

Five-Year Results of Rezūm™ Water Vapor Therapy

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Recently, [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 abstract form in the *Journal of Urology*.¹ The study found the Rezūm System, a water vapor thermal therapy, provided significant, sustained improvement of lower urinary tract symptoms (LUTS) and quality of life for patients suffering from BPH out to five years post-procedure. Five-year clinical data is a significant marker for physicians looking at treatments for patients, as it demonstrates long-term durability of results. This data was deemed as a “late-breaking” abstract by the American Urological Association, a distinction typically given to important clinical data that should be transmitted to urologists around the globe and not be delayed as it may impact clinical care.

As the Principal Investigator of the trial, I am pleased to share some key observations as they relate to other therapies currently available.

A Closer Look

This multicenter, randomized, controlled trial evaluated Rezūm Therapy in men with moderate-to-severe LUTS due to BPH, with the inclusion of the final surgical and BPH medication retreatment rates over five years. There were 135 treated subjects at 15 sites.

One of the most important markers from this study looked at retreatment rates in the five years after patients were treated with Rezūm Therapy. Patients had a 4.4% surgical retreatment rate and 11.1% initiated medical therapy. Patients were also assessed for symptom relief on the International Prostate Symptom Score (IPSS), peak urinary flow rate (Qmax), and quality of life measures (IPSS-QOL, BPH Impact Index) among others. At five years, patients demonstrated a 48% improvement from baseline in IPSS, a 49% improvement from baseline in Qmax and quality of life improvements from baseline of 46% IPSS-QOL, 49% BPH Impact Index.

Interestingly, this study included patients with a median lobe enlargement (MLE), which occurred in 31.1% of the cohort. Treatment of the median lobe was at the discretion of the physician, and 30 patients with MLE or central zone hyperplasia at the bladder neck received treatment.² It is speculated that the 4.4% surgical retreatment rate might have been as low as 2.2% as four of the six patients who had retreatment had an enlarged median lobe that was not initially treated during the index procedure.³

Other BPH Therapies

To put this into perspective, let’s take a look at another available therapy for BPH – the UroLift™ System. The UroLift pivotal trial, L.I.F.T., was also a multicenter, randomized, controlled trial of Prostatic Urethral Lift (PUL) in men with bothersome LUTS due to BPH. There were 206 subjects at 19 centers. Men with MLE were excluded from the study (about 38% of those screened).⁴

Through five-years of follow-up of men who received PUL therapy, 13.6% had surgical retreatment and 10.7% were taking medical therapy to treat LUTS. IPSS and Qmax improved by 35% and 50%, respectively, and IPSS-QOL and BPH Impact Index by 44% and 47%, respectively.⁵

According to the 2019 Updated AUA Clinical Guidelines on LUTS and surgical management, “Given that approximately one third of the initial study population experienced unsatisfactory results necessitating further treatment, patients selecting PUL should be informed that this is a relatively new intervention for LUTS/BPH with uncertainties in long-term durability, though such uncontrolled data are available.”⁶

Results in Practice

In my practice I’ve seen similar positive results with Rezūm Therapy. A busy physician came to me with significant LUTS and medications were no longer working. He underwent Rezūm Therapy and was back to work in his busy office practice and taking care of his own patients in the OR after a weekend. He was also able to discontinue all of his BPH medications. This was a nice outcome demonstrating the fast recovery found with the treatment in this patient.

Conclusion

From my perspective, the five-year data of the Rezūm System reflects excellent durability. These latest results expand upon the growing clinical evidence supporting the long-term durability of the Rezūm System as the leading minimally invasive option for men facing moderate-to-severe BPH-related symptoms. Physicians should continue to be responsive to individual patient clinical needs and patient personal preferences when deciding the most appropriate therapy.

References

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

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