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# *UroLift and Rezum: minimally invasive surgical therapies for the management of benign prostatic hyperplasia*

Joon Yau Leong, MD,<sup>1</sup> Anthony T. Tokarski, MD,<sup>1</sup> Claus G. Roehrborn, MD,<sup>2</sup> Akhil K. Das, MD<sup>1</sup>

<sup>1</sup>Department of Urology, Sidney Kimmel Medical College at Thomas Jefferson University, Philadelphia, Pennsylvania, USA

<sup>2</sup>Department of Urology, University of Texas Southwestern Medical Center, Dallas, Texas, USA

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**Introduction:** Minimally invasive surgical therapies for benign prostatic hyperplasia (BPH) are popular alternatives to the gold standard transurethral resection of the prostate (TURP). These procedures have fewer discernable side effects on urinary and sexual function, when compared to TURP, making it a desirable option for many patients.

**Materials and methods:** We provide an updated literature review on the current landscape of minimally invasive modalities, specifically the prostatic urethral lift (UroLift) and water vapor thermal therapy (Rezum), for the surgical treatment of BPH.

**Results:** Both UroLift and Rezum have demonstrated excellent efficacy and durability in relieving lower urinary tract symptoms (LUTS) in the BPH patient. When

compared to TURP, these minimally invasive therapies can be performed in an outpatient setting, with decreased hospitalization, operative and catheterization times, which minimizes overall healthcare costs. Moreover, these therapies have no discernable adverse effects on sexual function (both ejaculatory and erectile) or sexual satisfaction, making it a desirable option for many patients.

**Conclusions:** Both the UroLift and Rezum are office-based, minimally invasive techniques capable of providing durable, and significant relief of LUTS secondary to BPH. In select patients, they demonstrate comparable efficacy to TURP with the added advantage of preserving sexual function and minimizing patient morbidity and healthcare cost. An individualized, shared decision-making approach is essential in selecting the optimal treatment option for each patient.

**Key Words:** UroLift, Rezum, minimally invasive, benign prostatic hyperplasia, BPH

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## Introduction

Minimally invasive therapies are becoming a popular surgical alternative to the gold standard transurethral resection of the prostate (TURP) for the treatment of benign prostatic hyperplasia (BPH) in prostates up to 80 mL. While TURP is effective in treating patients with significant lower urinary tract symptoms (LUTS) secondary to BPH, it is also associated with bothersome urinary and sexual adverse effects, including urinary

incontinence and retrograde ejaculation. Currently, UroLift and Rezum are among the two popular office-based procedures that are approved by the American Urological Association (AUA) guidelines for the management of symptomatic BPH in patients who have failed medical management.<sup>1</sup> These novel therapies have shown to provide significant, and durable relief of LUTS secondary to BPH, with the added advantage of avoiding the TURP-related adverse effects. Herein, we provide an updated literature review on the current landscape of minimally invasive modalities, specifically the prostatic urethral lift (UroLift) and the water vapor thermal therapy (Rezum), for the surgical treatment of BPH.

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Address correspondence to Dr. Joon Yau Leong, Department of Urology, Thomas Jefferson University, 1025 Walnut Street, Suite 1100, Philadelphia, PA 19107 USA

## Rezum

The Rezum system (Boston Scientific, Marlborough, MA, USA) consists of a handheld delivery device and generator that utilizes convective water vapor energy ablation to reduce prostatic tissue and subsequently alleviate obstructive urinary symptoms. The vapor needle resides within the insulated lumen of the delivery device until it is deployed into the prostatic tissue. The needle is a flexible braided silicone tubing with 12 small emitter holes spaced around its tip at 120-degree intervals to allow a controlled, uniform circumferential dispersion of water vapor. The convective ablative technology is distinct from conductive heat transfer which results in non-uniform heat gradients and uneven treatment of the prostate gland.<sup>2</sup> This modality is indicated in men ages 50 years and above, and for prostate volumes between 30-80 grams. It is also indicated for treatment in patients with hyperplasia of the central zone and/or median lobe. Contraindications to this procedure include the presence of an artificial urinary sphincter or a penile prosthetic implant.

The objective of the Rezum procedure is to create a thermal lesion along the length of the prostatic urethra along each lateral lobe. This can be accomplished by creating contiguous, overlapping lesions between the bladder neck and proximal verumontanum, to target the bulk of the adenoma and to follow the natural slope of the urethra. The guidelines for determining the number of lesions are based on the length of the vapor treatment zone, ie the distance between the bladder neck and the verumontanum. If the distance between the bladder neck to the verumontanum is < 2 cm, 2-3 cm or > 3 cm, then 1-2, 2-3, and 3-4 estimated treatments per lobe is necessary, respectively. Excessive treatments may lead to prolonged irritative symptoms that may require prolonged catheterization. There are proprietary training modules developed by the company to allow urologists to familiarize themselves with the Rezum system.

McVary et al conducted a pivotal multicentered, randomized sham-controlled trial that randomized patients 2:1 to the thermal therapy (Rezum) versus control (rigid cystoscopy) arm.<sup>3</sup> The final 5-year outcomes were recently reported in 2021 and showed a continuous and substantial improvement in the IPSS (reduced 48%), Qmax (improved 44%), QoL (increased 45%) and BPHII (decreased 48%) scores. Surgical retreatment rates remained stable at 4.4% plus an additional 11.1% for medical treatment after 5 years. Moreover, procedure-related adverse events appeared to be transient and low, with the most common reported symptoms being dysuria (0.8%)

and hematuria (0.5%), both of which resolved within 3 months post-procedure.<sup>4</sup> Importantly, there were no reported cases of sexual dysfunction or sustained de novo erectile dysfunction over the period of the study.<sup>5,6</sup> Catheterization post-procedure was performed in over 90% of patients for a mean of 3.4 days, of which, only 32% truly necessitated catheterizations due to unsuccessful void trial prior to discharge.<sup>7</sup> Additional sub-analyses among men with identifiable median lobes within this trial demonstrated that treatment of the median lobe resulted in additional clinically meaningful improvement of IPSS (by 2.2 point) and Qmax (by 4.6 mL/sec).<sup>4</sup>

Gupta et al also performed an analysis comparing a subset of patients from the MTOPS trial who met the pivotal Rezum study criteria.<sup>8</sup> They found that symptom improvement (IPSS and Qmax) was significantly greater than either doxazosin or finasteride alone, but similar to that of combination drug use. Similarly, they found that with continued daily medication therapy, patients experienced reduced desire and erectile function with doxazosin, and significantly worse sexual desire, erectile and ejaculatory function with finasteride and combination drug therapy. Rezum therapy, however, was not associated with negative impacts in sexual function throughout the 3-year study period.<sup>9</sup>

Overall, contemporary literature has shown that a single water vapor thermal therapy treatment can provide significant and durable improvements in LUTS scores up to 5 years, even when compared to prolonged medication use, with the additional benefit of preserving sexual function.

## UroLift

The prostatic urethral lift (PUL) UroLift (Neotract, Pleasanton, CA, USA) is a minimally invasive technique that utilizes permanent nitinol implants to retract the obstructing lateral lobes towards the prostatic capsule, to allow expansion of the prostatic urethral lumen.<sup>10</sup> This procedure can be performed in an ambulatory setting and the implants are deployed under cystoscopic guidance with the aid of the UroLift delivery device. The mechanism of action is primarily mechanical which allows luminal expansion via a tissue-sparing approach. Moreover, pre-clinical research on canine models have demonstrated the initiation of acute ischemia over the prostatic tissue from the implants that leads to tissue remodeling and focal atrophy. This may factor into the demonstrated durability of the effect.<sup>11</sup>

The largest, multinational, randomized control trial investigating the utility of UroLift to date is

the L.I.F.T. study by Roehrborn et al. This study demonstrated rapid and significant improvement of urinary symptoms that were durable up to 5 years. Specifically, when compared to baseline, patient's AUASI improved by 7.6 points (36%), QoL improved by 2.3 points (50%), BPHII improved by 3.5 points (52%) and Qmax improved by 3.5 mL/sec (44%) at 5 years. Sexual function was excellently preserved as shown by the objectively measured SHIM, MSHQ-EjD function and MSHQ-EjD bother score, with no reports of de novo, sustained ejaculatory or erectile dysfunction. The authors also report a surgical retreatment rate of 13.6% over 5 years with a return to preoperative physical activity period of 8.6 days.<sup>12</sup>

A prospective, randomized controlled trial, known as the BPH6 study, was also performed among a multicentered European cohort and compared the PUL with the TURP procedure. In this study, patients who underwent the UroLift procedure showed a more rapid recovery period when compared to patients who underwent a TURP. Moreover, preservation of ejaculatory function, due to the lack of effect on the apical tissue around the verumontanum and the bladder neck, and speed of recovery was superior for PUL.<sup>13,14</sup> Yet another multicentered review reported substantial symptomatic relief with significant improvements in IPSS, QoL, Qmax and PVR parameters within 1 month of the PUL procedure. Sexual function was unchanged and side effects were minimal and transient. They report a 12.8% retreatment rate over 2 years and 86% catheter-free rate for patients who had an indwelling catheter before the procedure.<sup>15</sup>

Similar to the efforts of comparing the post-procedural sexual function between the Rezum pivotal study and patients from the MTOPS trial, Roehrborn et al performed an analysis with patients who underwent PUL from the L.I.F.T. study.<sup>16</sup> Indirect comparison found that PUL was superior to medical management for BPH in preserving both sexual function (erectile and ejaculatory) and sexual satisfaction. Limitations to the study include the use of two different patient-reported questionnaires, namely the IIEF or MSHQ for the L.I.F.T. study and the BMSFI for the MTOPS trial.

Next, contemporary research on PUL is based on enlarged lateral lobes alone. However, a recent study in 2018 known as the MedLift study sought to examine the utility and safety of the UroLift in the setting of obstructing median lobes. With appropriately deployed implants, a portion of the median lobe can be distracted distal to the bladder neck and affixed laterally to the prostatic urethra. This opens a channel around the median lobe and reduces the "ball-valve" motion caused by the enlarged median lobe. This

study was performed as a single-arm, prospective trial with a mean number of 1.3 implants deployed into the median lobe. Importantly, primary effectiveness and safety endpoints were met, with the patients among the MedLift arm demonstrating 57.7% IPSS improvement at 6 months. An effort was made to compare and combine the results from the MedLift trial to the L.I.F.T. study to demonstrate the full effect of the PUL and similar improvements of LUTS were found.<sup>17</sup>

The PULSAR (Prostatic Urethral Lift Subject with Acute Urinary Retention) clinical trial (NCT03194737) is currently underway to assess the utility of UroLift in patients presenting with acute urinary retention. They included patients in retention who has failed at least one void trial while on an  $\alpha$ -blocker. Primary assessment for this study was a void trial at 3 days  $\pm$  1 day post procedure. Preliminary results suggest that the improvement of LUTS is objectively better than that of the L.I.F.T. cohort at 6 and 12 months. With regards to patient experience, 67% of patients who stopped taking their  $\alpha$ -blockers remained medication free on follow up and 87.5% of patients reported an average of 8.5 days for a "return to normal" time period.

A retrospective review by Eure et al aimed to evaluate the safety and efficacy of PUL in the real world setting and determine if outcomes would hold up to those from controlled clinical studies. Overall, these men were found to be older and less symptomatic, and the authors found that PUL did in fact perform well in the real-world setting with regards to symptom relief, patient experience and overall morbidity. Only 72 patients (5.1%) of patients underwent surgical retreatment, 39 (2.8%) of which underwent a repeat PUL procedure. When stratifying based on prostate volume, there were no significant difference in symptomatic improvement, adverse event rates and catheter-free rates of prostates measuring  $> 80$  cc when compared to smaller prostates.<sup>18</sup>

With regards to safety of this procedure, an analysis of device malfunctions and complications related to BPH surgery using the MAUDE database revealed a total of 16 incidents with the UroLift device. Of these, 10 were due to failure to deploy implant, while the other 6 were due to needle detachment. When compared to the other treatment modalities including TURP, HoLEP, GreenLight, the 16 UroLift cases accounted for only 0.6% of all malfunctions reported in this database.<sup>19</sup>

Lastly, a small study published in 2020 aimed to evaluate the early postoperative patient experience between UroLift and Rezum over 2 months post-procedure. Although the preliminary data suggest better improved overall experiences for patients

undergoing PUL over Rezum with regards to sexual function, catheterization rates, recovery rates and symptomatic relief, one should take into account the mechanism of action for both these procedures. For the UroLift, the process of widening the urethral lumen is mechanical and more instantaneous, while with the Rezum procedure, there is likely to be tissue edema postoperatively requiring prolonged catheterization followed by long term prostatic volume reduction. As such, this study presents an important perspective to consider when assessing the risk/benefit profile for each patient and the importance of managing patient expectations during the process of informed consent.<sup>20</sup>

## Conclusion

Both the UroLift and Rezum are effective procedures for select patients desiring treatment of LUTS associated with BPH. It is currently included in the AUA guidelines for surgical management in patients who have prostate volumes up to 80 mL.<sup>1</sup> Aside from demonstrating comparable efficacy to current standard therapies for treating BPH, these procedures can be performed on an outpatient basis without the use of general anesthesia, and also has no discernible effects on sexual function, making this a desirable option for many patients. Ultimately, when selecting the optimum treatment option for patients, physicians should utilize an individualized, shared-decision making approach to achieve an informed preference between the surgeon and each patient. □

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