

# 5 YEAR RESULTS OF A MULTI-CENTER TRIAL OF A NEW GENERATION COOLED TUMT FOR BPH

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## Introduction

The five year IDE study of cooled High-Energy TUMT (CTC) has been completed by five US centers using the (CTC) treatment catheter from Urologix, Inc. The CTC has an advanced cooling system which allows it to provide a complete treatment in 28.5 minutes, versus a 60-minute treatment with the Targis® treatment catheter. Data from 6 weeks through 5 years support the efficacy and durability of the treatment. Only 3 of the 66 patients were lost to follow-up during the 5 years study.

## Materials and Methods

66 subjects completed a single Cooled ThermoTherapy™ treatment utilizing a CTC treatment catheter in an outpatient setting with oral and topical analgesia. Subjects were followed up at 1 week, 6 weeks, 3 months, 6 months, 1 year, then yearly thereafter through 5 years post treatment.

### Baseline Characteristics

	Mean	Range
Age	67.3	50.0 – 84.3
AUASS	20.8	9 – 32
Peak Flow/Qmax (cc/sec)	8.3	3.5 – 13.1
QOL Score	3.9	0 – 6
Post Void Residual (cc)	81.2	0 – 276
Prostate Weight (g)	49.6	14.8 – 97.8
PSA	3.3	0.3 – 11.4
Duration of BPH symptoms (months)	84.5	8 – 240

Primary enrollment criteria included:

- AUA Symptom Score (AUASS) ≥ 8
- Peak Urinary Flow Rate sustained for 2 seconds (Qmax) ≤ 15 cc/sec
- Washout period for BPH medications
  - 30 days for alpha blockers
  - 60 days for 5-alpha reductase inhibitors

At each visit, the following data was collected:

- American Urological Association Symptom Score (0-35)
- Peak urine flow rate sustained for 2 seconds (cc/sec)
- Quality of Life questionnaire (0-6)
- Concomitant treatments

## Paired results

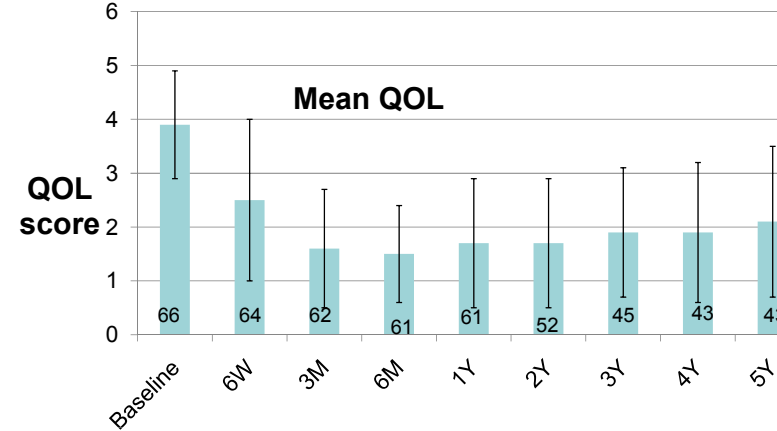
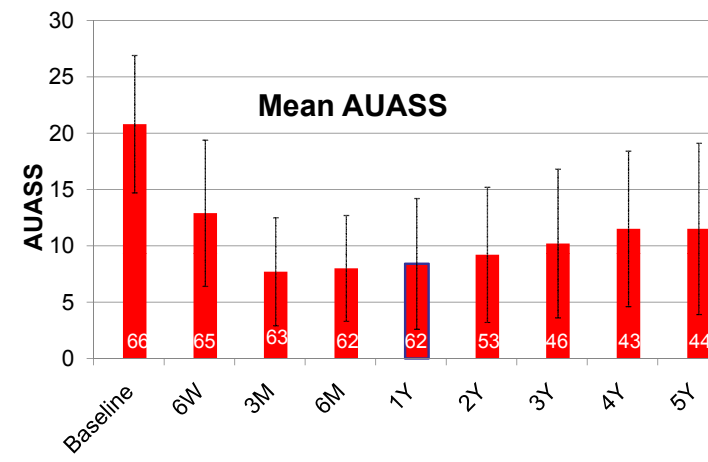
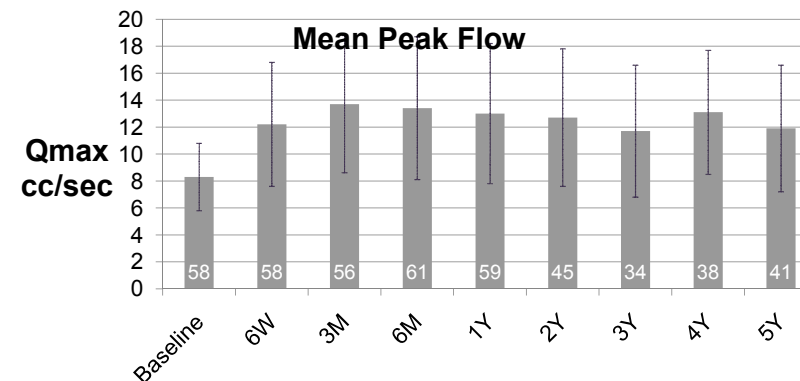
\*p < 0.0001 for all results, except for 3 year Qmax (p=0.0003). Error bars in all graphs represent ± 1 standard deviation

Qmax	N	BL	σ	Mean	σ	%Imp
6W	58	8.6	2.4	12.2	4.6	41.9%
3M	56	8.5	2.5	13.7	5.1	61.2%
6M	61	8.3	2.5	13.4	5.3	61.4%
1Y	59	8.5	2.4	13.0	5.2	52.9%
2Y	45	8.7	2.4	12.7	5.1	46.0%
3Y	34	8.6	2.6	*11.7	4.9	36.0%
4Y	38	8.9	2.4	13.1	4.6	47.2%
5Y	41	8.7	2.6	11.9	4.7	36.8%

AUASS	N	BL	σ	Mean	σ	%Imp
6W	65	20.8	6.1	12.9	6.5	38.0%
3M	63	20.7	6.1	7.7	4.8	62.8%
6M	62	20.4	6.1	8.0	4.7	60.8%
1Y	62	20.5	6.1	8.4	5.8	59.0%
2Y	53	20.2	6.2	9.2	6.0	54.5%
3Y	46	20.7	6.6	10.2	6.6	50.7%
4Y	43	20.8	6.4	11.5	6.9	44.7%
5Y	44	20.7	6.4	11.5	7.6	44.4%

QOL	N	BL	σ	Mean	σ	%Imp
6W	64	4.0	1.0	2.5	1.5	37.5%
3M	62	4.0	1.0	1.6	1.1	60.0%
6M	61	3.9	1.0	1.5	0.9	61.5%
1Y	61	4.0	1.0	1.7	1.2	57.5%
2Y	52	3.9	1.0	1.7	1.2	56.4%
3Y	45	4.0	1.0	1.9	1.2	52.5%
4Y	43	4.0	1.1	1.9	1.3	52.5%
5Y	43	4.0	1.1	2.1	1.4	47.5%

## Unpaired results



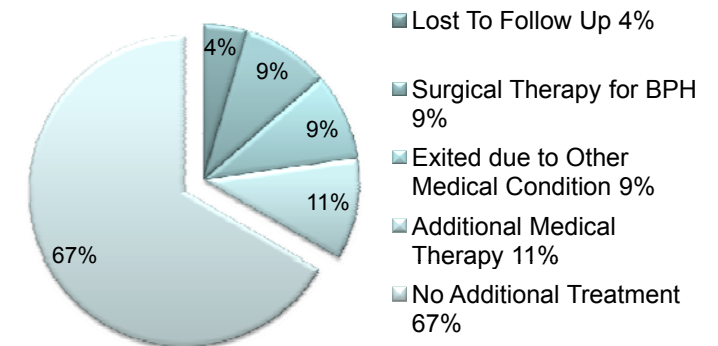
## Freedom from Retreatment

Retreatment was defined as any of the following:

1. Use of any BPH medication for > 2 weeks, > 90 days following treatment
2. Any salvage treatment for BPH (e.g. other microwave therapy, laser, TURP)
  - Retreatment has been reported by 20 subjects to date
  - 14 (21%) used BPH medication only
  - 6 (9%) had salvage treatment, either exclusively or along with medication

Freedom from	1Y	2Y	3Y	4Y	5Y
Salvage Treatment	96.9%	92.2%	92.2%	90.4%	90.4%
Any Treatment	92.3%	81.1%	76.1%	71.2%	70.0%

### 5-Year Visit Accountability



## Conclusions

- Treatment with the CTC catheter demonstrates efficacy and durability through at least 5 years in all three major BPH evaluation criteria: Qmax, AUASS, & QOL
- Retreatment rate for BPH continues to be low, 20 of 66, (~30% at 5 years), and appears to be stabilizing after the 2 year visits to a rate of about 3-5% a year
- Invasive retreatment therapies only required for <10% of subjects after 5 years