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EXPERIENCE

PD61-01 WATER VS WATER II: TWO YEAR COMPARISON OF AQUABLATION THERAPY FOR BENIGN PROSTATIC HYPERPLASIA

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Aquablation Therapy

BPH Surgery Reimagined

- Clarity
- Consistency
- Control

AQUABEAM® ROBOTIC SYSTEM

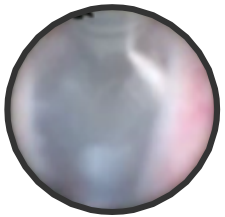
(Ultrasound and Articulating Arms not pictured)

The Aquablation Robotic Solution

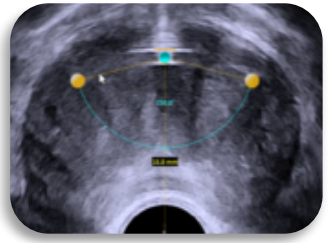
MULTI-DIMENSIONAL IMAGING

- Improved decision making
- Personalized treatment planning

Enhanced Information & Data Integration



Cystoscopic Visualization

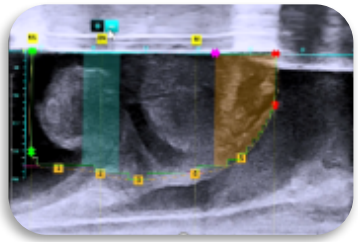


Ultrasound Visualization

AUTONOMOUS TISSUE REMOVAL

- Autonomous execution
- Precision and accuracy
- Tissue Removal

Personalized, Patient-specific Surgical Standardization



Optimal tissue removal plan for each patient

CAVITATING WATERJET

- Tissue-selective
- Eliminates thermal complications

Tissue-selective Cavitation

Aquablation FDA Clinical Trials

THE *ONLY* FDA PIVOTAL STUDY RANDOMIZED TO TURP
(GOLD STANDARD)

- Prostates 30 – 80 mL
- N = 181 (Aquablation therapy = 116, TURP = 65)
- 17 sites in the United States, UK, Australia & New Zealand (14 sites: no prior experience with Aquablation therapy)

RESULTS: Superior safety & non-inferior efficacy compared to TURP

THE *ONLY* PROSPECTIVE MULTICENTER STUDY SUCCESSFULLY COMPLETED FOR LARGE PROSTATES

- Prostates 80 – 150 mL
- N = 101
- 16 sites in the United States and Canada (9 sites: no prior experience with Aquablation therapy)

RESULTS: Safe & effective in larger prostates, without significant increase in procedure or resection time

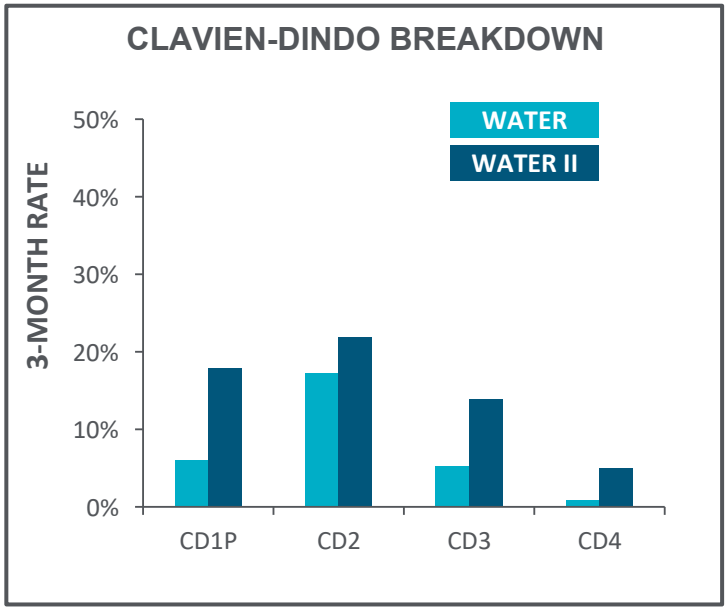
Baseline Characteristics

	WATER (n=116)		WATER II (n=101)		
	Mean	SD	Mean	SD	P value
Age	65.9	7.3	67.5	6.6	0.0854
BMI	28.4	4.1	28.3	4.1	0.8232
IPSS	22.9	6.0	23.2	6.3	0.6930
Prostate volume, mL	54.1 range (25-80)	16.3	107.4 range (80-150)	20.2	<0.0001
PSA, ng/mL	3.7	3.0	7.1	5.9	<0.0001
Qmax, mL/sec	9.4	3.0	8.7	3.4	0.111
MSHQ-EjD	8.1	3.7	8.1	3.9	0.9160
IIEF-5 (SHIM)	17.2	6.5	15.1	7.4	0.0500

Procedure Outcomes

	WATER (n=116)		WATER II (n=101)		
	Mean	SD	Mean	SD	P value
TRUS in to Cath in (min)	39.7	15.2	54.5	19.2	<0.0001
Resection Time (min)	3.9	1.4	8	3.2	<0.0001
Number of passes	1.1	0.3	1.8	0.6	<0.0001
Catheter days	2	2.3	3.9	3.6	<0.0001
Hospital length of stay (days)	1.4	0.7	1.6	1.0	0.0868
Hemoglobin at discharge	13.0	1.7	11.9	2.2	<0.0001

Safety Endpoint



OTHER NOTABLE SAFETY RATES	WATER (n=116)	WATER II (n=101)
Incontinence	0%	2% de novo
Erectile dysfunction	0%	0%
Ejaculatory dysfunction	10%	19%
Perioperative Transfusion	0.9%	5.9%
D/C to Day 30 Transfusion	0%	4.0%

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

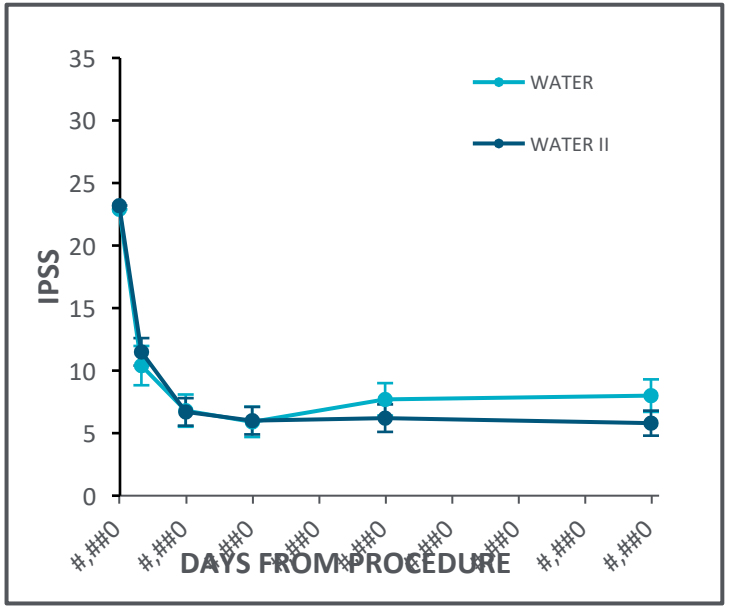
New Hemostasis Method: Focal Bladder Neck Cautery

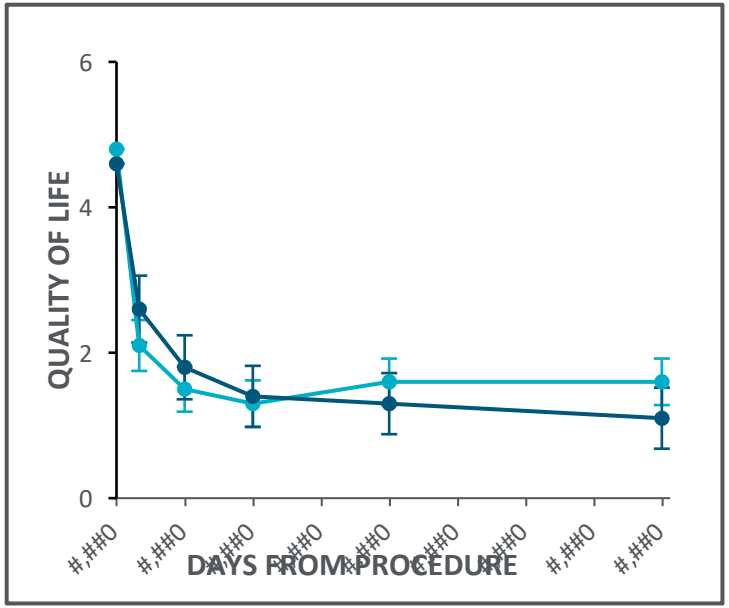
	2019	2020	TOTAL (prostate size 20 – 230mL)
NEW	0/16 (0.0%)	3/172 (1.7%)	3/188 (1.6%)
EXP	0/266 (0.0%)	0/173 (0.0%)	0/439 (0.0%)
ALL	0/282 (0.0%)	3/345 (0.9%)	3/627 (0.5%)

New sites defined as 20 or less Aquablation cases
Experienced sites defined as more than 20 Aquablation cases

Data as of 01Apr2020

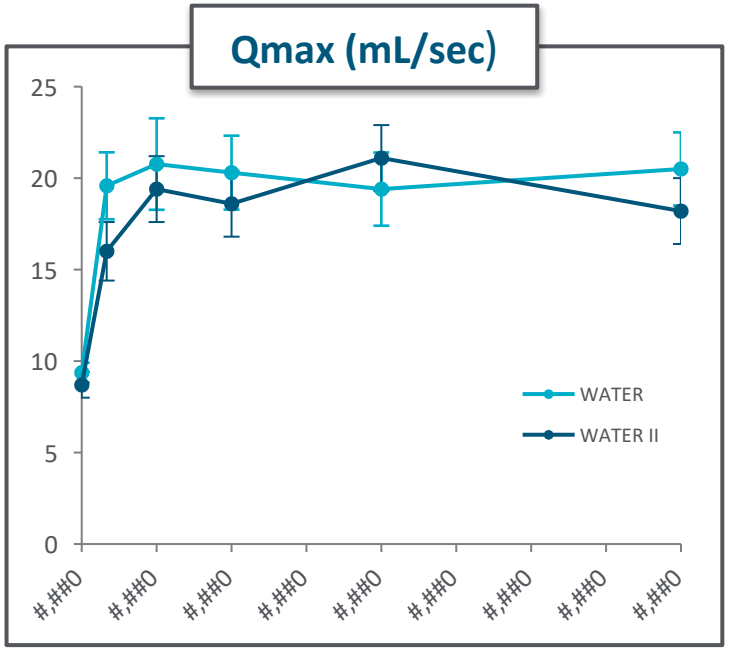
BPH Symptom Improvement

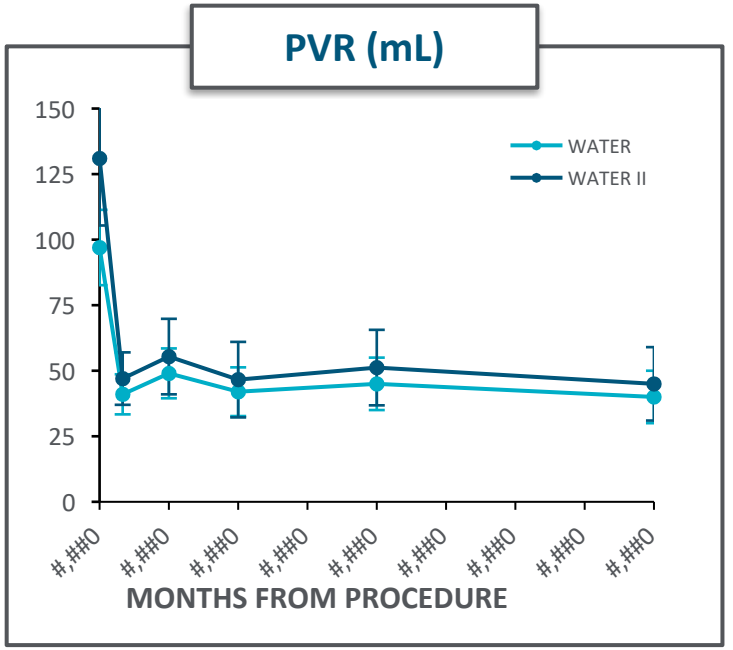




Data reported as mean (95% CI)

Uroflow: Qmax & PVR





Data reported as mean (95% CI)

Durability at 2-Years

	ANNUALIZED RETREATMENT RATE	PSA	
		Baseline	2-Year
WATER	2.2%	3.7	3.0
WATER II	1.0%	7.1	4.9

Limitations

We did not directly compare Aquablation to volume independent surgical alternatives, such as HoLEP and PVP.

With only a 36-month follow-up for WATER and 24-month follow-up for WATER II, longer-term follow-up data from these cohorts are needed to demonstrate the durability of the treatment outcomes.

Conclusion

First comparison of 2-year data from two prospective Aquablation clinical studies, comparing prostates < 80 mL vs. > 80 mL

- Aquablation therapy clinically normalizes outcomes among patients regardless of prostate size or shape
- Symptom improvement and flow rates were consistent in both studies with durable results out to two years
- Retreatment rates were low and similar across studies