PD56-05 THREE-YEAR OUTCOMES AFTER AQUABLATION COMPARED TO TURP: EFFICACY & EJACULATORY IMPROVEMENTS SUSTAINED

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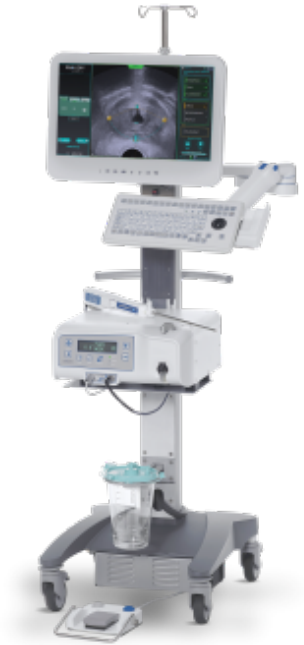
Aquablation Therapy



AQUABEAM® ROBOTIC SYSTEM

(Ultrasound and Articulating Arms not pictured)

- Clarity
- Consistency
- Control

BPH Surgery Reimagined

Real-time multi-dimensional imaging enables complete visibility of the entire prostate

Robotic execution delivers predictable clinical excellence across prostates of all sizes

Precise heat-free waterjet resection reduces risk of heat-based complications

Study Design

Randomized, double-blinded, global, multi-center phase III trial enrolling 181 men with moderate-to-severe LUTS related to BPH and prostate sizes between 30 – 80 mL

Primary safety endpoint was the occurrence of persistent CD Grade 1, Grade 2 or higher operative complications at 3-months.

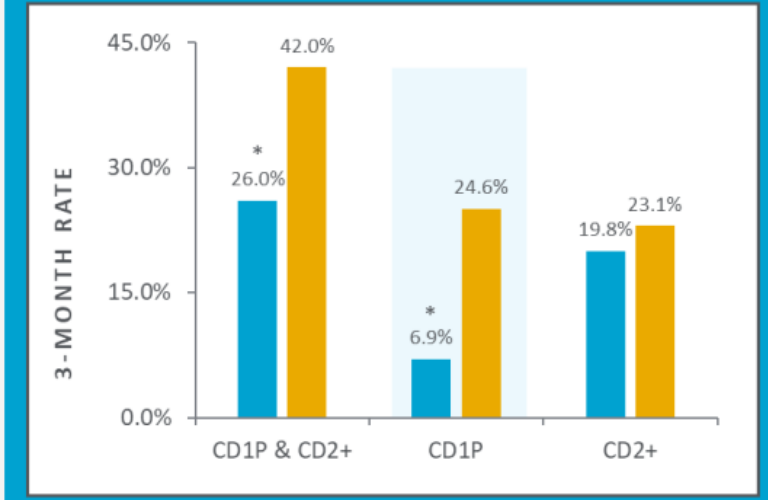
Primary efficacy endpoint was the reduction in IPSS score at 6-months.

Baseline Demographics & Operative Characteristics

	AQUABLATION (N=117)		TURP (N=67)		
	MEAN	SD	MEAN	SD	P Value
BASELINE DEMOGRAPHICS					
Age	66.0	7.3	65.8	7.2	0.8706
IPSS	22.9	6.0	22.2	6.1	0.4276
Prostate volume, mL	54.1	16.2	51.8	13.8	0.3062
Middle Lobe, %	50.4		52.2		0.8744
Voided volume, mL	235	100	249	113	0.4001
Qmax, mL/sec	9.4	3.0	9.1	2.7	0.5140
PVR, mL	97	79	112	93	0.2867
OPERATIVE CHARACTERISTICS					
Instrument in / catheter in time	32.8	16.5	35.5	15.3	0.2752
Resection time	3.9	1.4	27.4	12.5	< 0.0001
Length of stay	1.4	0.7	1.4	0.7	0.3357

Safety Summary

SAFETY SUMMARY: CLAVIEN-DINDO BREAKDOWN

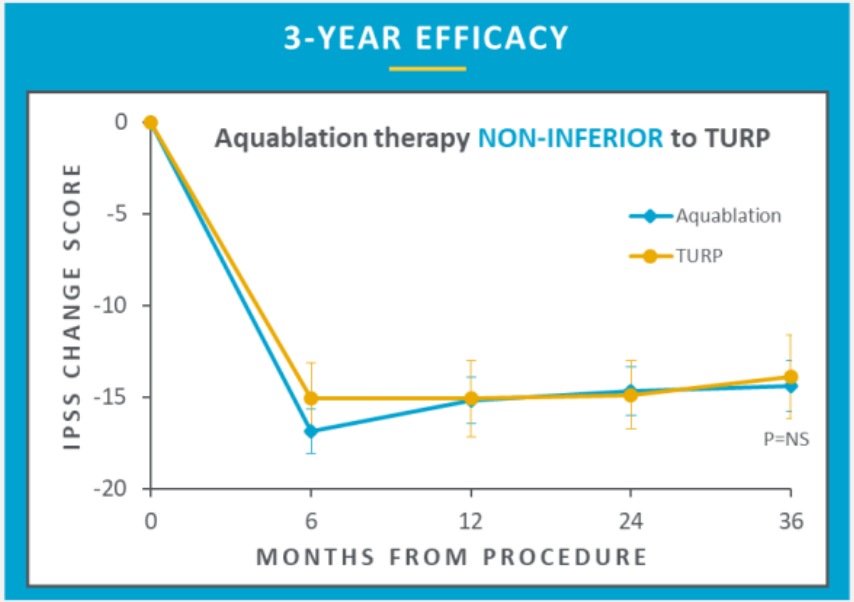


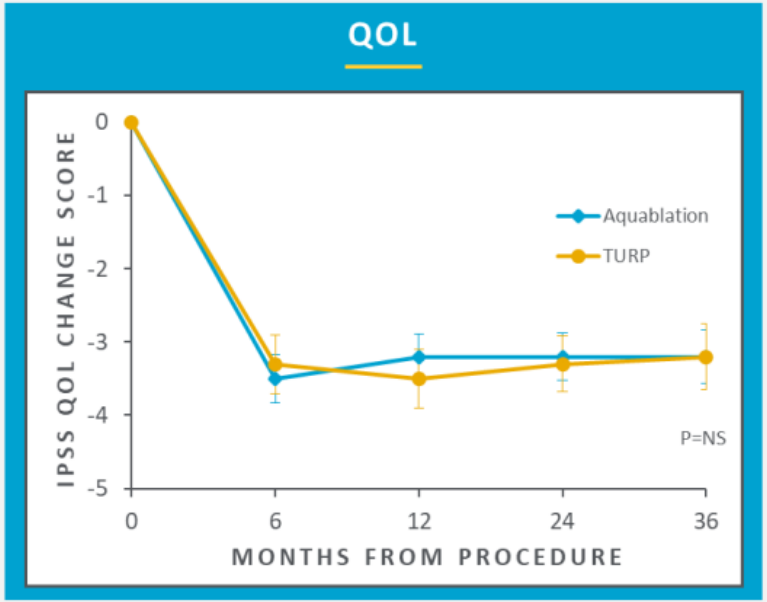
	AQUABLATION	TURP	P-VALUE
Incontinence	0%	0%	P = NS
Erectile Dysfunction[1]	0%	0%	P = NS
Retrograde Ejaculation[1]	10%	36%	P < 0.05

CD1P – Incontinence, erectile dysfunction, and ejaculatory dysfunction
CD2 – Events requiring pharmacological treatment, blood transfusions, endoscopic, surgical or radiological interventions

1. Based on sexually active men
* P<0.05

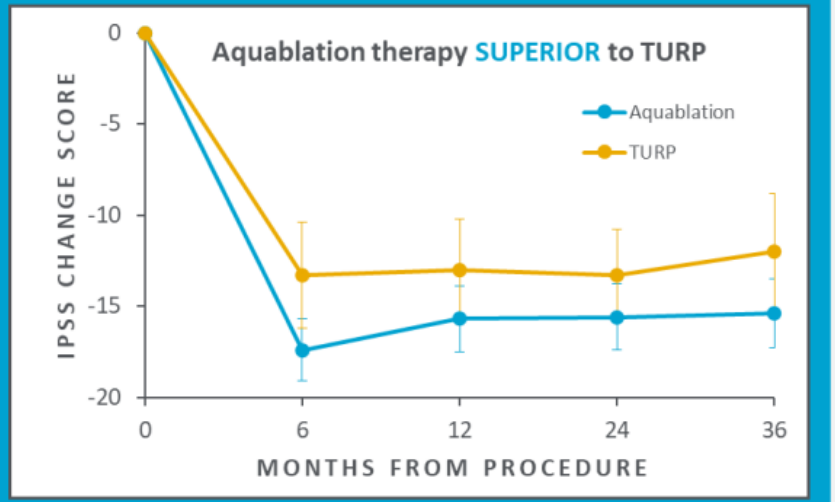
Results


3-YEAR EFFICACY
Aquablation therapy NON-INFERIOR to TURP
IPSS CHANGE SCORE
0
-5
-10
-15
-20
Aquablation
TURP
P=NS
0
6
12
24
36
MONTHS FROM PROCEDURE


QOL
IPSS QOL CHANGE SCORE
0
-1
-2
-3
-4
-5
Aquablation
TURP
P=NS
0
6
12
24
36
MONTHS FROM PROCEDURE

Results

≥50 ML SUBGROUP: 3-YEAR EFFICACY



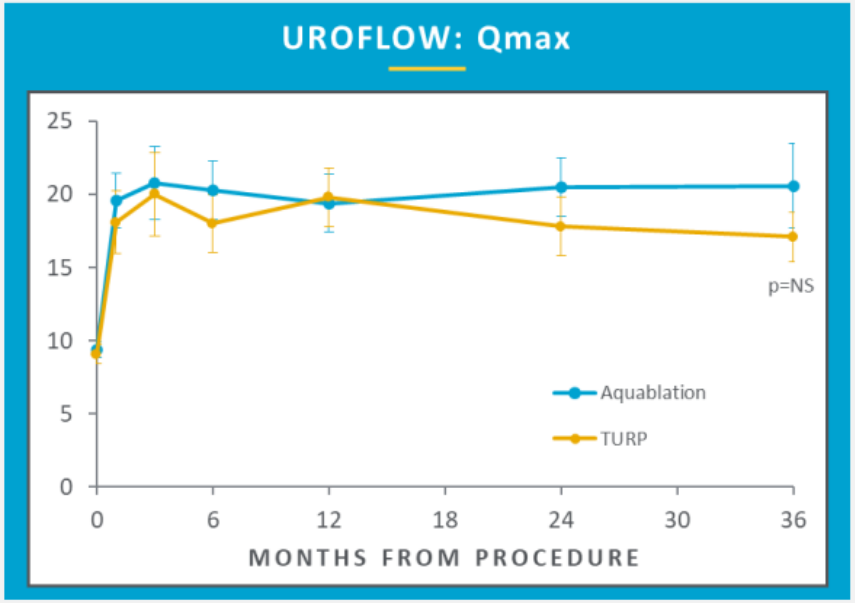
In the WATER Study,

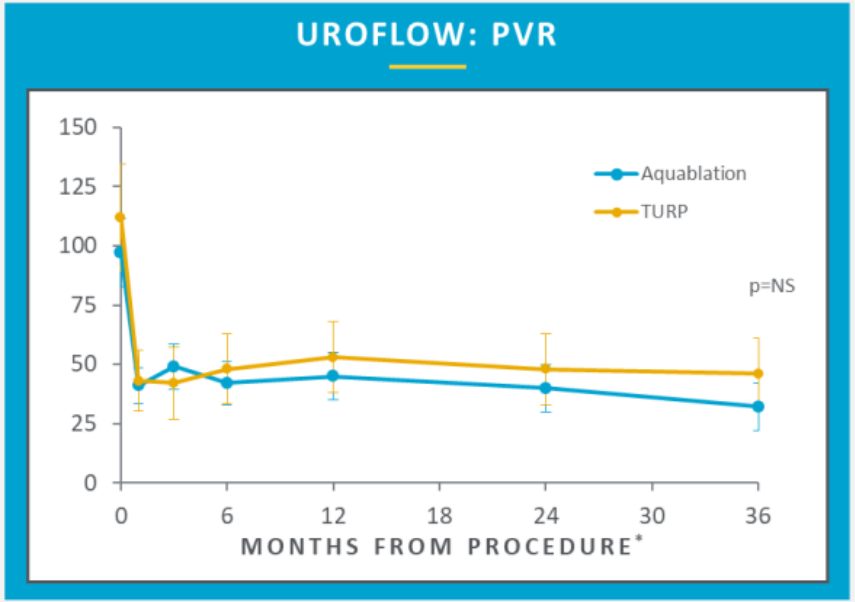
AQUABLATION THERAPY DEMONSTRATED

SUPERIOR SYMPTOM IMPROVEMENT

($P < 0.05$) TO TURP IN PROSTATES ≥ 50 mL

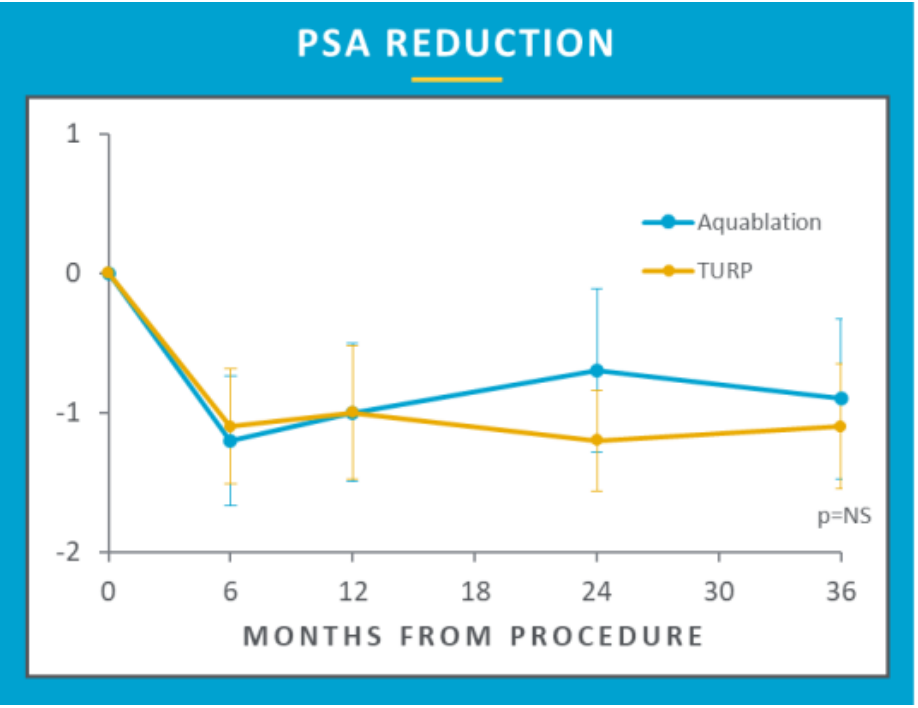
Results





*Data reported as mean (95% CI)

Results



Aquablation & TURP showed
no statistical difference in retreatment rates
at 6, 12, 24 or 36 months

Aquablation therapy demonstrated a
low average yearly retreatment rate of 1.4% per year

Conclusions

AQUABLATION THERAPY

Demonstrated superior symptom relief and safety compared to TURP in prostates ≥ 50 mL

- Aquablation saw consistent uroflow improvement from 6 months out to 36 months
- Low retreatment rates for both arms
- Combination of robotics and image guidance significantly reduces tissue removal time dependency from operator, prostate anatomy, and prostate size
- Aquablation demonstrated a significantly lower rate of sexual dysfunction at the primary safety endpoint of 3 months