

Procedural Approaches:

A Clinical Summary from The Rezūm System – A Minimally Invasive Water Vapor Thermal Therapy for Obstructive Benign Prostatic Hyperplasia

Published in “How I Do It” in the *Canadian Journal of Urology International*, June 2019¹

Contributors: Christopher H. Cantrill, MD^a; Kevin C. Zorn, MD^b; Dean S. Elterman, MD^c; Ricardo R. Gonzalez, MD^d

The Versatility of Rezūm™ Water Vapor Therapy for Treating BPH Patients in Clinical Practice

The Rezūm Therapy procedure provides versatility for application to a variety of prostate gland morphologies including the median lobe or enlarged central zone. We have been able to offer this minimally invasive treatment option to men disenchanted with suboptimal LUTS improvements on medical therapy or facing the need for long-term medical therapy, and in selected patients as an alternative to more invasive surgical approaches.

Median Lobe Obstruction

For median lobe tissue, entering from a point midway from the base to apex at a 45 degree angle is most useful. For most median lobes, two treatments are adequate.* With larger protrusions, a stacked treatment may be required. Starting about 0.5 cm from the distal aspect of the protrusion and working back to the base in 1 cm increments allows for complete treatment. Wider based median lobes may also require a single treatment placed at the apex of the median lobe to ensure complete treatment of the median lobe tissue.

Rezūm Therapy Patients Previously Treated for BPH

When a patient has had a prior PUL, there may be an increased risk of exposure of the internal implant stainless steel tab. It is recommended to perform a post-treatment cystoscopy at 3 months to ensure no foreign body is present within the prostate fossa that would need to be removed due to the risk of encrustation. Patients with prior radiation have been intentionally avoided due to the loss of the intracellular spaces replaced by scar tissue.

The retreatment rate for Rezūm Therapy randomized controlled trial patients over 3 years* of follow-up was reported to be 4.4% (6 of 135 patients) including 2 patients with Rezūm Therapy, 3 with TURP, 1 prostatectomy (see sidebar).² Four of these six secondary interventions included the presence of a median lobe, identified but not previously treated.² Given that no permanent implant is placed, as with PUL, failure is typically due to residual tissue and there is no hesitation to consider repeat Rezūm Therapy treatment of patients with suboptimal results after appropriate evaluation.

Treating Patients in Urinary Retention

Treating patients in urinary retention managed either by clean intermittent catheterization (CIC) or with an indwelling Foley catheter is feasible and successful with careful patient selection. In this situation, it is recommended to perform urodynamic studies prior to proceeding to ensure detrusor function is not impaired enough to prevent emptying once the prostate obstruction is relieved. Flexible cystoscopy and prostate ultrasound represent further baseline evaluations.²

Obviously, these patients need complete sterilization of bacteriuria prior to Rezūm Therapy treatment. Prolonged catheter management — either continuous or CIC — following treatment is critical to allow post-procedural bladder drainage. Persistent catheter drainage for approximately 1 month following the procedure is typical in those who present in urinary retention. This is based on timing of symptom improvement observed as early as within 1 month in the Rezūm pivotal trial. During the acute inflammatory period following treatment, it would not be expected to see

resolution of obstruction until a month or more. If the patient fails trial of void at 1 month, consider repeat voiding trials at 1- to 2-week intervals or management with CIC and tracking residual volumes.

Side Bar

Since publication of this article, [results](#) of a five-year clinical trial confirming the long-term durability of Rezūm™ Water Vapor Therapy for treatment of benign prostatic hyperplasia (BPH) were published in the *Journal of Urology*.³ The data supports the previous three-year data with consistent surgical retreatment rate of 4.4%.³

- a. Urology San Antonio, San Antonio, Texas, USA
- b. Department of Urology, University of Montreal Hospital Center, Montreal, Quebec, Canada
- c. Division of Urology, University Health Network, University of Toronto, Toronto, Ontario, Canada
- d. Houston Methodist Hospital, Houston, Texas, USA

*This statement reflects the experience of the authors. It is important to follow the treatment guidelines provided in the Rezūm Instructions for Use. Treatments in excess of those recommended in the guidelines may lead to prolonged irritative symptoms and/or catheterization.

References

1. Cantrill CH, Zorn KC, Elterman DS, Gonzalez RR. The Rezūm system – A minimally invasive water vapor thermal therapy for obstructive benign prostatic hyperplasia. *Can J Urol*. 2019;26(3):9787-93.
2. 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*. 2018 Jan;111:1-9.
3. 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.

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 case studies are not necessarily predictive of results in other cases. Results in other cases may vary.

For information purposes only. The content of this article/publication is under the sole responsibility of its author/publisher and does not represent the opinion of BSC.

Drs. Cantrill, Zorn, Elterman and Gonzalez are Boston Scientific consultants.

All trademarks are the property of their respective owners.

© 2021 Boston Scientific Corporation or its affiliates. All rights reserved. URO-1019003-AA MAY 2021