

CLINICAL BRIEF

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Three-Year Outcomes of the Prospective, Randomized Controlled Rezūm System Study: Convective Radiofrequency Thermal Therapy for Treatment of Lower Urinary Tract Symptoms due to Benign Prostatic Hyperplasia¹

McVary KT, Roehrborn CG

Urology. In press.

KEY FINDING

The minimally invasive convective radiofrequency (RF) thermal therapy is an office or ambulatory outpatient procedure with minimal transient perioperative side effects. It provides early effective and durable relief of BPH symptoms with preservation of sexual function in subjects followed to 3 years and is applicable to treatment of the median lobe and hyperplastic central zone tissue.

STUDY OBJECTIVE

To report 3-year outcomes of a prospective, multi-center, randomized, blinded control trial with convective RF water vapor thermal therapy for moderate to severe lower urinary tract symptoms (LUTS) due to benign prostatic hyperplasia (BPH).

STUDY METHODS

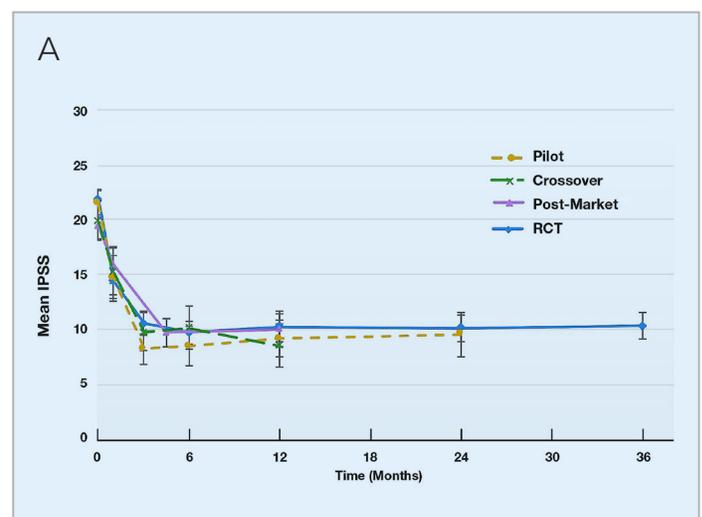
- Prospective, randomized, controlled, double-blinded study
- 197 subjects from 15 sites in the United States
- 2:1 ratio allocation to treatment and control arms
 - 136 subjects randomized to convective water vapor thermal therapy (treatment) and 61 subjects to rigid cystoscopy (control)
- All subjects were unblinded at conclusion of the 3-month follow-up visit
 - 53/61 subjects in control group qualified and crossed over to receive thermal therapy within the 6-month follow-up
- Standard BPH outcomes were measured at 2 weeks and at 1, 3, 6, 12, 24 and 36 months post-treatment

KEY EFFICACY RESULTS

- Convective RF thermal therapy yielded IPSS improvements 160% when compared to control subjects at 3 months ($p < 0.0001$).
- Maximal symptom relief of at least 50% improvements in IPSS mirrors results in published studies, including a real-world experience with community urologists (Figure A).
- 30/135 (22%) subjects received treatment to a median lobe or enlarged central zone.
- Subjects with a treated median lobe and those without a median lobe had similar significant improvements in IPSS and urinary flow rate through 3 years.

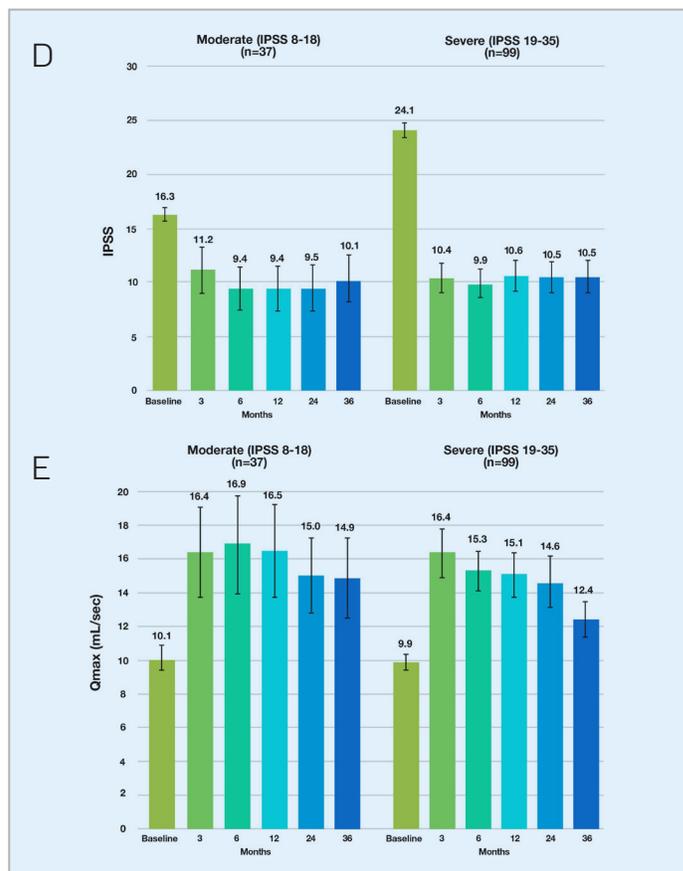
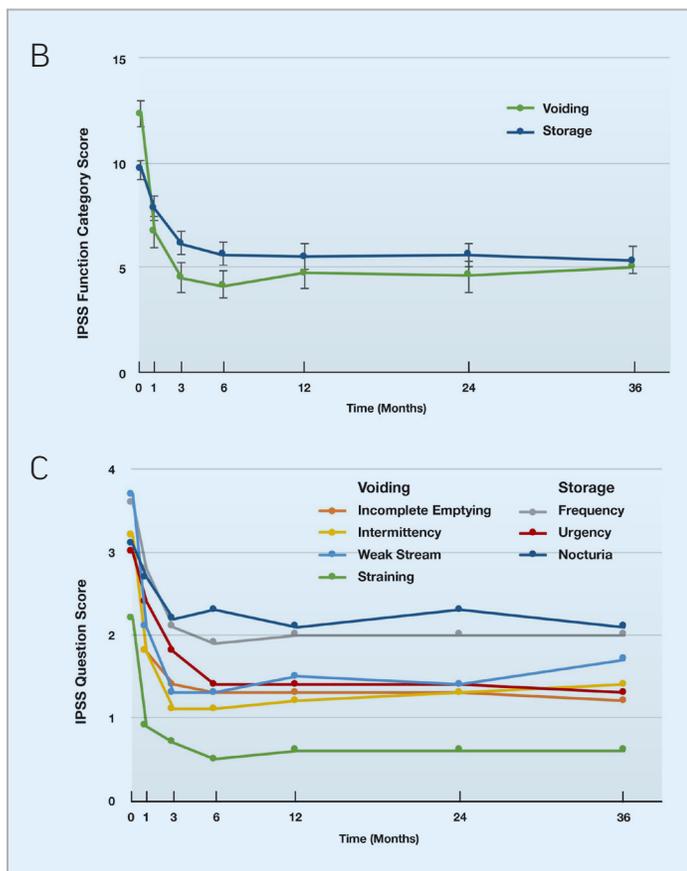
"With...the profiles of safety, no reported occurrences of erectile dysfunction, and durability of LUTS relief as well as cost-effectiveness, convective RF water vapor thermal therapy warrants use as a first-line treatment for moderate to severe LUTS/BPH."

— Dr. Kevin McVary, SIU School of Medicine



- Seven individual domains of the IPSS for voiding and storage functions indicated significant relief of symptoms at 1 month and remained significant throughout 3 years, $p < 0.0001$ (Figures B and C).

- Symptomatic relief reflected in IPSS and Qmax outcomes was achieved in subjects with moderate and severe LUTS through 3 years (Figures D and E).



- No late related adverse events occurred and no de novo erectile dysfunction was reported.
- The sexually active 90/135 (67%) subjects had no negative changes in IIEF-EF and MSHQ-EjD function scores throughout 3 years of follow-up; however, the ejaculatory bother score (MSHQ-EjD) improved over baseline from 12 to 36 months ($p < 0.03$).
- After ablation of the median lobe, the 30 subjects had significantly decreased PVR from 24 to 36 months ($p < 0.04$).
- The surgical retreatment rate was 4.4% over 3 years. 3% (4/135) were due to presence of median lobe, identified, but not previously treated.

CONCLUSIONS

The minimally invasive convective RF thermal therapy is an office or ambulatory outpatient procedure with minimal transient perioperative side effects. It provides early effective and durable relief of BPH symptoms with preservation of sexual function in subjects followed to 3 years and is applicable to treatment of the median lobe and hyperplastic central zone tissue.

REFERENCE

1. McVary KT, Roehrborn CG. Three-year outcomes of the prospective, randomized controlled Rezūm system study: Convective radiofrequency thermal therapy for treatment of lower urinary tract symptoms due to benign prostatic hyperplasia. *Urology*. In Press.

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