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Study Title: REZŪM™ WATER VAPOR THERMAL THERAPY FOR LOWER URINARY TRACT SYMPTOMS ASSOCIATED WITH BENIGN PROSTATIC HYPERPLASIA: 4-YEAR RESULTS FROM RANDOMIZED CONTROLLED STUDY

Authors: McVary KT, Rogers T, Roehrborn CG.

Objective

To report 4-year outcomes of the randomized controlled trial of water vapor thermal therapy for treatment of moderate-to-severe lower urinary tract symptoms (LUTS) due to benign prostatic hyperplasia (BPH).

Materials and Methods

- Prospective, randomized, controlled and double-blinded study
- All subjects were unblinded at conclusion of the 3-month follow-up visit; 53 subjects in control group qualified and crossed over to receive thermal therapy within the 6-month follow-up
- 2:1 ratio allocation to treatment (convective water vapor thermal therapy) and control arms (rigid cystoscopy)
- 188 Men ≥ 50 years old, International Prostate Symptom Score (IPSS) ≥ 13 , maximum flow rate (Qmax) ≤ 15 ml/s and prostate volume 30 to 80 cc from 15 sites treated with Rezūm System thermal therapy
- Standard LUTS outcomes were measured at 2 weeks and at 1, 3, 6, 12, 24, 36 and 48 months post-treatment; crossover subjects followed to 36 months

Results

- Moderate-to-severe LUTS were significantly improved within ≤ 3 months after thermal therapy and remained consistently durable through 4 years (see Figure 1):
 - IPSS improvement of -10.1 points (46.7%)
 - Quality of Life (QOL) improvement of -2.0 points (42.9%)
 - Qmax improvement of +4.2 mL/s (49.5%)
 - BPH Impact Index (BPHII) improvement of -3.5 points (52.2%)
- Outcomes were similarly sustained in crossover subjects at 3 years.
- 58 of 188 (30.9%) subjects received treatment to a median lobe or enlarged central zone and showed similar improvements.
- Surgical retreatment rate was 4.4% over 4 years.
- No late-related adverse events or de novo erectile dysfunction were reported.

"This four-year study supports the use of the first-of-its-kind Rezūm System as a minimally invasive alternative for men with moderate-to-severe BPH who do not want to rely on pharmaceutical management of their symptoms. The data demonstrate that this advanced technology can empower urologists to achieve significant clinical improvements and deliver an impactful, durable response for their patients."

Dr. Kevin McVary, FACS, lead author and co-principal investigator of the Rezūm II Trial

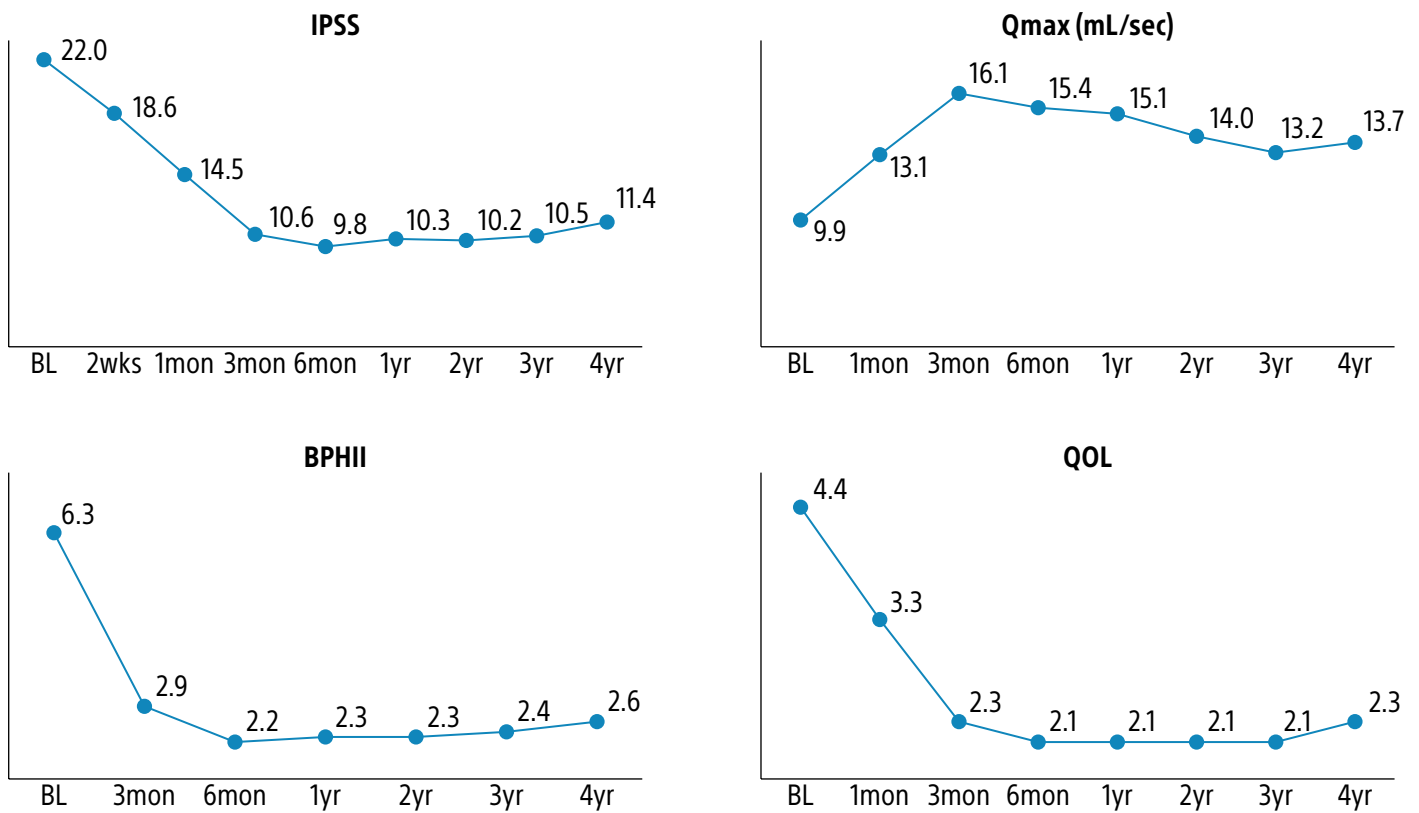


Figure 1: Outcomes for water vapor thermal therapy over 4 years for the initial active treatment arm including IPSS, Qmax, QOL and BPH Impact index. Changes relative to baseline are significant at all time points, $P < .0001$. Abbreviations: BPHII, BPH Impact index; IPSS, International Prostate Symptom Score; Qmax, peak urinary flow rate; QOL, quality of life.

Conclusions

Water vapor thermal therapy represents a new technological approach for thermal ablative reduction of benign prostate adenomas. The study suggests it provides effective symptom relief and improved QOL that remained durable throughout 4 years. The study also suggests that the procedure has a minimal physician learning curve, and that early intervention with this thermal therapy rather than use of pharmaceutical agents or invasive surgery may be an ideal option for men.

View clinical data:

[https://www.goldjournal.net/article/S0090-4295\(19\)30070-6/abstract](https://www.goldjournal.net/article/S0090-4295(19)30070-6/abstract)

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