AQUABLATION®
Therapy by PROCEPT BioRobotics

WATER II Study

Aquablation Procedural Outcomes in Large Prostates (80-150g)

12 Month Results

CUA 2019 Potential Conflict of Interest Disclosure

Speaker /Chair Name	Advisory Boards	Speaker's Bureau	Payment/Honoraria	Grants/ Research Support	Clinical Trials	Investments	Patents
Naeem Bhojani	Boston Scientific	----------	Astellas Pfizer	----------	Procept: Water II study	----------	----------

Aquablation Therapy with the AQUABEAM® Robotic System

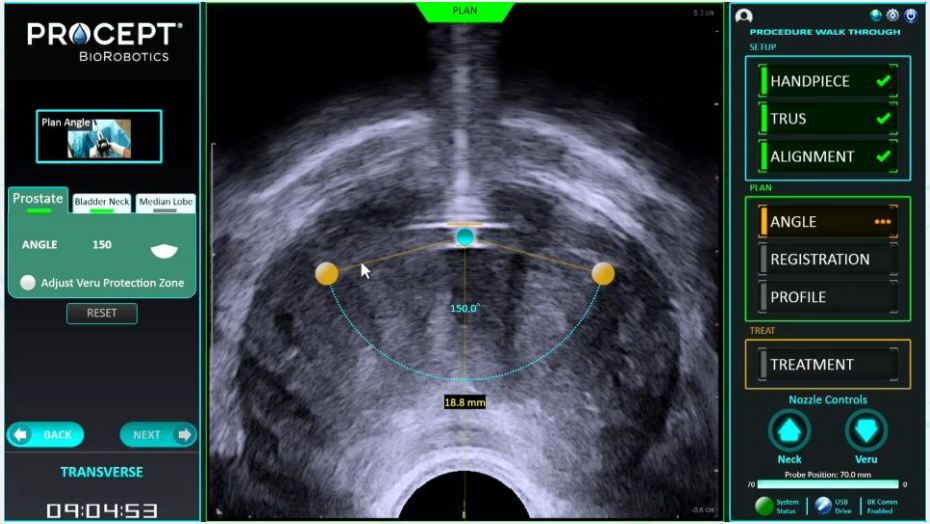
Prostate tissue resection with a heat-free waterjet

Real-time image guidance
Intra-procedural bi-plane TRUS imaging plus cystoscopic visualization

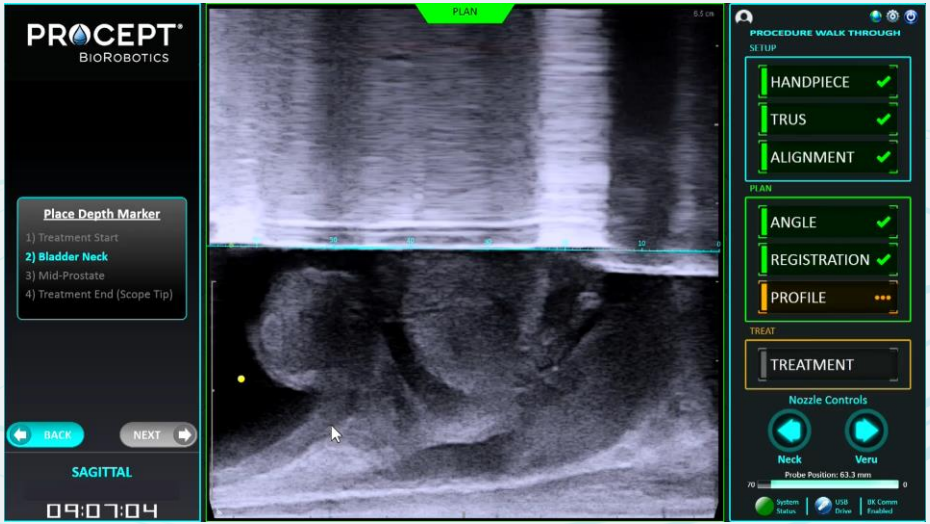
Surgical planning
Surgeon defined treatment plan prior to Aquablation therapy

Robotic execution
Robotically controlled, heat-free tissue removal

Aquablation Procedural Planning

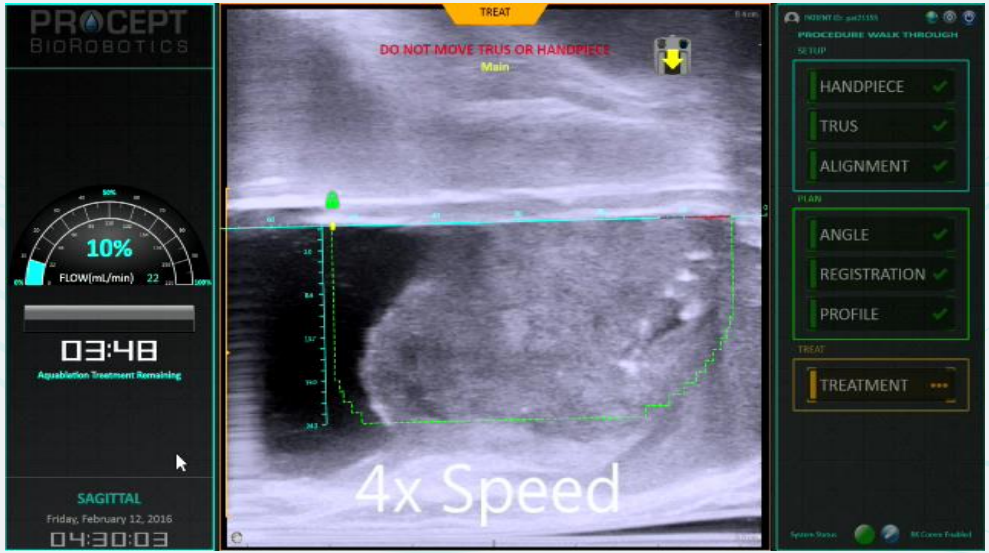


Angle Planning
Transverse View



Contour Planning
Sagittal View

Heat-Free Waterjet Resection



Tissue Resection

Veru Cut

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WATER Study

Aquablation Procedural Outcomes in small to medium Prostates (30-80g)

Trial Design

275 men
with moderate to severe LUTS due to BPH

Inclusion
45-80 years of age, 30-80 gram prostates by TRUS, intravesical lobe permitted, IPSS ≥ 12, Qmax ≤ 15

Exclusion
prostate cancer, prior BPH surgery, neurogenic bladder

- **(72)** screen fail / withdraw
- **(19)** roll-in
- **(3)** randomized, but not treated

Yes (n=181)

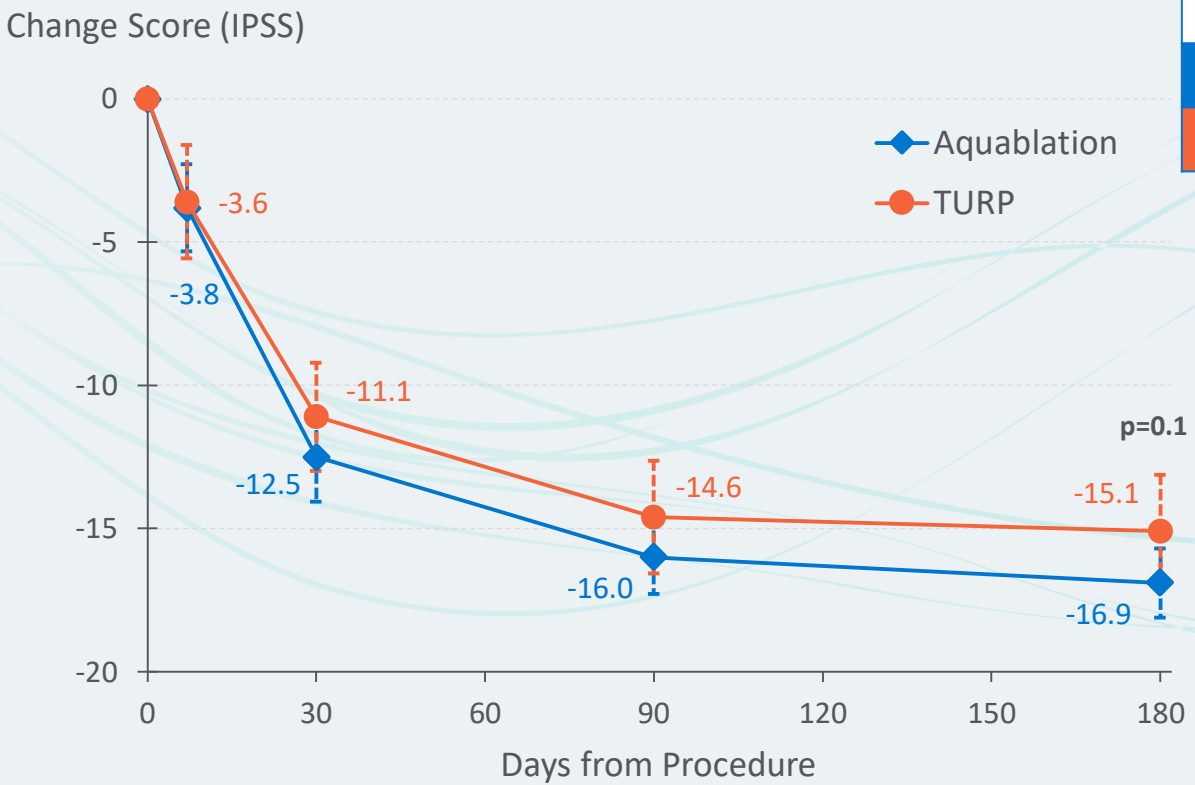
Blinded and randomized 2:1*

- Aquablation (n=116)
- TURP (n=65)

Blinded Investigator Follow-up:
1 week, 3 months, 6 months, 1 year, annually through 3 years
CEC blinded for all adjudications

*Stratified by IPSS and center

Primary Endpoint: 6 Month Efficacy



IPSS Score	Baseline	6 months
Aquablation	22.9 ± 6.0	5.9 ± 5.0
TURP	22.2 ± 6.1	6.8 ± 5.5

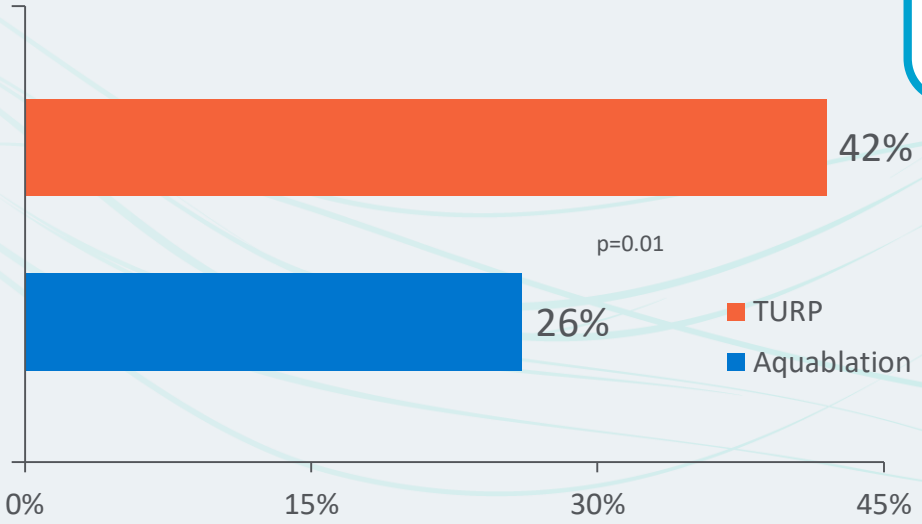
Aquablation therapy non-inferior to TURP

- 14/17 sites had no prior Aquablation therapy experience
- Median (range) of 5 (1-18) Aquablation procedures/surgeon

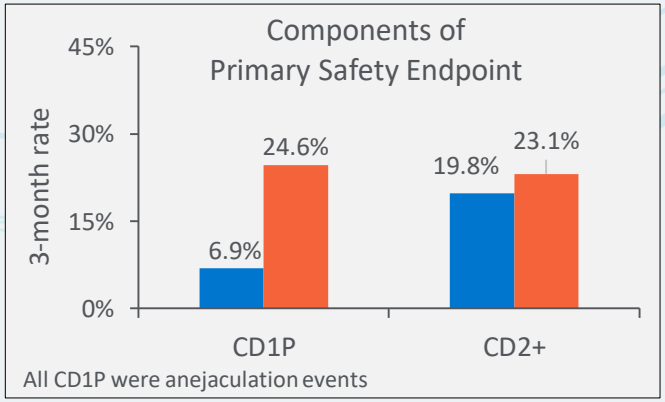
Data reported as mean (95% CI)

Primary Endpoint: 3 Month Safety

Clavien-Dindo grade 1 persistent (CD1P) events and grade 2 or higher (CD2+) events*



Aquablation therapy superior to TURP



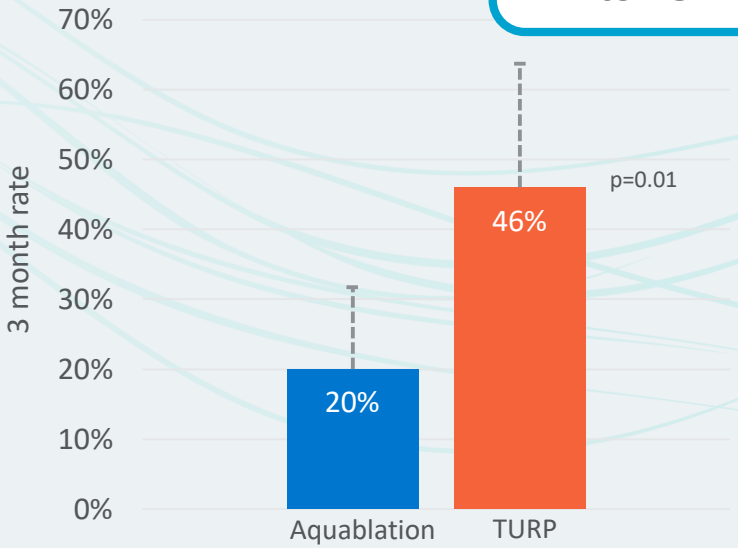
Safety results held consistent at 6 months

* Primary Safety: possibly, probably, definitely
CD1P – Incontinence, erectile dysfunction, and ejaculatory dysfunction
CD2+ – Events requiring pharmacological treatment, blood transfusions, endoscopic, surgical or radiological interventions

Pre-specific Subgroup Analysis: >50g Prostate

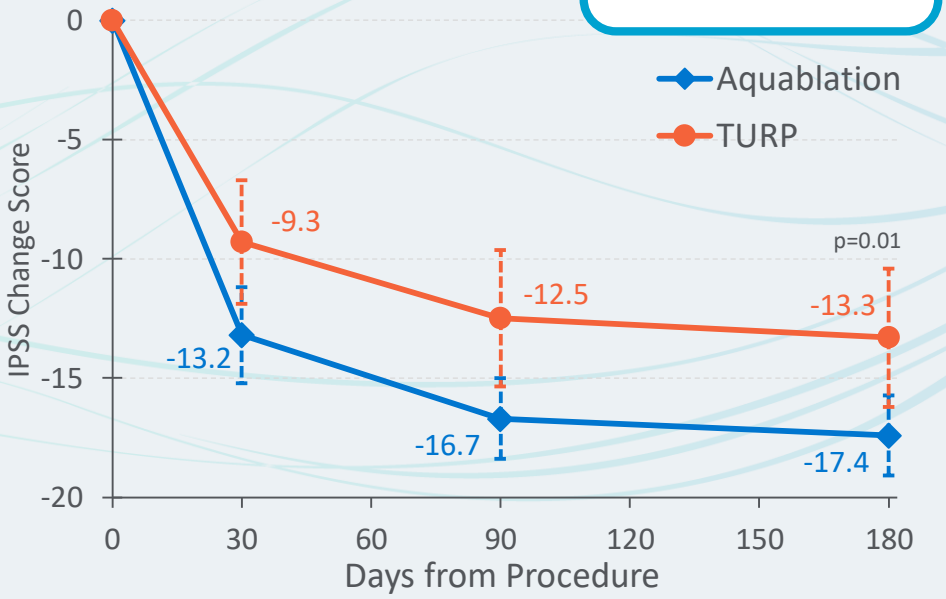
Primary Safety Endpoint

Aquablation therapy superior to TURP



Primary Efficacy Endpoint

Aquablation therapy superior to TURP



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WATER II Study

Aquablation Procedural Outcomes in Large Prostates (80-150g)

Enrolling Centers

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United States	Site PI / Treating Surgeon(s)	Enrolled
San Diego Clinical Trials	Dr. Mo Bidair	25
Adult & Pediatrics Urology	Dr. Andrew Trainer, Dr. Andrew Arther	12
Virginia Urology	Dr. Eugene Kramolowsky	10
University of Southern California	Dr. Mihir Desai, Dr. Leo Doumanian	6
Albany Medical College	Dr. Ronald Kaufman	4
Indiana University Health	Dr. James Lingeman, Dr. Amy Krambeck	4
Urology of Virginia	Dr. Gregg Eure	4
Wake Forest School of Medicine	Dr. Gopal Badlani	4
The University of Vermont Medical Center	Dr. Mark Plante	4
VA Long Beach Healthcare System	Dr. Edward Uchio, Dr. Greg Gin	4
Mayo Clinic Arizona	Dr. Mitch Humphreys	2
UT Southwestern Medical Center	Dr. Claus Roehrborn	2
Icahn School of Medicine at Mount Sinai	Dr. Steven Kaplan, Dr. Jay Motola	1

Canada	Site PI / Treating Surgeon(s)	Enrolled
University of Montreal Hospital Center	Dr. Kevin Zorn, Dr. Naeem Bhojani	12
University of Toronto	Dr. Dean Elterman	4
University of British Columbia	Dr. Larry Goldenberg, Dr. Ryan Paterson, Dr. Alan So	3

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Trial Design

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114 men
with moderate to severe LUTS due to BPH

↓

Inclusion

45-80 years of age, 80-150cc prostates by TRUS, intravesical lobe and prior BPH surgery permitted, IPSS ≥ 12, Qmax ≤ 15

Exclusion

prostate cancer, urinary catheter use daily for 90 or more days → **(13)** screen fail / withdraw

↓

Yes (N=101)

↓

Aquablation (N=101)

Investigator Follow-up:
1 month, 3 months, 6 months, and 1 year
CEC adjudicates all adverse events

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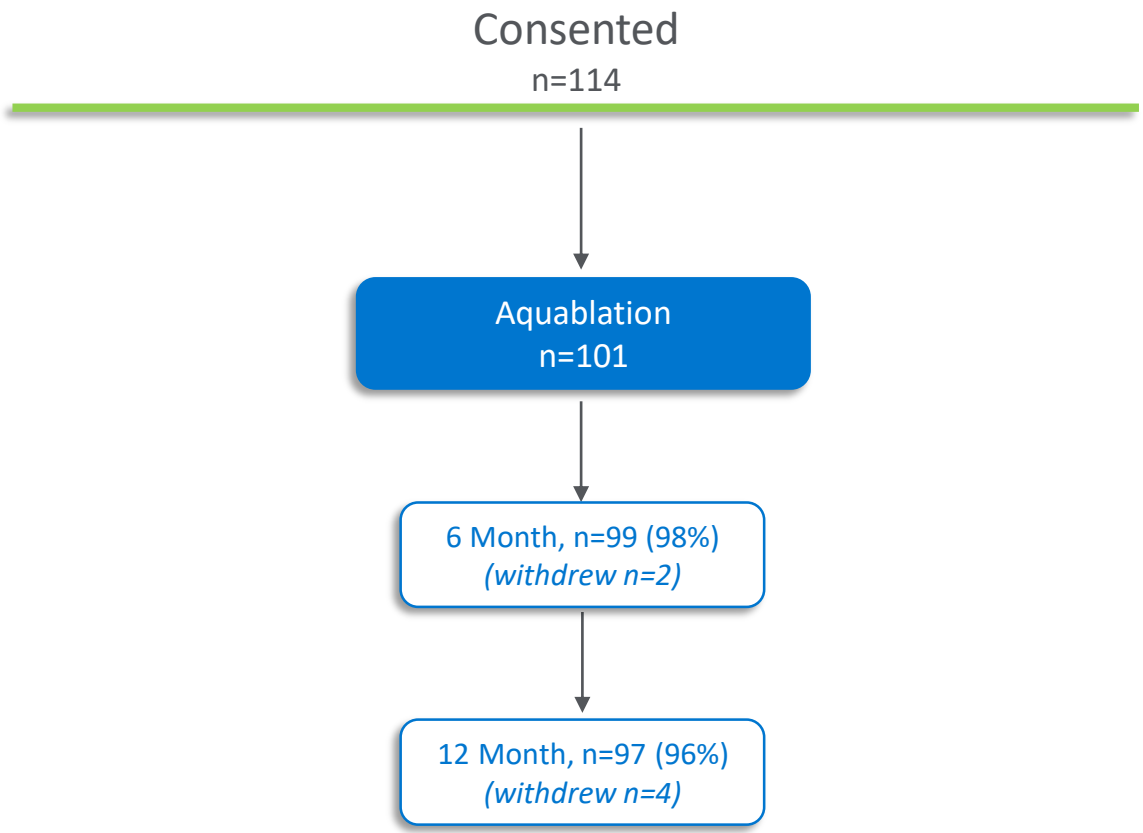
Subject Follow-up



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Primary Endpoints

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3 Month Safety: Proportion difference in persistent Clavien-Dindo (CD) grade 1 event or a CD grade 2 or higher event by month 3 (probably or definitely related)

- CD Grade definitions for post-operative complications
  - Grade 1 = persistent erectile dysfunction, ejaculatory dysfunction or incontinence
  - Grade 2 = requires pharmaceutical treatment
  - Grade 3 = requires surgical, endoscopic, or radiologic intervention
  - Grade 4 = life threatening
  - Grade 5 = death
- Compared to an OPC of 65%, 80% power
- Success is defined as the upper 95th confidence interval of the event rate is less than 65%

3 Month Efficacy: Change in IPSS at 3 months

- Compared to an OPC of 11 points, 99% power
- Success is defined as the lower 95th confidence interval of the change in IPSS is greater than 11

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Baseline Patient Demographics

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	Aquablation (n=101)	
	Mean	SD
Age	67.5	6.6
BMI	28.4	4.2
IPSS	23.2	6.3
Prostate volume, cc	107.4	22.1
Middle Lobe, %	83.2	
Intravesical comp., % of ML	96.4	
Intravesical protrusion, cm	1.8	0.8
PSA, ng/mL	7.1	5.9
Voided volume, cc	170	66
PVR, cc	131	125
Qmax, cc/sec	8.7	3.4
MSHQ-EjD, range 0-15	8.1	3.9

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Intra-operative Results

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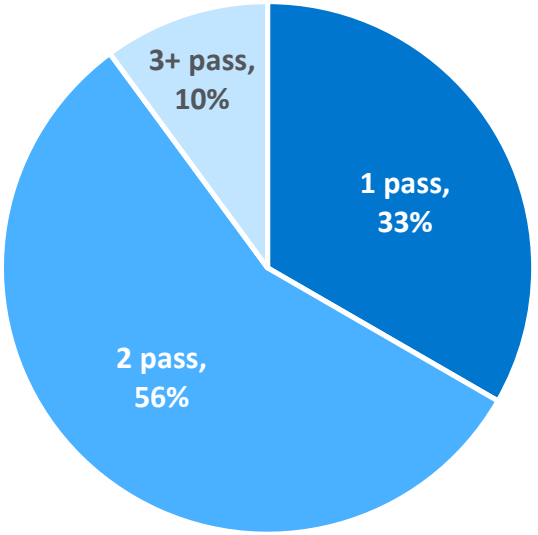
Characteristics	Results
Spinal: General anesthesia	82% : 18%
TRUS insertion to catheter placement	55 ± 19 minutes
Handpiece in/out time	37 ± 37 minutes
Aquablation resection time	8 ± 3 minutes
Average number of passes	1.8 passes

Number of Aquablation Treatment Passes per Case



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Hemostasis Method Following Aquablation

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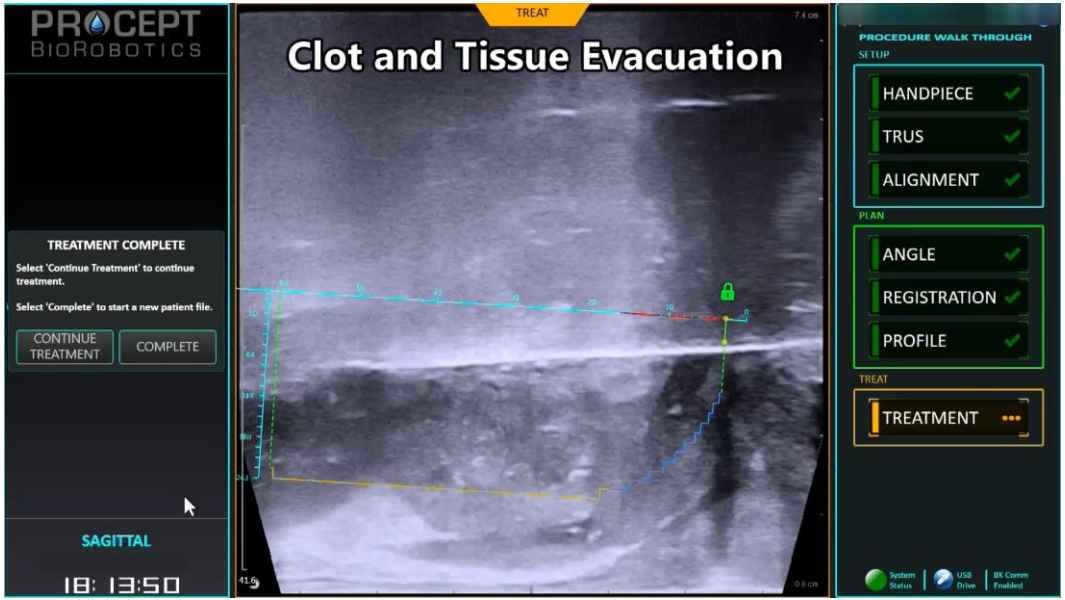

Post-Operative Management	
Bladder neck traction (n)	98
Intra-prostatic catheter placement (n)	3
Average length of traction (hours)	18 ± 10
Catheter length of duration (hours)	94 ± 84
Length of stay (days)	1.6 ± 1
Procedure performed without cautery (%)	100%

Catheter Tensioning Device

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Change in IPSS at 12 Months

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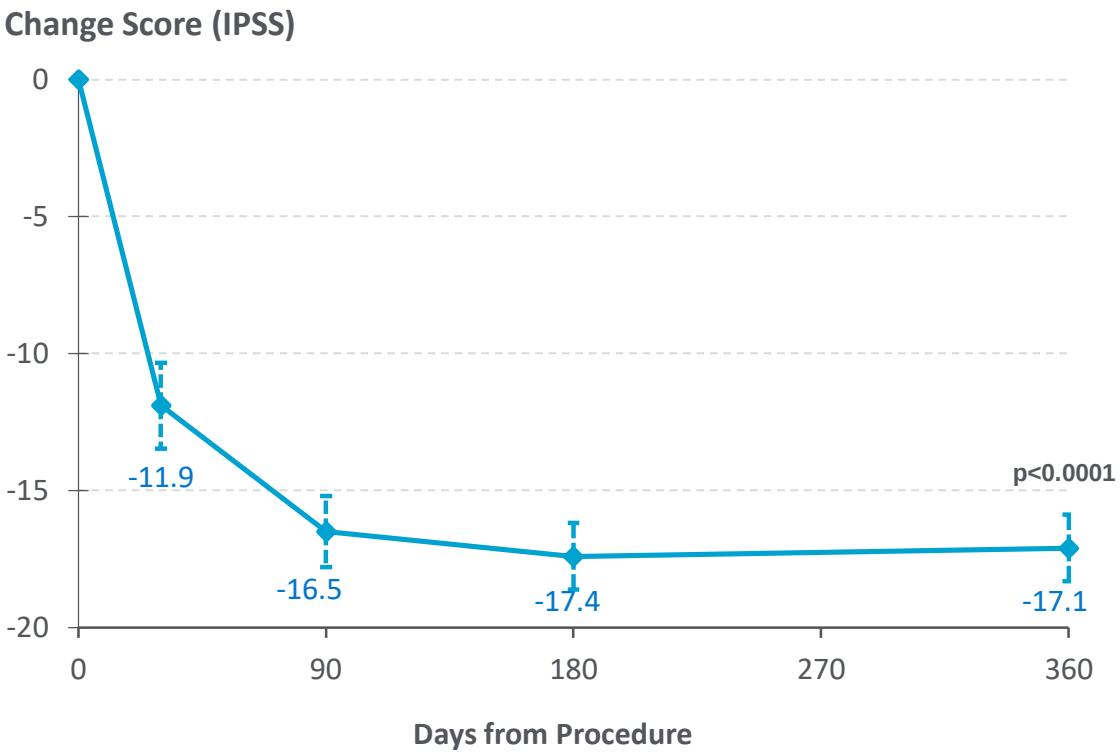

	Baseline	12 months
IPSS Score	23.2 ± 6.3	6.2 ± 5.0

- 9 sites with no prior experience
- 7 sites with median = 4 cases experience

Data reported as mean (95% CI)

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Uroflow – Qmax & PVR

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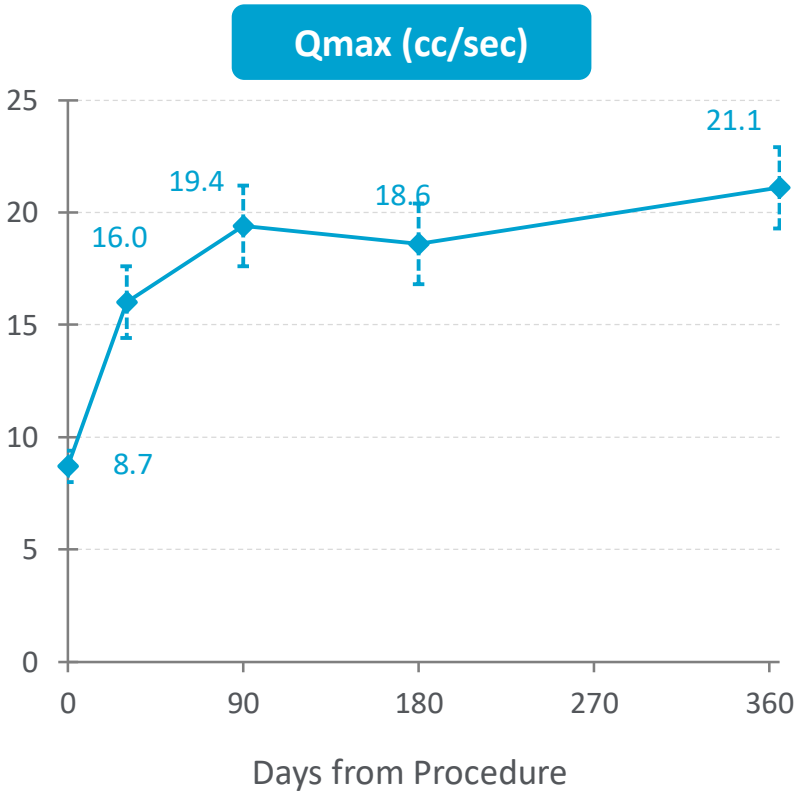

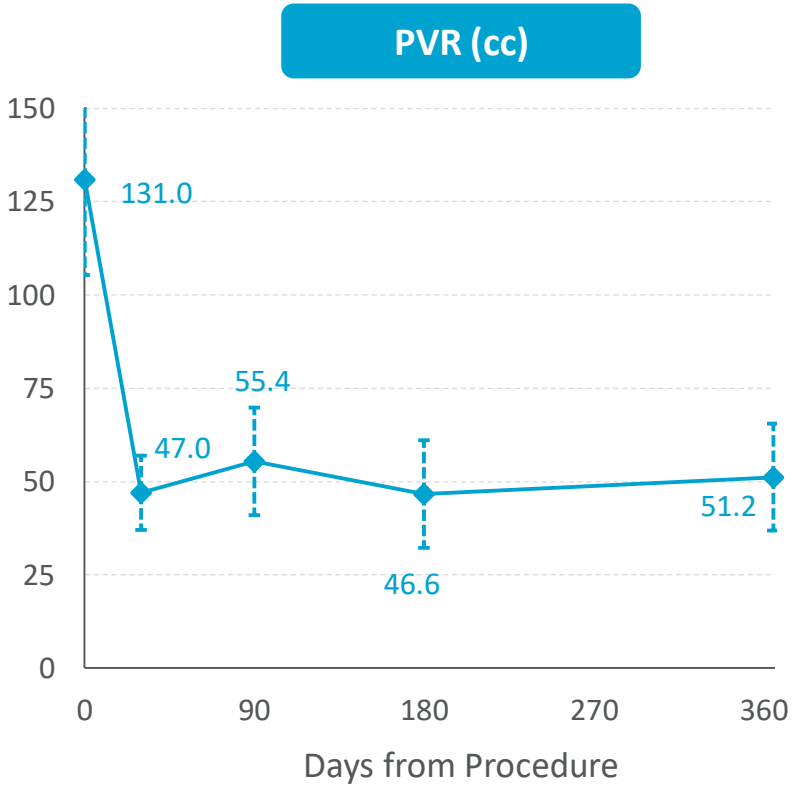

Data reported as mean (95% CI)

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Prostate Volume Reduction – 3 Month TRUS

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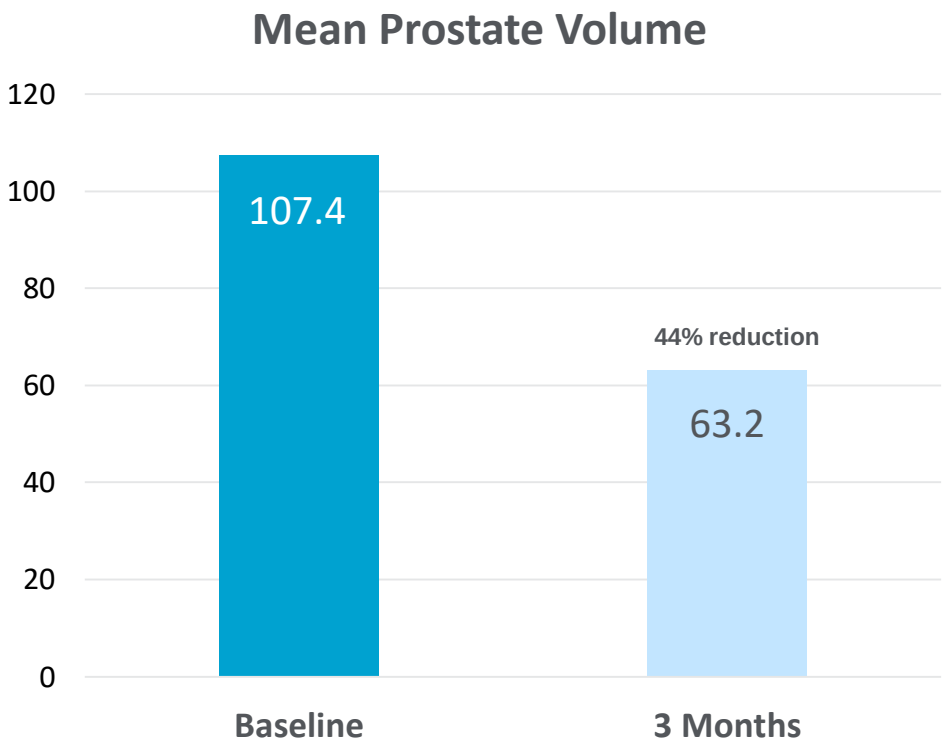

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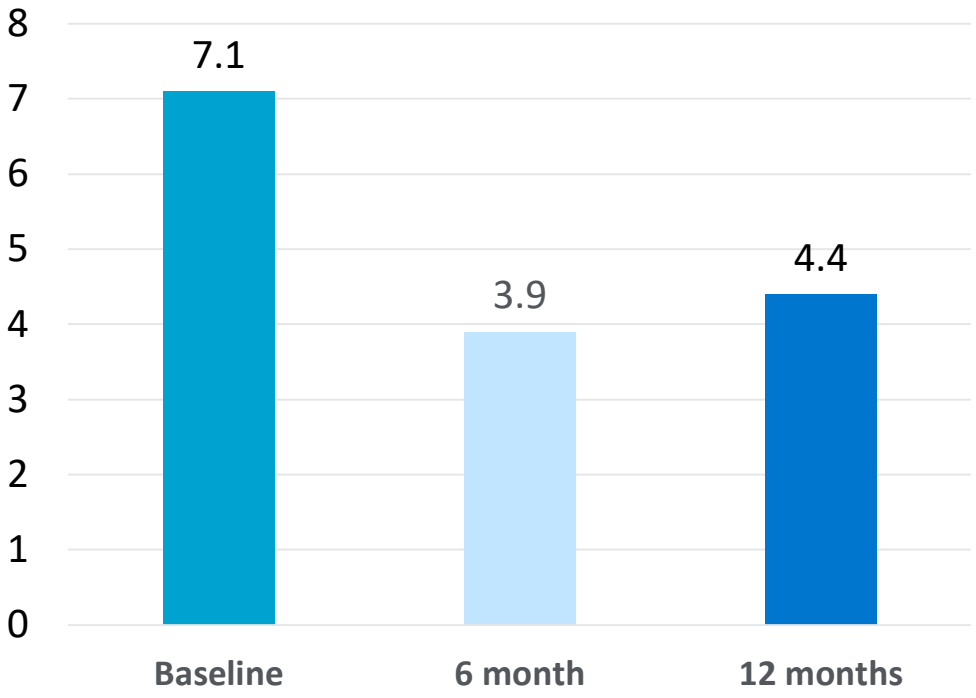
PSA Reduction



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12M Ejaculatory Function (MSHQ)

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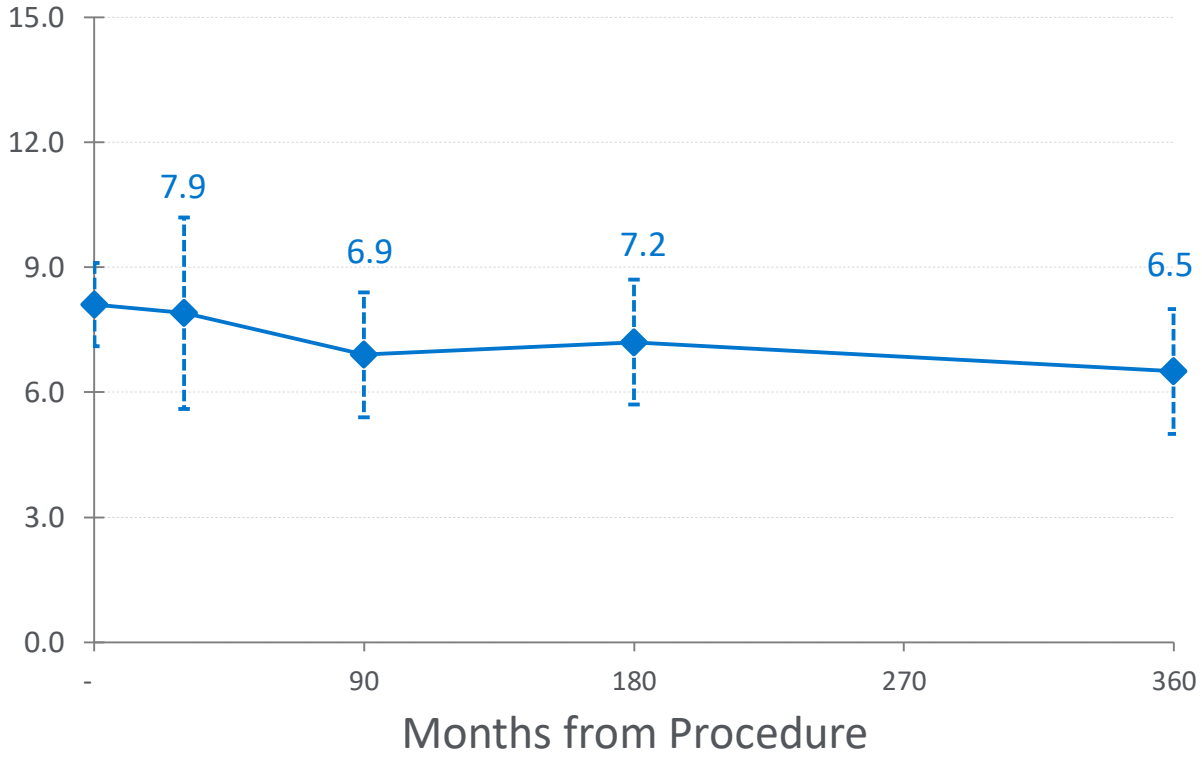

MSHQ-EjD

- 3 questions
- Max score 15
- Self-reported

Data reported as mean (95% CI)
Men who were sexually active at both baseline and follow up visit

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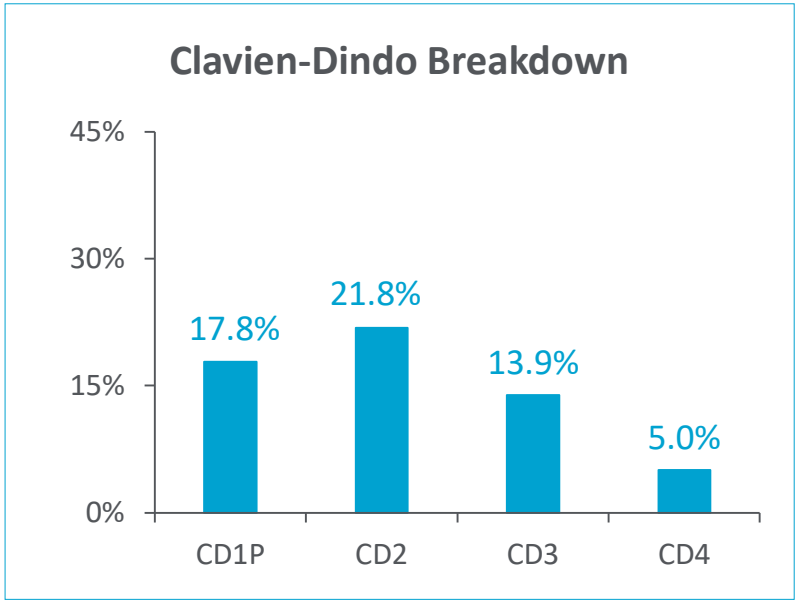
Safety at 12 Months



Other Notable Safety Rates:

- De novo Incontinence = 2%
- Sexual dysfunction:
  - Erectile dysfunction = 0%
  - Ejaculatory dysfunction*= 19%
  - Retreatment for BPH symptoms = 0%

* Defined as absence of ejaculate; Sexually active men only

1. CD grade definitions: CD1P (ejaculatory dysfunction, incontinence), CD2 (requiring pharmacological treatment, blood transfusions), CD3 (endoscopic or surgical interventions), CD4 (complications requiring ICU management)

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Major Bleeding Events

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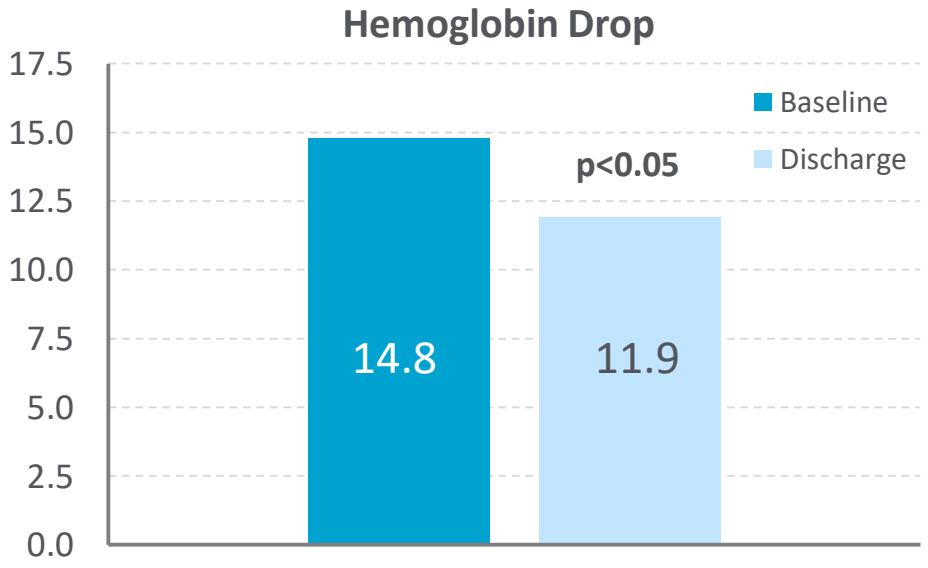
Major Events	Prior to Discharge	Discharge to Day 15	Day 16 to 1 Month	> 1 Month
Transfusion	6	2	2	0
Return to OR	1	2	1	0



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Conclusion

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- Aquablation is a transurethral surgical alternative for larger prostates (80-150cc) with statistically significant reduction in IPSS and improvements in Qmax.
- Despite increased prostate size in WATER II, hemostasis was achieved without cautery in all cases.
- Aquablation demonstrates short learning curve:
  - *9 of the 16 sites with no prior experience*
- Combination of robotics and image guidance significantly reduces tissue removal time which is independent of prostate size
- Aquablation demonstrates durable 1 year results with:
  - Sustained decrease in symptom scores and increase in flow rates
  - Preservation of antegrade ejaculation
  - No reinterventions

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Aquablation Hemostasis Analysis

801 Aquablation Procedures with Various Hemostasis Methods

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Methods

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- 801 Aquablation procedures (average prostate volume 67cc ± 33cc, range 20-280cc)
  - All clinical trial cases that utilized the current robot generation
  - Three large commercial centers (consecutive patients)
- 39 transfusions (4.9%)
- Hemostasis characteristics analyzed:
  - Traction force
    1. Firm traction (>1.3 pounds-force [lbf])
    2. Traditional Catheter Tension (adhere to leg, gauze knot, no traction)
  - Cautery
    1. Selective focal bladder neck (BN) cautery performed after Aquablation
    2. No cautery utilized

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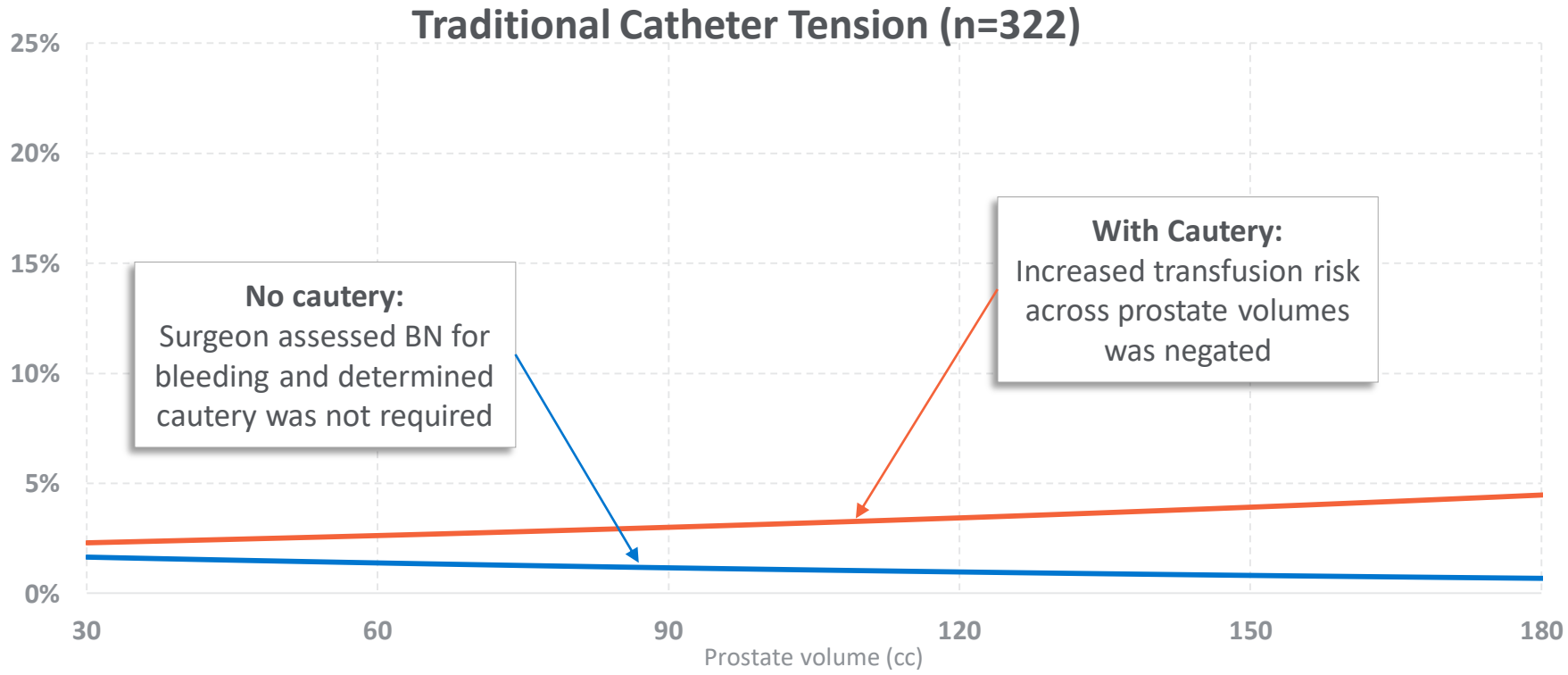
Selective focal bladder-neck cautery with traditional catheter tension reduced transfusion rates to 2% across all prostates volumes



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Complication	Events	Patients, *n*	Rate, %
Clavien–Dindo grade 1			
Bleeding	6	6	5.9
Cardiac	1	1	1.0
Dysuria	8	8	7.9
Gastrointestinal symptoms	6	4	4.0
Meatal stenosis	1	1	1.0
Other	11	7	6.9
Pain	7	5	5.0
Scrotal oedema	3	3	3.0
Sexual	1	1	1.0
Urinary frequency	1	1	1.0
Urinary incontinence	7	7	6.9
Urinary retention	2	2	2.0
Urinary urgency	3	2	2.0
Total	57	31	30.7
Clavien–Dindo grade 2			
Bleeding	8	6	5.9
Cardiac	1	1	1.0
Dysuria	1	1	1.0
Infection	2	2	2.0
Other	2	2	2.0
Pain	1	1	1.0
Urinary frequency	1	1	1.0
UTI	4	4	4.0
Urinary urgency	1	1	1.0
Total	21	19	18.8
Clavien–Dindo grade 3			
Bleeding	7	6	5.9
Dysuria	1	1	1.0
Meatal stenosis	2	2	2.0
Urethral stricture	1	1	1.0
Urinary incontinence	1	1	1.0
Total	12	11	10.9
Clavien–Dindo grade 4			
Bleeding	2	2	2.0
Cardiac	2	2	2.0
Cerebrovascular accident	1	1	1.0
Multisystem organ failure	1	1	1.0
Total	6	5	5.0

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