Effects of Urethral Temperature on Patient Outcomes for Benign Prostatic Hyperplasia with Cooled High Energy TUMT

Abstract # 1944

William Utz, MD (Edina, MN)

Moderated Poster #1944
AUA 2009

Introduction & Methods

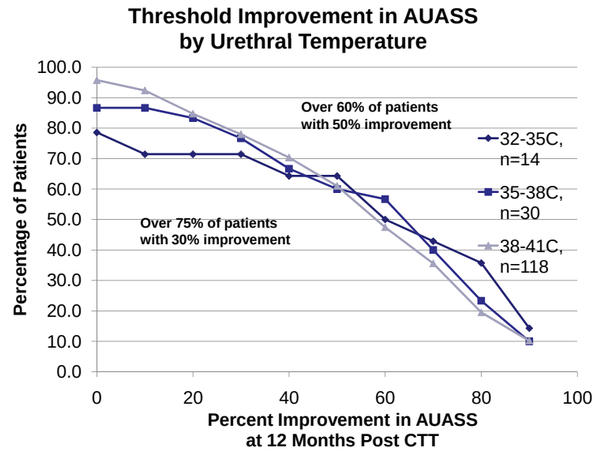
The Urologix Cooled ThermoTherapy™ (CTT) System employs High Energy TUMT with an advanced cooling system. Anecdotal reports have shown that many physicians modify the urethral temperature set point from the default 40°C to positively impact patient comfort during the procedure. The objective of this retrospective analysis was to determine the effects on patient outcomes of different urethral temperatures during treatment.

Methods: 189 men with original control unit treatment files were examined from a pooled database of previous CTT System multi-center studies[1]. All subjects had baseline AUASS score of >7 and a Qmax <15. Each file was analyzed to determine different treatment sensor readings, including the maximum urethral temperature sustained for at least 7 minutes (approximately 25% of treatment time). Sensor readings were compared to corresponding percent AUASS change and Qmax change at both 6 and 12 months using simple linear regression. Treatment files were categorized into three groups based on urethral temperature, and paired t-tests were performed.

Demographics

N = 189	Mean	Range
Age	**66.1**	**47-86**
AUASS	**20.9**	**9-34**
Peak Flow/Qmax (cc/sec)	**8.8**	**2.0-14.4**
QOL Score	**3.9**	**0-6**
Post Void Residual (cc)	**84**	**0-285**
Prostate Weight (g)	**40.3**	**19-101**
PSA	**3.05**	**0.2-15**
Duration of BPH Symptoms (years)	**5.76**	**0-25**

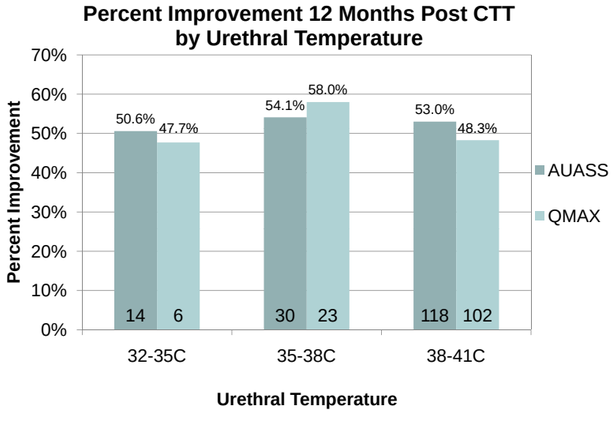
Threshold Improvement



Discussion

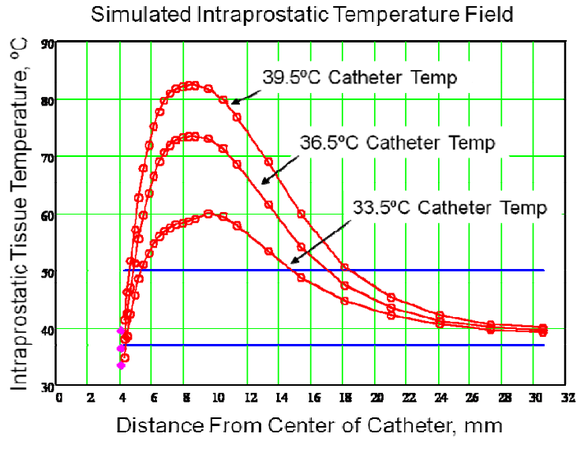
Pearson correlation coefficient between urethral temperature and AUASS percentage change at 6 & 12 months was 0.006 & 0.038, and 0.028 & 0.127 for Qmax (showing no correlation). Mean AUASS improvement from baseline was statistically significant ($p < 0.001$) in all three temperature groups at 1 year from baseline. Mean Qmax improvement was also significant ($p < 0.02$) for the groups at 1 year. The differences between groups for AUASS and Qmax were not significant (P=0.25 to 0.80 for comparisons). The mean VAS score was 4.3 with the group scores being 3.7, 5.4 and 4.1 from low to high temperature groups. The study was not powered to evaluate differences in VAS score as the power was adjusted for patient comfort. 70% of the patients completed the treatment in the higher treatment group with a mean VAS score of 4.1. Data from intra-prostatic temperature mapping studies[3] have confirmed the temperatures reached are similar to thermal model projections. MRI analysis and pathology studies[4] have confirmed the presence of significant tissue necrosis at these temperatures.

Paired Mean Improvement



Thermal Model[2]

Urethral MDS Temp by Group Mean >	33.5° C	36.5° C	39.5° C
Max. Intraprostatic Temp. for Average +1 sd for Perfusion	56.4°C	59.1°C	67.3°C
Max. Intraprostatic Temp. for Average Perfusion	72.7°C	73.4°C	77.5°C
Max. Intraprostatic Temp for Average -1 sd for Perfusion	79.8°C	82.3°C	87.3°C



Conclusions & References

- With High Energy TUMT from Urologix, clinically significant improvement is seen at one year with MDS temperature settings from 32 to 41°C.
- The intra-prostatic temperatures remain well above 50° C needed for tissue necrosis[5] in 28.5 minutes in all three groups.
- Since long term studies have been performed on MDS temperature set points above 35°C, prospective studies to determine the impacts on durability and post treatment catheter rates for temperatures below 35°C need to be performed.
- This study, at one year, demonstrates High Energy TUMT provides significant patient outcomes with customized settings.

References:

1. Data on file at Urologix, Inc.
2. Ramadhyani & Rudie, A Mathematical Model to Predict Intra-Prostatic Temperatures and Tissue Necrosis During Transurethral Microwave Thermal Ablation of the Prostate, Bioengineering Conference, June 2003.
3. Larson, et al., Detailed Interstitial Temperature Mapping During Treatment with a novel TUMT system in patients with BPH, Journal of Urology, vol 159, Jan 1998.
4. Larson, Bostwick & Corica, Temperature Correlated Histopathologic Changes following Microwave Thermoablation of obstructive tissue in patients with BPH, Urology, vol 47, 1996.
5. Bischof, et. al., Heat Sensitivity of Human Prostate Tissue: Implications for Thermal Therapy, Poster AUA 2003.

Source of funding is Urologix, Inc.