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**Study Title:** FIVE YEAR RESULTS OF THE PROSPECTIVE, RANDOMIZED CONTROLLED TRIAL OF WATER VAPOR THERMAL THERAPY FOR TREATMENT OF LOWER URINARY TRACT SYMPTOMS DUE TO BENIGN PROSTATIC HYPERPLASIA

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## Introduction and Objective

We report the five-year results for the active treatment arm of the multicenter, randomized, controlled trial of water vapor thermal therapy in men with moderate-to-severe lower urinary tract symptoms (LUTS) due to benign prostatic hyperplasia (BPH) with the inclusion of the final surgical and BPH medication retreatment rates.

## Methods

- 197 subjects  $\geq 50$  years old with IPSS  $\geq 13$ , maximum flow rate (Qmax) 5-15 ml/s and prostate volume 30-80 cc were randomized 2:1 (thermal therapy Rezūm System: sham control rigid cystoscopy).
- Thermal therapy involved injection of water vapor into obstructive tissue, possibly including the middle lobe and/or enlarged central zone.
- The primary outcome was change in IPSS; other outcomes assessed included changes in quality of life and Qmax.
- The study assessed each subject for retreatment of BPH after the index procedure.
- Subjects who received secondary surgical treatment for LUTS/BPH were included in the surgical retreatment results and subjects who initiated BPH medication (alpha-blocker, or 5-ARIs) were included in the medication retreatment results.

## Results

- In the randomized comparison at 3 months, mean IPSS reduction from baseline was 11.2 and 4.3 pts for active (n=136) and control (n=61) subjects, (Rezūm: Sham respectively)  $p < 0.0001$ .
- Reduction in IPSS was sustained in the active treatment arm at five years, with a mean reduction from baseline of 10.4 points. The change from baseline in maximum urinary flow rate was 6.4 ml/sec at 3 months and 4.3 ml/sec at five years.
- Within the active treatment group, the surgical retreatment rate was 4.4%, while 11.1% of the treatment-arm subjects initiated BPH medication at 5 years.
- On a per subject basis, improvements of symptoms (50% IPSS), quality of life (46% IPSS-QOL, 46% BPH Impact Index) and flow rate (69% Qmax) occurring within  $\leq 3$  months were sustained to five years with improvements of 48%, 46%, 49%, and 49%, respectively ( $p < 0.0001$ ).

## Conclusions

Treatment-arm results show that the minimally invasive water vapor thermal therapy offers significant improvements in LUTS, QOL and flow rate sustained through 5 years.

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