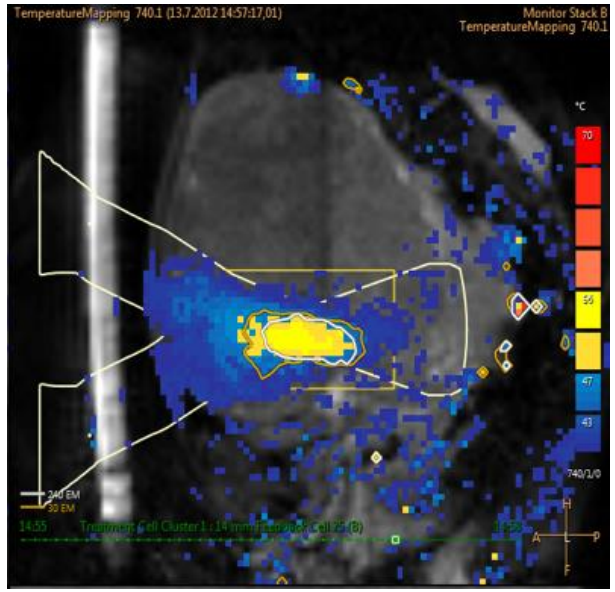
CURRENT APPROVALS

- Europe: CE Marked
- China: CFDA Approved

Over 200 publications from leading U.S. & European clinicians and hospitals

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





SONALLEVE: **Market Development Strategy**

1. U.S. & Western Markets

- Partner with Cologne to continue to develop critical clinical data for cancer and highly symptomatic chronic diseases
- Deploy recurring revenue business model for all new clinical applications
- Enter U.S. market with Humanitarian Device Exemption indication (similar to orphan drug indication for rare diseases)
  - Application filed with FDA
  - FDA manufacturing site inspection completed successfully
- Potential applications include:
  1. Pain management
  2. Osteoid Osteoma
  3. Pancreatic cancer
  4. Hyperthermia
  5. Neuro-modulation

2. China

1. Continue working with Philips as distribution partner, in concert with a small Profound direct sales team
2. Marketing for treatment of uterine fibroids
3. Reference site in S. Korea, treating 200 patients/year

In **Summary**

Introducing TULSA-PRO to U.S. market

- Pre-reimbursement TAM $50 - $100 million/year
- Potential to expand TAM by 10X or more following reimbursement

Business model is capital efficient

- TULSA-PRO: focus on U.S.
- Sonalleve: focus on Asia with larger distribution partner

Future investments:

- Strategically expand U.S.-based sales team as we continue to work with MRI partners, Philips and Siemens
- Clinical trials for TULSA-PRO for reimbursement
- Continued product evolution

PROFOUND