



# What's New in Rezum: a Transurethral Water Vapour Therapy for BPH

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## Abstract

**Purpose of Review** Rezum is a new minimally invasive treatment for benign prostate enlargement using thermal transurethral water vapour therapy. We review the evidence with advantages and disadvantages of this technique.

**Recent Findings** There are five studies reported including a randomised control trial looking at the outcomes of Rezum. The outcomes show an IPSS reduction by 45–60%, QoL improvement with a score reduction of 37–59%, the Qmax improvement by 44–72% and the PVR reduction by 20–38%.

**Summary** Convective water vapour therapy using the Rezum system has been shown to have successful outcomes in the treatment of LUTS resulting from BPH. The reported complications are infrequent and often minor, and it seems to be relatively cost-effective.

**Keywords** Rezum · Water vapour therapy · BPH · LUTS · Minimally invasive therapy · TURP

## Introduction

Benign prostatic hyperplasia (BPH) is a common, progressive, non-malignant urological condition associated with ageing in males. Histology at autopsy has revealed a prevalence greater than 50% at 60 years of age [1]. It can lead to debilitating lower urinary tract symptoms (LUTS) categorised by voiding dysfunction, irritative or obstructive urinary symptoms as a result of bladder outflow obstruction [2]. With an ageing global population, it represents a significant burden in terms of both morbidity and cost [3].

Management of BPH is tailored on the severity of symptoms that are measured by validated self-reported scoring

systems. Examples include the International Prostate Symptom Score (IPSS), and International Continence Society male questionnaire [4]. Other clinical parameters which help assessment include maximum urinary flow rate (Qmax), post-void residual volume (PVR), prostatic size and bladder pressure studies which are used in some cases to guide clinical management [5]. Conservative treatment with lifestyle modifications or pharmacological therapy may be indicated in patients with mild symptoms. Pharmacotherapy has been shown to demonstrate significant relief of milder LUTS, although the effect may be limited in those with moderate to severe symptoms [6].

The gold standard surgical treatment for more severe symptoms remains transurethral resection of prostate (TURP). While treatment outcomes following TURP are good, it usually requires a spinal or general anaesthesia, has a 2–3-day inpatient stay and the complication rates are higher in medically co-morbid patients [5]. Post-operative complications such as urethral stricture, stress incontinence, erectile dysfunction (ED) and retrograde ejaculation (RE) can all negatively effect patient outcome and quality of life (QoL) [7].

Recent focus has shifted to the development and implementation of newer minimally invasive surgical treatments (MISTs) with the aim of surgically managing BPH within an outpatient or day case setting. Treatment methods include mechanical expansion with devices such as Urolift, wherein an implant is inserted to separate the prostatic lobes, and thermal,

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which utilises targeted heat to bring about a reduction in prostatic volume [7, 8]. Another method is prostatic artery embolisation or PAE that aims to cause ischaemic necrosis and shrinkage of the prostate by diminishing local blood supply [9]. Although not widely adopted, there are thermal procedures such as Transurethral Needle Ablation (TUNA) and Transurethral Microwave thermotherapy (TUMT) which necessitate longer interventional time and extensive energy delivery [10••].

To overcome these limitations, the Rezum system (NxThera, Maple Grove, MN, USA), which received approval by the US FDA in 2015, employs water vapour as a vector for thermal energy. More recently, Rezum was integrated by the National Institute of Clinical Excellence (NICE) into its treatment pathway for lower urinary tract symptoms in males [11]. This paper will evaluate current research in Rezum, focussing on safety profile; new developments and efficacy at long-term follow-up.

## The Procedure

The Rezum system aims to cause immediate cell necrosis in the prostate without the need for long conduction times or high-energy transfer as in TUNA and TUMT. This is achieved using convective thermal transmission rather than conduction. The system implements convective water vapour energy (WAVE), using thermal energy generated via radiofrequency. A bedside radiofrequency device is utilised, with energy being transferred via a disposable, transurethral applicator [12•]. A retractable needle is inserted into the targeted treatment area at a fixed depth of 10.25 mm. The prostate can be visualised throughout the procedure via an integrated cystoscope, aided by saline irrigation.

As opposed to other treatments, heat is applied in short, 9-s bursts. During this time, large amounts of energy are released in the form of water vapour (540 cal/mL H<sub>2</sub>O). Heat disperses rapidly throughout the prostatic interstitium, resulting in rapid change in tissue temperature to roughly 70 °C, bringing about cell death [13]. The nature of water vapour as an outlet for thermal energy limits transfer to the targeted prostatic capsular zone and ensures necrosis without burning. The resultant area of necrosis measures around 1–2 cm. The aim of the procedure is to create overlapping lesions running in parallel with existing urethral anatomy. Average treatment requires 4.6 nine-second applications and is dependent on the length of prostatic urethra and presence of median lobe [14]. Treatment in this manner has been shown to result in improvement in reported LUTS in those with moderate-severe symptoms with a decreased effect on reported sexual function. Moreover, objective improvement has been recorded in clinical trials [15–18]. Mynderse et al. conducted a study evaluating the effect of Rezum on the prostate using serial magnetic resonance imaging (MRI), showing a resolution of ablative

lesions and one third reduction in overall prostate and transition zone volumes in 6 months [12•].

However, as with most interventions, Rezum may not be suitable for all patients with LUTS as a result of BPH, and previous trials have incorporated stringent exclusion criteria. These exclusion criteria included those patients with a history acute urinary retention, large post-void residual volume (> 300 ml), recurrent or active urinary tract infection, and previous prostate intervention or surgery. It was also contraindicated in those with confirmed or suspected diagnoses of prostate malignancy with multiple trials excluding those with documented PSA > 2.5. This can be extrapolated to those who have received previous radiotherapy for prostatic malignancy. However, more recent research is emerging in which broader inclusion criteria have been implemented, and in preceding research, candidates with the presence of prostatic median lobe have not been excluded [14].

Prior to the procedure, a cystoscopy is performed to visualise anatomy and plan the treatment. It can be used in conjunction with imaging techniques such as transrectal ultrasonography. The use and type of anaesthesia and sedation are variable from oral sedation to prostate block, intravenous sedation, and spinal or general anaesthesia [17].

## Results

There are five studies [10••, 16, 18–20] reported including a randomised control trial looking at the outcomes of Rezum. The outcomes show an IPSS reduction by 45–60%, QoL improvement with a score reduction of 37–59%, the Qmax improvement by 44–72% and the PVR reduction by 20–38%. A summary of the results is listed in Table 1, detailing the type of study and key measurable outcomes identified at their longest follow-up duration.

Dixon et al. designed a pilot study looking at the effectiveness of convective radiofrequency water vapour thermal therapy as a treatment whilst also assessing the therapy's safety profile. This took the form of a non-randomised pilot study looking at Rezum outcomes in 65 patients up to 2 years post-procedure, follow-up at 1 week and 1, 3, 6, 12, and 24 months. Inclusion criteria comprised of patients ≥ 45 years with no previous surgical interventions, prostate volume 20–120 cc, IPSS ≥ 13, Qmax ≤ 15 mL/s with a voided volume ≥ 125mls and PVR < 300 mL [15]. Favourable outcomes were seen as early as 1-month post-procedure with improvements in IPSS, QoL, Qmax, benign prostatic hyperplasia impact index (BPHII) and PVR [16]. Maximal improvements in these areas were seen 3 months post-procedure with improvements that remained consistent on 24-month follow-up. In particular, the mean IPSS improvement at 3 months showed a 13.4-point reduction (61% reduction). This was sustained at 24 months with mean improvement of 12.1 point reduction (55.7% mean

**Table 1** All studies reporting on Rezum with outcome measures and follow-up (IPSS International prostate symptom score, QoL quality of life, Qmax maximum urinary flow rate, PVR postvoid residual urine, IIEF-EF international index of erectile function)

Year	Type of study	Authors	Number of participants	Duration of follow-up (months)	IPSS (%reduction)	QoL (% reduction)	Qmax (mL/s) (% improvement)	PVR (% reduction)	IIEF-EF (%improvement)
2016	Pilot study	Dixon et al.	65	24	55.7 (n = 43)	59 (n = 43)	44.5 (n = 39)	19.8 (n = 38)	30.5 (n = 31)
2017	Cross-over study	Roehrborn et al.	53	12	56 (n = 45)	55 (n = 45)	53 (n = 45)	17 (n = 44)	18 (n = 26)
2017	Retrospective study	Darson et al.	131	12	45.2 (n = 87)	37.8 (n = 74)	51.4 (n = 7)	34.9 (n = 35)	n/a
2017	Retrospective study	Mollengarden et al.	129	6	60 (n = 89)	n/a	71.7 (n = 43)	32.3 (n = 99)	n/a
2019	Randomised control trial	McVary et al.	197	48	46.7 (n = 81)	42.9 (n = 90)	49.5 (n = 81)	38 (n = 89)	7.6 (n = 58)

reduction from baseline) [16]. Of note, there were no clinically significant adverse effects seen on sexual function at any time point throughout the study.

The longest duration follow-up currently available is an ongoing 5-year double-blind randomised control trial by McVary et al. with 4-year follow-up data. A crossover study was conducted with the 61 subjects who initially underwent the sham procedure with subsequent unblinding at 3 months and 3-year follow-up. Inclusion criteria for the RCT included men aged > 50 with an IPSS ≥ 13, Qmax ≤ 15 mL/s and a prostate volume between 30 and 80 cc. A total of 197 fulfilled the inclusion criteria and 135 randomly selected were allocated to receive Rezum therapy and 61 to receive a sham procedure [17]. Statistically significant improvement seen in IPPS, QoL, Qmax and BPHII after 3 months with improvements sustained at a 4-year follow-up [10••]. Interestingly, notable improvement, on average greater than 50% in objective and subjective domains, was evidenced in subjects with severe LUTS (categorised as IPSS 19–35). This group comprised 72.5% of the cohort, demonstrating the effectiveness of Rezum in severe disease. As in the pilot study, there were no new de novo cases of ejaculatory dysfunction reported at 48-month follow-up [10••]. Surgical re-treatment rates are an important consideration when evaluating any new therapy’s efficacy, at 48-month follow-up re-treatment rates that were reported at 4.4%, which compares favourably with TURP and other MIST procedures [10••]. The crossover cohort outcomes were similar to that of the main trial. Significant improvements were observed across subjective and uroflowmetric parameters. Implementing a crossover trial in this way emphasises the significance of recorded improvements, as the patient cohort act as their own control group and study power is therefore increased [18].

Two retrospective studies have also been conducted assessing Rezum [19, 20]. Mollengarden et al. conducted a retrospective study looking at a single surgeon’s experience and results using the Rezum procedure in 129 patients [20]. This study was limited due its variation in baseline patient characteristics and incomplete follow-up potentially affecting the results. Most notably, a significant proportion of patients participating in the study did not undergo a period of medication washout prior to procedure. In spite of this, it is argued that this may more closely represent outcomes likely to be seen in current clinical practice [20]. Statistically significant improvement was seen in IPSS, Qmax and PVR at follow-up at 6 months (Table 1). Maximal improvement was seen after 3 months post-procedure, in keeping with results from other studies discussed. There was improvement in LUTS with a voiding symptom reduction by 74% and storage symptom reduction by 49% [20]. Their trial measured outcomes not generally recorded in other studies, including prostate volume reduction, patient satisfaction and percentage reduction in the use of BPH-related medication. Outcomes showed a 17%

reduction in prostate volume based on TRUS, 89.5% of patients had stopped using pharmacological management for LUTS symptoms and 86% of patients would recommend this procedure to a friend [20]. An objective reduction in prostatic volume had only previously been observed in the work of Mynderse et al. via serial gadolinium enhanced MRI [12]. This noted reduction in the prostate volume further establishes the efficacy of Rezum treatment. Re-treatment rates were measured at 2.3%; however, their follow-up duration was shorter than other studies.

Darson et al. conducted another retrospective study analysing the outcomes of Rezum in 131 patients. There were no strict inclusion criteria, and patient selection was left at the discretion of the clinician, meaning that there was a greater variation in patient demographics and broader spectrum of prostate volume. This ranged from 12.9 to 183 cc, and 12% of patients had prior prostate surgical or MIST intervention [19]. At 12-month follow-up, the mean IPSS reduction was 45.2%, a mean Qmax improvement of 51.4% and a mean PVR volume reduction of 34.9%. These findings are consistent with results from other studies conducted; however, it is important to note that there was a significant loss to follow-up at 12 months.

The above two retrospective studies had broader inclusion criteria and replicated the successful outcomes seen in RCTs. Nonetheless, these cohorts may be more representative of the real-world population and further emphasise the potential of Rezum therapy.

### Advantages of Rezum

The efficacy of Rezum system has been demonstrated with a reduction of symptomatic LUTS during a medium-term follow-up. Improvement in both storage and voiding symptoms has been reported at 4 years with a mean IPSS improvement of 46.7% [10]. In an indirect comparison with pharmacotherapy by Gupta et al., Rezum was found to have an equal, sustained improvement in symptom score when compared to combination medical therapy and better outcomes when compared with monotherapy. Moreover, clinical progression was five times more likely in the pharmacotherapy cohort than with Rezum [21]. It seems that Rezum as a primary intervention could reduce the burden of polypharmacy and associated side effects.

Rezum can also be carried out in patients with median lobe or elevated bladder neck unlike PAE or Urolift [10]. The system can be delivered in an outpatient or office setting and administered over a short treatment time (average 8 min) [20]. Previous trials have performed the procedure predominantly using oral sedation, negating the need for general anaesthesia and reducing its associated risks. The combination of short procedural time and length of stay allows more procedures to be carried out with higher patient turnover thereby reducing the overall cost.

A key benefit of Rezum therapy is the preservation of sexual function, an area commonly affected by other surgical treatments for BPH. At the time of publication, no cases of de novo sexual dysfunction have been reported. Mollengarden et al. noted retrograde ejaculation in 3.1% of subjects; however, no individual baseline data was available, and hence it is difficult to categorise it as de novo. Moreover, ejaculatory bother score has been shown to improve after thermal therapy in some studies [22]. As for efficacy, McVary et al. compared outcomes of sexual function after Rezum therapy and pharmacotherapy. Those treated with Finasteride, Doxazosin or combination therapy reported worsening sexual desire and function, while no negative impact on sexual function was reported with Rezum [23].

A cost-analysis report has been conducted in the USA, evaluating the expenses associated with medical therapy, MISTs and TURP. This report evaluated immediate, procedural price and costs of longer-term follow-up. Rezum was noted to be comparatively effective in terms of health and financial burden. While clinical improvement was found to be greater with TURP, fewer adverse events in Rezum therapy amounted to an overall reduction in cost. Similar efficacy was noted with alternative MISTs such as Urolift; however, Rezum was notably cheaper to deliver [24].

Convective water vapour therapy has been demonstrated to have a strong safety profile with minimal intra-procedure complications, and the majority of post-intervention complications were Clavien-Dindo types I–II [10].

### Disadvantages of Rezum

There are certain disadvantages of Rezum, but some of them can be attributed to the patient selection reported in the initial studies. In the next few years, it will be clear on whether this selection criteria can be broadened and become more inclusive. Patient groups included in existing clinical trials dictate its current scope of use. In the study performed by McVary et al., inclusion was limited to those with prostatic volume of 30 to 80 cc and only those above 50 years of age. Moreover, those included were required to have a Qmax  $\leq$  15 ml/s and PVR  $\leq$  250 ml. Those with a history of urinary retention or UTI were also excluded. As a result, Rezum has not been utilised in randomised control trial in patients with larger prostate size or those with significant outflow obstruction [10]. Dixon et al. have used broader inclusion criteria, with a minimum age of 45 years and in prostatic volume  $\leq$  120 cc; however, perhaps there is scope to apply the technique to a wider group [16]. Other retrospective studies have employed wider inclusion criteria too [19, 20].

Previous criticism of Rezum has noted a lack of long-term follow-up. Ongoing data has been collected from only one randomised control trial, currently at 48 months post-intervention. Initial improvements in symptoms have been sustained

over this time, with 4.4% proceeding to retreatment [10••]. Further follow-up is required to evaluate the efficacy of Rezum, its place in treatment guidelines, QoL and eventual cost. While the minimally invasive administration of Rezum offers extensive benefit, the lack of collected tissue specimen could be a disadvantage as the incidental detection of prostate cancer after TURP varies between 1 and 13% [25, 26].

The requirement for catheterisation varies between studies. In the work by Dixon et al., catheterisation was performed at the clinician's discretion with 55% catheterised before discharge and a further 17% catheterised later due to haematuria, decreased voiding and pain [15]. In the study conducted by Mollengarden et al., patients were either catheterised or a Spanner Prostatic stent was inserted ahead of discharge, with the latter being in situ for 2–5 weeks. Standard catheters were removed within 1 week [20].

## Complications

In the longest running randomised control trial using convective water vapour therapy to date, the majority of complications arose in the initial 30-day period following intervention and were deemed mild–moderate in severity [17] (Table 2). The most frequently reported adverse events had significant overlap with complications after rigid cystoscopy including UTI, dysuria, and acute urinary retention or worsening LUTS. In the trial by Mollengarden et al., 23% developed UTI post-procedure; however, none of the patients were pyrexial or had a positive urine culture, and it is debateable on whether this was a true UTI or post-procedure LUTS [20]. Moreover, in this trial, patients were discharged with Prostatic Spanner—increasing likelihood of UTI or LUTS.

**Table 2** Reported complications of convective thermal water vapour therapy

Authors	Complications (adverse related events), <i>n</i>	
	Clavien-Dindo I/II	Clavien-Dindo III/VI
Dixon and colleagues (2016) ( <i>N</i> = 65)	<p><i>N</i> = 45</p> <p>Urinary retention: <i>n</i> = 22 (33.8%)</p> <p>Dysuria: <i>n</i> = 14 (21.5%)</p> <p>Urgency: <i>n</i> = 13 (20%)</p> <p>UTI (suspected): <i>n</i> = 13 (20%)</p> <p>Haematuria: <i>n</i> = 9 (13.8%)</p> <p>Poor stream: <i>n</i> = 9 (13.8%)</p> <p>Pain/discomfort: <i>n</i> = 7 (10.8%)</p> <p>Nocturia: <i>n</i> = 5 (7.7%)</p> <p>Frequency: <i>n</i> = 4 (6.2%)</p> <p>Fever: <i>n</i> = 3 (4.6%)</p> <p>Dribbling: <i>n</i> = 2 (3.1%)</p> <p>Scrotal pain: <i>n</i> = 2 (3.1%)</p> <p>Incontinence (urge): <i>n</i> = 1 (1.5%)</p>	<p><i>N</i> = 3 (4.6%)</p> <p>Urinary retention: 1</p> <p>Poor stream:</p> <p>Urinary frequency: 1</p>
Roehrborn and colleagues (2017) ( <i>n</i> = 53)	<p><i>N</i> = 25</p> <p>Dysuria: <i>n</i> = 10 (18.9%)</p> <p>Gross hematuria: <i>n</i> = 6 (11.3%)</p> <p>Urinary retention: <i>n</i> = 3 (5.7%)</p> <p>Suspected urinary tract infection: <i>n</i> = 4 (7.5%)</p> <p>Decreased ejaculatory vol: <i>n</i> = 3 (5.7%)</p> <p>Urinary frequency: <i>n</i> = 3 (5.7%)</p> <p>Hemospermia: <i>n</i> = 2 (3.8%)</p> <p>Terminal dribbling: <i>n</i> = 1 (1.9%)</p>	<p><i>N</i> = 3 (5.6%)</p> <p>Bladder neck contracture: 1</p> <p>Stone formation: 1</p> <p>Sepsis: 1</p>
Darson and colleagues (2017) ( <i>n</i> = 153)	<p><i>N</i> = 19</p> <p>Acute urinary retention: <i>n</i> = 14 (10.7%)</p> <p>Frequency, urgency, frequency and urgency, haematuria and nocturia: <i>n</i> = 5 (≤ 3.8%)</p>	<p>Nil</p>
Mollengarden and colleagues (2017) ( <i>n</i> = 129)	<p><i>N</i> = 61</p> <p>UTI: <i>n</i> = 22 (17.1%)</p> <p>Urinary retention: <i>n</i> = 16 (12%)</p> <p>Post-void dribbling: <i>n</i> = 5 (3.9%)</p> <p>Urinary incontinence: <i>n</i> = 5 (3.9%)</p> <p>Erectile dysfunction: <i>n</i> = 4 (3.1%)</p> <p>Retrograde ejaculation: <i>n</i> = 4 (3.1%)</p> <p>Prostate tissue sloughing: <i>n</i> = 2 (1.6%)</p> <p>Epididymo-orchitis: <i>n</i> = 2 (1.6%)</p>	<p><i>N</i> = 12 (excluding repeat cystoscopy for LUTS)</p> <p>Urinary retention: <i>n</i> = 2 (1.6%)</p> <p>Urethral stricture: <i>n</i> = 5 (3.9%)</p> <p>Additional BPH surgery: <i>n</i> = 3 (2.3%)</p> <p>Bladder stone: 1</p> <p>Bladder neck contracture: 1</p>
McVary and colleagues (2019) ( <i>n</i> = 197)	<p><i>N</i> = 52</p> <p>Dysuria: <i>n</i> = 23 (16.9%)</p> <p>Haematuria: <i>n</i> = 16 (11.8%)</p> <p>Frequency and urgency: <i>n</i> = 8 (5.9%)</p> <p>UTI (suspected): <i>n</i> = 5 (3.7%)</p> <p>Urinary retention: <i>n</i> = 5 (3.7%)</p>	<p><i>N</i> = 2</p> <p>Bladder neck contracture and bladder calculi: 1 report</p> <p>Urinary retention: 1 report</p> <p>Hospitalisation due to nausea and vomiting: 1 report</p>

In the work by Dixon et al., 45 patients reported 125 adverse events. Of these, the vast majority were reported as Clavien-Dindo grades I–II. The first 30 days post-intervention carried the greatest risk with 75% of adverse events occurring during this time and were mostly self-resolving [16]. In the McVary et al. study, there were no reports of complications outside of the initial 30 days and no reports of new onset or worsening sexual dysfunction [27].

Rare serious complications have arisen in clinical trial with a reported singular incidence of urosepsis after follow-up cystoscopy [18]. In another cohort, patients developed two serious complications in the form of a bladder neck contracture and bladder calculi [18]. Furthermore, in the trial conducted by Dixon et al., one Clavien-Dindo grade IIIb event has been reported, wherein a subject developed urinary retention 33 days after Rezum and progressed to have a TURP procedure [16].

### Future Considerations

Overall, the data presented using Rezum shows substantial improvements in LUTS with the added benefit of a strong safety profile. While a great deal of research is ongoing, the current literature available has its limitations. At the time of publication, there is only one double-blinded RCT in process. In order to further evaluate the efficacy of the procedure, further randomised control trials are required. Furthermore, although the trial is robust, NxThera, the manufacturer of Rezum, has sponsored this ongoing trial, potentially representing a conflict of interest.

The above trial has collected data up to 48 months post-intervention, representing the longest duration follow-up available. In a society with an ageing population and increased life expectancy, one can extrapolate that patients will live for longer with LUTS, emphasising the importance of sustainable treatment. As a result, longer-term follow-up data is required analysing prolonged symptom relief and retreatment rates. Previous concerns have been expressed about the application of convective water vapour therapy in the non-trial setting [13]. Two retrospective studies have yielded promising results in a wider cohort, more representative of those presenting to specialist urology services [19, 20]. It seems that provided that the initial results are replicable, there will be a much wider uptake of this new office-based technology, although currently more evidence is needed to further promote clinical application.

### Conclusion

Convective water vapour therapy using the Rezum system has been shown to have successful outcomes in the treatment of LUTS resulting from BPH. It seems to be well tolerated with

good subjective and objective results. The reported complications are infrequent and often minor, and it seems to be relatively cost-effective. It has proven to be versatile across a variety of prostatic sizes and characters while preserving patients' sexual function.

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### Compliance with Ethical Standards

**Conflict of Interest** Zachary Green and Jennifer Westwood each declare no potential conflicts of interest.

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**Human and Animal Rights and Informed Consent** This article does not contain any studies with human or animal subjects performed by any of the authors.

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