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 ≥50 years old with IPSS ≥13, maximum flow rate (Qmax) 5-15 ml/s and prostate volume 30-80 cc were randomized 2:1 (thermal therapy Rezûm 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, (Rezûm: 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 ≤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.