

## TULSA-PRO<sup>®</sup> ABLATION CLINICAL TRIAL (TACT)

<b>n=115</b> men	<b>13</b> clinical sites	<b>5</b> countries	<b>45-80</b> years old	<b>Prostate Cancer Risk</b> Intermediate (67%) Low (33%)
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### PSA primary efficacy endpoint **resolutely met:**

- PSA reduction  $\geq 75\%$  achieved in **110 of 115 (96%)**
- Median (IQR) PSA reduction was **95% (91-98%)**
- Median (IQR) PSA nadir was **0.34 (0.12-0.56) ng/ml**

### Prostate volume **significantly reduced:**

- Median perfused prostate volume decreased **91%** from **37 cc to 3 cc**
- Significant volume reduction demonstrating effective prostate ablation
- Prostate ablation confirmed on Contrast Enhanced MRI
- Adjusting PI-RADS<sup>®</sup> for post-ablation setting, MRI has **96% Negative Predictive Value** for absence of GG2 disease on 1-year biopsy (central radiology)

### Prostate Volume Reduction

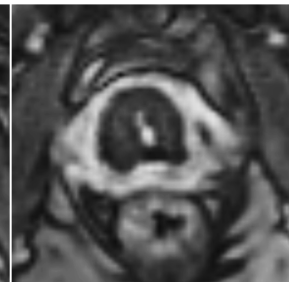
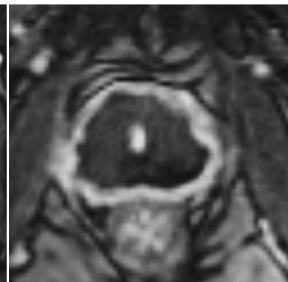
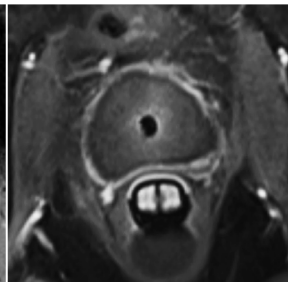
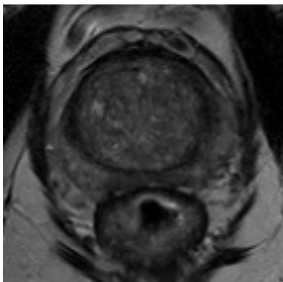
**Screening**  
T2w MRI

**Immediate Post**  
CE-MRI

**1-month Post**  
CE-MRI

**3-month Post**  
CE-MRI

**12-month Post**  
T2w MRI



PSA 5.5 ng/ml  
58 cc

PSA 6.0 ng/ml

PSA 0.3 ng/ml

PSA < 0.1 ng/ml

PSA < 0.1 ng/ml  
0.5 cc

## TACT Summary & Literature Review

	TACT Study	Literature Review		
	TULSA <sup>13</sup>	Prostatectomy	Radiation	HIFU
<b>Biopsy/ Histology</b>	21% Clinically significant 14% Insignificant disease (GG1, ≤2 cores, <50% CCL) 65% Negative	16 – 24% +Margin <sup>1</sup> (Meta-Analysis) 10 – 15% +Margin <sup>2</sup> (RCT) 24% +Margin <sup>3</sup> ( ProtecT)	28% Clinically significant <sup>4</sup> 20% Insignificant disease <sup>4</sup> (Positive w. treatment effect) 52% Negative <sup>4</sup>	59 – 61% Negative <sup>5-6</sup> (Intent to treat) 63% Negative, after 40% having repeat HIFU and 39% ADT <sup>7</sup>
<b>Erectile Dysfunction</b> erections insufficient for penetration	23% Grade 2 Medication Indicated No Grade 3 ED	79% <sup>9</sup> (Range: 25 - 100%) <sup>1-4</sup>	63% <sup>9</sup> (Range: 7 - 85%) <sup>1-5</sup>	58% <sup>7</sup> (Range: 44 - 67%) <sup>6-8</sup>
<b>Urinary Incontinence</b> moderate to severe	2.6% Grade 2 Pads Indicated No Grade 3 Incontinence	15% <sup>9</sup> (Range: 0 - 50%) <sup>1-4</sup>	4% <sup>9</sup> (Range: 2 - 15%) <sup>1-5</sup>	3% <sup>5</sup> (Range: 3 - 22%) <sup>6-8</sup>
<b>Urethral Stricture</b> moderate to severe	2.6%	9% <sup>11</sup> (Range: 3 - 26%) <sup>1-4</sup>	2% <sup>11</sup> (Range: 1 - 9%) <sup>1-5</sup>	35% <sup>5</sup> (Range: 9 - 35%) <sup>6-8</sup>
<b>GI Toxicity</b> moderate to severe diarrhea, urgency, incontinence, fistula	None	15% <sup>9</sup> (Range: 0 - 24%) <sup>1-4</sup>	25% <sup>9,12</sup> (Range: 0 - 40%) <sup>1-5</sup>	7% <sup>5</sup> (Range: 1 - 21%) <sup>6-8</sup>

1. Tewari et al 2012 (Meta-Analysis); 2. Yaxley et al 2016 (RCT); 3. Hamdy et al 2016 (ProtecT RCT); 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 2012; 13. Eggenner et al, Pivotal Trial of MRI-Guided Transurethral Ultrasound Ablation in Men with Localized Prostate Cancer, J Urol 2019.

For more information on TACT data visit: <https://profoundmedical.com/investors/#tactdata>

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