

# Final Five-Year Results from the Rezūm™ Water Vapor Therapy Pivotal Clinical Trial: A Closer Look at the Data

Editorial Commentary by Kevin T. McVary, MD, FACS

Director, Center for Male Health, and Professor of Urology at Stritch School of Medicine, Loyola University Medical Center and Principal Investigator of the pivotal clinical trial

The final five-year outcomes of the [Rezūm™ Water Vapor Therapy pivotal trial](#) have been published in the *Journal of Urology*.<sup>1</sup> This latest data publication confirms Rezūm Therapy safely and effectively reduces benign prostatic hyperplasia (BPH) symptoms while preserving sexual function out to five years.

This pivotal trial was conducted at 15 centers in the United States with follow-up through five years. In total, 197 men with moderate-to-severe lower urinary tract symptoms (LUTS) due to BPH entered the study. From the 61 participants in the control arm, 53 requalified and after three months received treatment as part of the crossover group and were followed for five years.

Now, over a year after sharing my initial observations from the abstract for this paper, I am pleased to give you my perspectives on these important outcomes below.

## Retreatment Rates and the Middle Lobe

One of the most important findings looked at durability and retreatment rates after five years; patients treated with Rezūm Therapy had a 4.4% surgical retreatment rate and 11.1% initiated medical therapy. In the pivotal trial for another available BPH therapy – the UroLift™ system – men receiving this therapy had a 13.6% surgical retreatment rate and 10.7% were taking medical therapy after five years.<sup>2</sup>

One notable difference is that the UroLift pivotal trial excluded patients with a prostate median lobe enlargement (MLE). The Rezūm Therapy pivotal trial included men with obstructive middle lobes, which occurred in 30.9% of the cohort. Of the six patients in the Rezūm Therapy pivotal study treatment arm who required surgical retreatment, four had an enlarged median lobe that was not initially treated during the index procedure. So it is speculated that the 4.4% surgical retreatment rate for Rezūm Therapy patients could have potentially been reduced to 2.2%.<sup>3</sup> This finding re-emphasizes the importance of [treating the median lobe](#). Rezūm Therapy is capable of treating difficult anatomic variants like obstructive middle lobe without physicians having to learn an advanced technique in a physician's office under local anesthesia and provide long-lasting results.

## Sexual and Erectile Dysfunction

At the time the study abstract was published, there was no data reported on the impact of Rezūm Therapy on sexual dysfunction and sustained de novo erectile dysfunction (ED). Now, I'm pleased to share that in addition to the significant improvement of LUTS observed at three months (and remained durable through five years), there were no reports of de novo device or procedure-related erectile dysfunction throughout the duration of the study.

This is significant, as medical therapy in place of surgical treatment for BPH [may impact sexual function](#) and can result in general BPH symptom progression.<sup>4,5</sup> Likewise, TURP, another common treatment, can lead to erectile and ejaculatory dysfunction and possible incontinence.<sup>6,7</sup> These side effects leave many men seeking less invasive treatment options like the Rezūm Therapy or UroLift, both MISTs. Rezūm Therapy offers robust functional outcomes but does so without the historic tradeoffs of limited durability or compromised sexual function.

In the Rezūm Therapy pivotal trial, sexual function was assessed using IIEF-EF, MSHQ-Function and MSHQ-EjD. Modest changes were observed in IIEF-EF and MSHQ-Function at five years consistent with the aging of the treated cohort, with changes of  $-2.4 \pm 9.2$  and  $-2.0 \pm 3.9$ , respectively. MSHQ-EID Bother score improvement remained consistent through the length of follow-up with a 16% improvement at 60 months. Despite the majority of those in this study experiencing severe LUTS at enrollment (72.5% with IPSS 19-35), outcomes improved from the first visit three months post-procedure through the final visit at 60 months after a single Rezūm Therapy procedure (IPSS reduced 48%, QOL increased 45%, Qmax improved 44%, BPHII decreased 48%) with preservation of sexual function. To achieve similar results with UroLift prostatic urethral lift, permanent implants are required and the surgical retreatment rates appear higher.<sup>8\*</sup>

## A Real-World Perspective

LUTS associated with BPH are often accompanied by sexual dysfunction, including ED and ejaculatory problems, and interest in sexual intercourse declines with severity of LUTS.<sup>9</sup> Naturally, many men may prefer a procedure that doesn't have a negative effect on sexual function yet many medical therapies for BPH can cause sexual side effects.<sup>10</sup> As a medical community, we should be considering BPH treatments that are effective and durable but can also preserve sexual function. Rezūm Therapy challenges the long-held algorithm of men needing endless medications followed by an invasive surgery if their LUTS progresses. Physicians can now offer a minimally invasive option that removes the obstructive tissue and treats the associated symptoms without permanent implants or prescriptions. Now patients no longer have to choose which symptoms or side effects they want to continue to tolerate and can receive an effective and durable treatment in their urologist's office.

## Conclusion

Patients who may be candidates for Rezūm Therapy are often referred to more invasive surgical techniques such as TURP, HoLEP, or other laser treatments that can involve greater bleeding risks, longer-term recovery time, declines in measures of sexual function, and other undesirable side effects. However, the results of this trial reinforce Rezūm Therapy's clinically meaningful outcomes related to sexual and erectile dysfunction, along with the outcomes and proven durability previously published last year. The positive safety profile, long-term durability, and maintenance of sexual function make me feel confident in [Rezūm Therapy](#) as an optimal treatment choice for appropriate patients with moderate-to-severe LUTS.

## References

1. McVary KT, Gittelman MC, Goldberg KA, et al. Final 5-year outcomes of the multicenter randomized sham-controlled trial of Rezūm water vapor thermal therapy for treatment of moderate-to-severe lower urinary tract symptoms secondary to benign prostatic hyperplasia. *J Urol*. 2021 Apr 19. Online ahead of print.
2. Roehrborn CG, Gange SN, Shore ND, et al. The prostatic urethral lift for the treatment of lower urinary tract symptoms associated with prostate enlargement due to benign prostatic hyperplasia: the L.I.F.T. study. *J Urol*. 2013 Dec;190(6):2161-7.
3. McVary KT, Rogers T, Roehrborn CG. Rezum water vapor thermal therapy for lower urinary tract symptoms associated with benign prostatic hyperplasia: 4-year results from randomized controlled study. *Urology*. 2019 Apr;126:171-9.
4. Gupta N, Rogers T, Holland B, et al. Three-year treatment outcomes of water vapor thermal therapy compared to doxazosin, finasteride and combination drug therapy in men with benign prostatic hyperplasia: Cohort data from the MTOPS trial. *J Urol*. 2018 Aug;200(2):405-13.
5. Erdemir F, Harbin A, Hellstrom WJ. 5-alpha reductase inhibitors and erectile dysfunction: the connection. *J Sex Med*. 2008 Dec;5(12):2917-24.
6. El-Assmy A, ElShal AM, Mekawy R, et al. Erectile and ejaculatory functions changes following bipolar versus monopolar transurethral resection of the prostate: a prospective randomized study. *Int Urol Nephrol*. 2018 Sep;50(9):1569-76.
7. Friedl A, Schneeweiss J, Stangl K, et al. The adjustable transobturator male system in stress urinary incontinence after transurethral resection of the prostate. *Urology*. 2017 Nov;109:184-9.
8. Miller LE, Chughtai B, Dornbier RA, et al. Surgical reintervention rate after Prostatic Urethral Lift: systematic review and meta-analysis involving over 2,000 patients. *J Urol*. 2020 Nov;204(5):1019-26.
9. Bruskevitz RC. Quality of life and sexual function in patients with benign prostatic hyperplasia. *Rev Urol*. 2003 Spring;5(2):72-80.
10. Yu ZJ, Yan HL, Xu FH, et al. Efficacy and side effects of drugs commonly used for the treatment of lower urinary tract symptoms associated with benign prostatic hyperplasia. *Front Pharmacol*. 2020 May 8;11:658.

Caution: U.S. Federal law restricts this device to sale by or on the order of a physician.

CAUTION: The law restricts these devices to sale by or on the order of a physician. Indications, contraindications, warnings and instructions for use can be found in the product labelling supplied with each device. Information for use only in countries with applicable health authority registrations. This material not intended for use in France.

Products shown for INFORMATION purposes only and may not be approved or for sale in certain countries. Please check availability with your local sales representative or customer service. IMPORTANT INFORMATION: These materials are intended to describe common clinical considerations and procedural steps for the use of referenced technologies but may not be appropriate for every patient or case. Decisions surrounding patient care depend on the physician's professional judgment in consideration of all available information for the individual case. Boston Scientific (BSC) does not promote or encourage the use of its devices outside their approved labeling. Case studies are not necessarily representative of clinical outcomes in all cases as individual results may vary.

\*Results from different clinical investigations are not directly comparable. Information provided for educational purposes only.

Kevin T. McVary, MD, is a Boston Scientific consultant and was compensated for his contribution to this article.

All trademarks are the property of their respective owners.

© 2021 Boston Scientific Corporation or its affiliates. All rights reserved. URO-1029509-AA JUN 2021