

CLINICAL BRIEF

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Erectile and Ejaculatory Function Preserved with Convective Water Vapor Energy Treatment of LUTS Secondary to BPH: Randomized Controlled Study¹

McVary KT, Gange SN, Gittelman MC, Goldberg KA, Patel K, Shore ND, Levin RM, Rousseau M, Beahrs JR, Kaminetsky J, Cowan BE, Cantrill CH, Mynderse LA, Ulchaker JC, Larson TR, Dixon CM, Roehrborn CG

KEY FINDINGS: Convective Water Vapor thermal therapy provides rapid and sustainable improvement in LUTS and urinary flow over a 12-month period while preserving erectile and ejaculatory functions. No de novo ED was reported.

STUDY ANALYSIS OBJECTIVE

Determine whether water vapor thermal therapy, when conducted in a randomized controlled trial, had any effect on erectile and ejaculatory function while demonstrating significant improvement in LUTS and urinary flow rates secondary to BPH.

STUDY METHODS

- Prospective, randomized, controlled, single-blind study at 15 sites in the United States.
- Men ≥ 50 years with International Prostate Symptom Scores (IPSS) ≥ 13 ; peak flow rate (Q_{max}) ≥ 5 to ≤ 15 mL/s, prostates 30-80 cm.³
- 197 men were randomized 2:1 between Rezūm (n=136) and the control (n=61) arm. See *Minimally Invasive Prostate Convective Water Vapor Energy Ablation: A Multicenter, Randomized, Controlled Study for the Treatment of Lower Urinary Tract Symptoms Secondary to Benign Prostatic Hyperplasia*² for detail on protocol and LUTS specific results.
 - At baseline, 32% of the observed treatment subjects and 33% of the control subjects were not sexually active and were eliminated from the sexual function analysis.
- Radiofrequency thermal water vapor was injected into lateral and median lobes for BPH treatment and simulated the treatment with a rigid cystoscopy and simulated treatment sounds for the control.

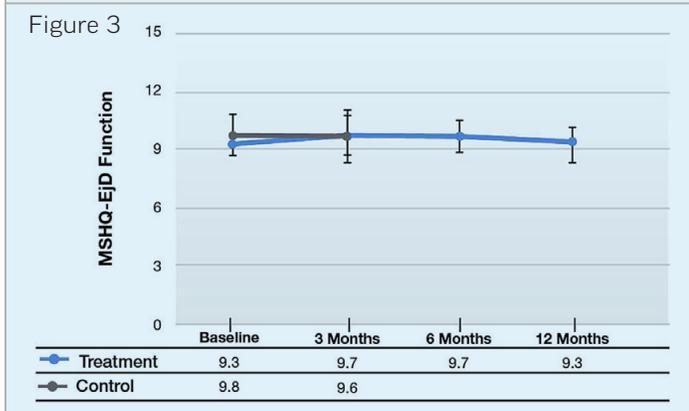
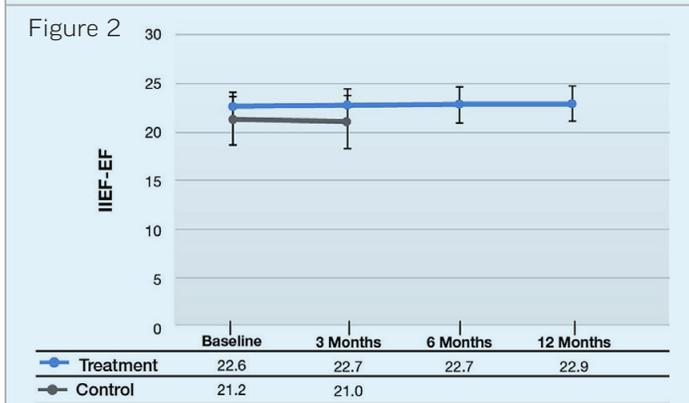
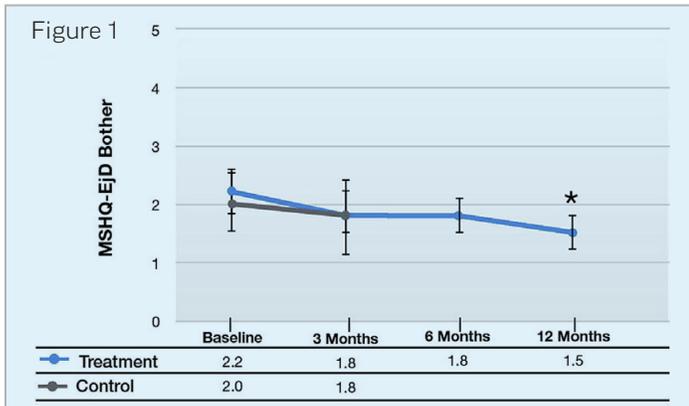
“Based on the conservation of sexual function and efficacy in treating LUTS/BPH, the water vapor thermal therapy could be offered as first-line treatment in lieu of drugs for patients with moderate to severe LUTS.”

Table 1. Minimal clinically important differences of changes in IIEF-EF score at 3 and 12 months after water vapor thermal therapy

IIEF-EF baseline severity	Month 3 (n = 90 sexually active)			Month 12 (n = 77 sexually active)		
	n/N	MCID* Increase, mean \pm SD	Range	n/N	MCID* Increase, mean \pm SD	Range
Severe (1–10)	2/7	12.5 \pm 4.9	9–16	2/3	11.5 \pm 3.5	9–14
Moderate (11–16)	9/15	10.1 \pm 4.6	5–17	6/13	11.2 \pm 4.4	7–18
Mild (17– \leq 25)	18/68	4.0 \pm 2.2	2–10	13/61	5.3 \pm 2.8	2–12
Improved scores, n (%)	29/90 (32)			21/77 (27)		

IIEF-EF = International Index of Erectile Function erectile function domain; MCID = minimal clinically important difference.

*MCID is a minimal IIEF-EF score increase of 2 for men with mild erectile dysfunction, an increase of 5 for moderate erectile dysfunction, and 7 for severe erectile dysfunction.



KEY RESULTS

- No de novo ED occurred after thermal therapy.
- 32% of subjects achieved minimal clinically important differences (MCIDs³) in EF scores at 3 months, and 27% at 1 year including those with moderate to severe ED (Table 1). The MCID measurement is the first use of this assessment in a nonpharmacological intervention study related to ED.
- Ejaculatory bother score improved 31% over baseline at 1 year (Figure 1).
- IIEF (Figure 2) and MSHQ-EjD Function (Figure 3) scores were not different from control at 3 months or from baseline at 1 year.

LIMITATIONS

- Primary endpoint was LUTS, not sexual function; however, well-established patient-reported questionnaires were used. The study was not powered to assess sexual function; however the results of this study would lead to the same conclusions if observed in a study 10x as large.
- Other possible influential conditions that might effect changes in LUTS/BPH treatment and related sexual function were not evaluated (e.g. obesity, smoking, weight loss, etc).

CONCLUSIONS

Convective water vapor thermal therapy provides rapid and sustainable improvement of LUTS and urinary flow over a 12-month period without negative effects on erectile and ejaculatory function as measured by validated questionnaires. No de novo ED was reported. These results support the application of WAVE technology as a safe and effective minimally invasive therapeutic alternative for symptomatic BPH without compromising sexual function including treatment of patients with a median lobe.

REFERENCES

1. McVary K, Gange S, Gittelman M et al. Erectile and Ejaculatory Function Preserved With Convective Water Vapor Energy Treatment of Lower Urinary Tract Symptoms Secondary to Benign Prostatic Hyperplasia: Randomized Controlled Study. *The Journal of Sexual Medicine*. 2016. doi:10.1016/j.jsxm.2016.03.372.
2. McVary KT, Gange SN, Gittelman MC, et al. Minimally Invasive Prostate Convective Water Vapor Energy Ablation: A Multicenter, Randomized, Controlled Study for the Treatment of Lower Urinary Tract Symptoms Secondary to Benign Prostatic Hyperplasia. *The Journal of Urology*. 2016;195(5):1529-1538. doi:10.1016/j.juro.2015.10.181.
3. Rosen RC, Allen KR, Ni X, et al. Minimal clinically important differences in the erectile function domain of the International Index of Erectile Function Scale. *Eur Urol* 2011;60:1010-1016.

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