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TOPIC PAPER

# Beyond medications: office-based procedures for benign prostatic obstruction

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## Abstract

**Purpose** When medications fail to satisfactorily treat bothersome lower urinary tract symptoms (LUTS) due to benign prostatic obstruction (BPO), procedural treatments are indicated. There is much interest in minimally invasive office-based treatments which can be performed under local anesthesia, allow fast recovery and have minimal morbidity. The purpose of this article is to review recent literature regarding safety and efficacy of office-based minimally invasive therapies for BPO.

**Methods** A literature search using PUBMED and Medline was performed regarding minimally invasive office-based treatments for BPO, including the prostatic urethral lift (Urolift), water vapor therapy (Rezum) and stents. Literature published within the last 5 years were reviewed.

**Results** The prostatic urethral lift (Urolift) is a safe and efficacious treatment for LUTS–BPO whilst also preserving sexual function. Rezum appears to be a safe and effective treatment in Phase 2 trials. Memokath prostatic stents do not appear to be a durable treatment; Allium prostatic stents warrant further investigation prior to recommendation.

**Conclusions** The prostatic urethral lift (Urolift) is a safe and effective treatment for LUTS–BPO whilst preserving sexual function. Rezum also appears to be a safe and effective treatment in small RCTs comparing performance with TURP. Memokath prostatic stents do not appear to have treatment durability. Further studies would be warranted to determine whether Allium prostatic stents are safe effective treatments for LUTS–BPO.

**Keywords** Benign prostatic hyperplasia · Lower urinary tract symptoms · Minimally invasive surgical procedures · Stents · Water

## Introduction

There has been consistent strong interest in minimally invasive procedural treatments for lower urinary tract symptoms (LUTS) due to benign prostatic obstruction (BPO) over the past couple of decades, with particular interest in procedures that can be performed in an office setting, under local anesthesia with minimal morbidity and quick recovery as an alternative to traditional transurethral resection of the prostate (TURP). Minimally invasive cavitating prostate technologies such as water vapor therapy (Rezum System) have generated much interest. Implant devices such as the prostatic urethral lift (Urolift) have gained popularity; however, other implants such as stents have had limited uptake.

The purpose of this article is to review recent literature (within the last 5 years) on the safety and efficacy of these novel office-based procedures and introduce experimental office-based procedures designed for the treatment of LUTS–BPO. Injectable medications into the prostate and oral medications are not within the scope of this article, nor are operating room-based procedures performed for LUTS–BPO. Table 1 outlines the key features of each office-based treatment being discussed in this review.

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**Table 1** Summary of minimally invasive office-based procedures and key features

| Procedure | Commercially available? | Local anaesthesia possible? | Outpatient treatment possible? | Clinical trial data[a] | Adverse events |
|---|---|---|---|---|---|
| Rezum | Yes | Yes | Yes | Phase 2 trial completed and published. | Post procedure acute urinary retention in 50% |
| Urolift | Yes | Yes | Yes | Phase 3 trial completed and published. | No significant |
| TIND | Yes | Yes | Yes | Phase 2 trial completed and published; Phase 3 trial in progress | Urinary tract infection |
| Memokath stent | Yes | Yes | Yes | Phase 3 trial completed and published | Migration/explantation |
| Allium stent | Yes | Yes | Yes | Limited | Unknown |

[a]English language publications on PUBMED or Medline

## Cavitating prostate technologies

### Rezum

The Rezum procedure (Rezum System, NxThera Inc, Minnesota USA), which utilizes radiofrequency energy to heat water which then induces postoperative necrosis to cavitate the prostate, is increasingly gaining popularity as further evidence demonstrating its safety and efficacy emerges. Over the last few years, several trials regarding the Rezum procedure have since been published reporting statistically significant improvements in IPSS, peak urinary flow rate ($Q_{max}$) and IPSS quality of life (IPSS QoL) scores with the additional advantage of preserving sexual function [1–3]. These findings were further validated in a recent multicenter, randomized controlled trial completed in 2016 with a 12-month follow-up. A total of 197 men were randomized to either the Rezum ($n=136$) or control treatment which consisted of rigid cystoscopy with simulated active treatment sounds ($n=61$). The Rezum technology resulted in significant improvements in IPSS score and $Q_{max}$ ($p<0.0001$). No de novo erectile dysfunction was reported; adverse events were mild to moderate and transient. Some adverse events were related to the endoscopic procedure including haematuria, dysuria and urinary retention often requiring insertion of indwelling catheter for a median in-hospital duration of 4.1 days. [7, 8] [ClinicalTrials.gov ID: NCT01912339] [4]. The duration of catheterization is a potential limitation. Nevertheless, the performance of the Rezum System for treating LUTS–BPO appears promising. However, further trials are needed to evaluate its long-term efficacy and cost effectiveness.

## Mechanical devices

### Prostatic urethral lift

The prostatic urethral lift (PUL) procedure (Urolift System, Neotract, California USA) is a minimally invasive treatment which involves implanting tensioning sutures to separate the encroaching prostate lobes for the treatment of LUTS–BPO (Fig. 1). It has been described as a safe alternative for men who are unsuitable for long-term pharmacological therapies for LUTS–BPO but who are also not suitable for more major surgery such as TURP. Phase 3 trials have shown that the Urolift procedure is effective in providing statistically significant ($p<0.05$) improvements in symptom relief (IPSS) and quality of life (IPSS QoL), with preservation of ejaculatory and erectile dysfunction [5–8]. In 2013, a large randomized prospective study comparing Urolift and TURP treatment was conducted. Outcomes based on six key parameters including continence, preservation of erectile and ejaculatory function, safety, quality of recovery and relief of symptoms (BPH-6) were assessed. Improvements in IPSS, IPSS QoL and $Q_{max}$ were achieved by both Urolift and TURP treatments. Patients who underwent the PUL had a shorter hospital length of stay (1.0 versus 1.9 days, $p<0.0001$), faster time to resuming preoperative function (11 versus 19 days, $p<0.04$), and improvements in ejaculatory function ($p=0.03$). Conversely, the TURP group reported worse sexual function postoperation ($p<0.0001$) [6]. The Urolift was approved by the FDA (September 2013) and by the UK National Institute for Clinical and Health Excellence (September 2015) as safe and effective for implementation [9].

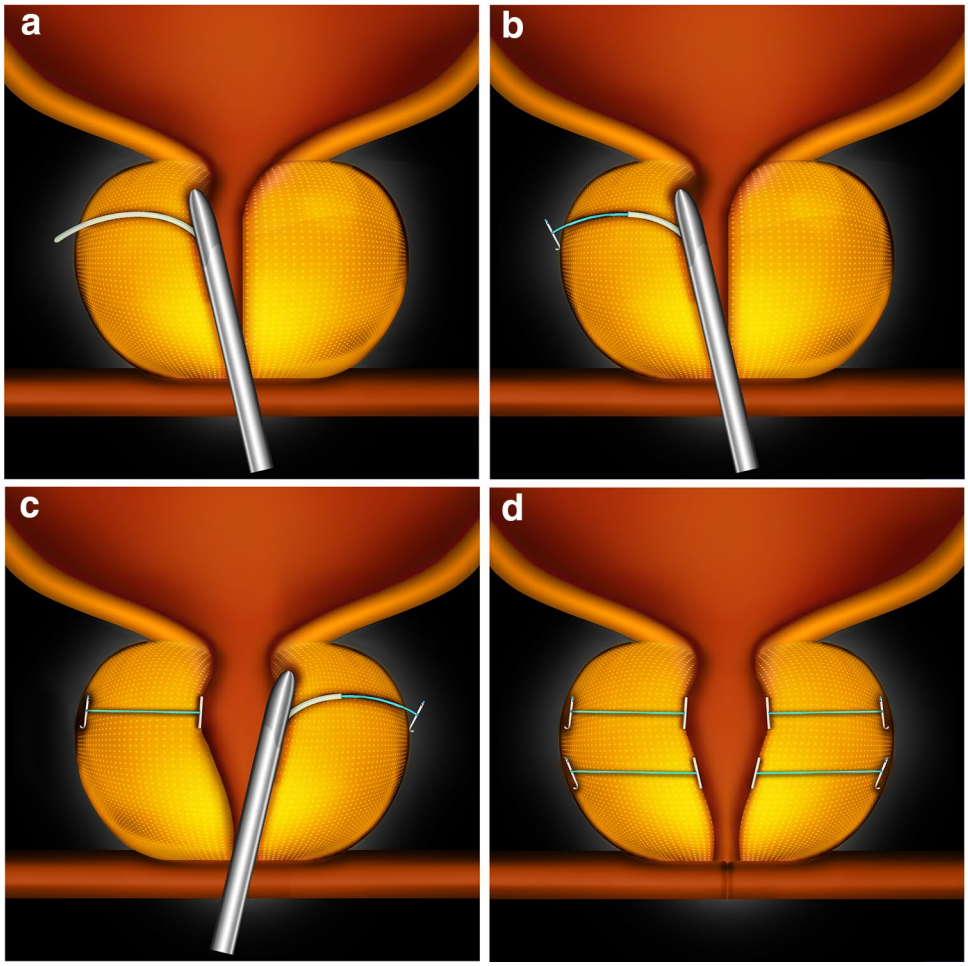


**Fig. 1** The prostatic urethral lift (Urolift) is a mechanical treatment for LUTS-BPE achieved by transurethrally deploying a needle beyond the prostate capsule (**a**) and implanting tensioned suture-based implants (**b**, **c**) that mechanically retract the encroaching prostatic lobes (**d**) (Images provided with permission to reproduce from Neotract Inc)

### Temporary implantable nitinol device (TIND)

The TIND (iTind, Medi-Tate Ltd, Or-Akiva, Israel) is a device comprised of elongated expandable struts made of nitinol which radially expand the bladder neck and prostatic urethra, causing ischemic necrosis and incision of the tissue [10]. The TIND is implanted for 5 days and then removed under endoscopic vision. A prospective study reported that the TIND was associated with 41% improvement in IPSS ($p < 0.001$), and 4.4 ml/s improvement in $Q_{max}$ ($p < 0.001$) at 12 months [11]. Post-operative complications were mild including urinary tract infection and transient urinary retention [11]. A follow-up study in men with prostate sizes < 60 cc also found that these improvements were maintained up to 36 months post procedure [12]. These findings suggest that the TIND may be a safe and well-tolerated procedure with reasonable durability. Currently, Phase 3 trials are underway and results have yet to be published [ClinicalTrial.gov ID NCT01436877 and NCT02145208].

## Prostatic stents

### Memokath stent

The Memokath stent is a nickel–titanium alloy coil that expands with heat and is resistant to compression. Recently, there have only been few publications on Memokath stents for treatment of LUTS–BPO. A recent retrospective review found that 62.5% (90/144) patients who presented with bladder outlet obstruction and/or urinary retention secondary to prostatic obstruction and who underwent Memokath stent placement experienced improvement in postvoid residual urine volume ($p < 0.0001$) [13]. Stent failure was reported in 37.3% (54/144) patients with the median time to stent failure being 6 months post-operation. The complication rate was 37.5% and included problems such as stent removal due to migration, occlusion and irritative voiding symptoms [13]. With this high retreatment rate, Memokath does not appear to be an effective long-term treatment and large prospective clinical trials are currently lacking.

### Allium stent

The Allium TPS is a flexible nitinol-built polymer-covered stent which prevents tissue ingrowth and reduces encrustations. There are limited published English studies about the role of Allium stents for the treatment of LUTS–BPO; however, there are multiple studies regarding the role of Allium stents in treating bulbar urethral strictures [14, 15]. A study of 51 patients reported improvement in IPSS, $Q_{max}$ and IPSS QoL, and no complications over a 12-month follow-up period after treatment with the Allium stent for LUTS–BPO [16]. Further well-designed studies would be required to confirm the role of Allium stents in the management of LUTS–BPO.

## Conclusions

The prostatic urethral lift (PUL, Urolift) is a safe and effective office-based procedure treatment of LUTS–BPO and has the advantage of preserving erectile and ejaculatory function. The Rezum procedure is gaining popularity as evidence supporting its safety and efficacy is growing, though further studies regarding its performance and cost-effectiveness are needed. The TIND is promising as it appears well tolerated and improves LUTS durable to 36 months in studies. Memokath stents do not appear to be an effective long-term solution for LUTS–BPO due to a high retreatment rate; further studies are warranted of the Allium stent to determine its role in the treatment armamentarium of LUTS–BPO.

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### Compliance with ethical standards

**Conflict of interest** PUT has no conflicts of interest. ASJC has received an honorarium from Astellas Pharma Australia Pty Ltd for speaking at a symposium.

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