



A scoping review of office-based prostatic stents: past, present, and future of true minimally invasive treatment of benign prostatic hyperplasia

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Received: 6 January 2023 / Accepted: 29 June 2023

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Abstract

Purpose To conduct a scoping review of the existing literature and recent developments on prostatic stents for the treatment of benign prostatic hyperplasia (BPH).

Methods A comprehensive search was performed on Embase, MEDLINE, and Web of Science to identify English literature on prostatic stents for the treatment of BPH. Additional studies and upcoming devices were identified through grey literature search and expert consultation. Study characteristics and stent information were extracted and tabulated narratively.

Results Of the 1171 search results, 64 studies were included in this review. iTiND was the prostatic stent with the most long-term evidence. iTiND is a safe and effective minimally invasive treatment for BPH that preserves sexual function. Adverse events are mild and transitory. Emerging stents (e.g. Zenflow, Butterfly, Urocross, and Exime) had 7/64 eligible studies, where no studies had long-term follow-up. These newer stents show promising results for quality of life and BPH symptom management; however, long-term monitoring and head-to-head comparisons are needed.

Conclusion Over the last 50 years, prostatic stents have evolved and demonstrated improved clinical efficacy. iTiND provides a safe and effective outpatient treatment of LUTS secondary to BPH preserving erectile and ejaculatory function. Emerging prostatic stents are a promising, effective, and safe intervention in well-selected patients interested in its benefits.

Keywords Prostatic stent · Benign prostatic hyperplasia · LUTS · Minimally invasive · Technology

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Introduction

Benign prostatic hyperplasia (BPH) is a common urologic condition which affects approximately 50% of men above the age of 60 that presents with lower urinary symptoms (LUTS) [1]. Therapeutic options range from observation to surgical management. Medical treatment is a non-invasive option; however, adverse events such as depression or sexual dysfunction can be deterrents to treatment adherence [2, 3]. Presently, transurethral resection of the prostate (TURP) remains the gold-standard surgical treatment of LUTS secondary to BPH [4]. However, this effectiveness is accompanied by postoperative complications such as ejaculatory and erectile dysfunctions, and clot retention [5]. Additionally, TURP requires anesthesia and thus may not be suitable for elderly comorbid patients.

Historically, patients have had to choose between medical and surgical treatment. The concepts of minimally invasive surgical therapy (MIST) and true minimally invasive surgical therapy (TMIST), namely prostatic stents, have emerged to bridge the gap between medical and surgical therapies [6]. Sexual health, often diminished through side effects in medical or surgical therapies, is a decisive factor for men when selecting treatment options [7]. Prostatic stent technology initially emerged as an intervention for BPH in 1969, and since then, various types of prostatic stents have been developed and used as a MIST or TMIST to alleviate LUTS in patients with BPH [7]. While different prostatic stents slightly vary in their mechanism, all involve mechanical force to retain urethral patency without prostatic tissue removal or detriment of erectile and ejaculatory function. At the moment, many prostatic stents are undergoing clinical trials with promising efficacy and improved safety profiles.

Therefore, in this scoping review, we characterize the existing literature on prostatic stents and explore the recent rapid developments in this space.

Methods

This review was designed in alignment with the Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR). A systematic search of literature was performed on Embase and MEDLINE via Ovid, and Web of Science (all databases) up to November 15, 2022. The search strategy can be found in Online Appendix 1. Additional studies were collected from searching bibliographies of systematic reviews and literature reviews. Grey literature was obtained by searching conference websites and Google,

given the novelty of emerging prostatic stents. Inclusion criteria required studies to (1) mention at least one prostatic stent, (2) enrolled patients with BPH, and (3) were available in English. Studies were excluded if they were (1) conducted on animals, (2) preclinical studies, and (3) were either an editorial, commentary, literature review, guideline, or systematic review. There were no filters on publication date.

Two independent reviewers (AVN, IV) screened the abstracts and reached consensus through discussion. All reviewers (AVN, IV, RF) were involved with independent full-text screening and agreed upon the final included articles through discussion. Extraction was completed by all reviewers to obtain study characteristics, studied stents, and key findings related to any of the following domains: mechanism of action, periprocedural outcomes, complications, efficacy, and safety. The stents were narratively summarized and tabulated. A full list of the included studies and respective stents with their references can be accessed in Online Appendix 2. A summary of highlighted stents is demonstrated in Table 1.

Results

After duplicate removal, 931 citations were retrieved for title and abstract screening. Full-text articles were obtained for 535 studies. Finally, 64 studies were included in this review. The PRISMA flow diagram of study selection is depicted in Online Appendix 3. Distribution of included studies characteristics can be found Online in Appendix 4.

Past Stents

UroLume

The UroLume (American Medical Systems, Minnetonka, Minnesota) stent was one of the first permanent stents developed with the literature dating back to 1991, marking the beginning of stent technology as an intervention for BPH. Made of alloy material which can be integrated into the urethra, this stent is a self-expanding mesh cylinder which is endoscopically implanted with local, regional, or general anesthetic, improving the prevalence of LUTS [8]. Preliminary studies have reported no indwelling catheters required postoperatively [9]. However, over the course of 10 years, adverse events have been reported through a long-term prospective study, including excessive tissue proliferation, stent stenosis, and discomfort [10].

Table 1 Selected stent characteristics

Stent	Description	Anesthetic	Approvals
Past stents			
Biodegradable/dissolvable	Poly-L-lactic, poly-L-glycolic, braided poly(lactic-co-glycolic acid) copolymers	Local	No
Memocath/Memokath	Permanent thermo-expandable titanium-nickel spiral; shape-memory	Local	No
UroLume	Permanent flexible self-expanding device; braided mesh cylinder made from Elgiloy	Local, regional, or general	FDA
Urospiral	Flexible stainless steel spiral metal wire; consists of spiral loops with straight wire and distal 2 spiral loops	Local	No
Trestle	Temporary polyurethane stent	Local	No
Present stents			
Allium	Triangular, coiled, elastic and flexible stent with nitinol and covered with co-polymer	Local or regional	Approved in European Union, Israel, Australia, South Africa, and South Korea
iTiND	Three nitinol struts, an anti-migration anchoring leaflet and a polyester retrieval suture	Sedation or local	FDA
Spanner	Temporary intraurethral prostatic stent; available in 20Fr or 22Fr; available from 4 to 9 cm	None	FDA
Future stents			
Butterfly	Nitinol implant shaped like a butterfly	Local	No
ClearRing/ProArc	Nitinol C-shape ring	“Reduced” anesthesia	No
Exime	Coiled tube in silicone with non-resorbable monofilament	Local	No
Urocross	Nitinol device with a quadrant, strut-like design	Local or general	No
Zenflow	Designed to be permanent; small nitinol device	Local	No

FDA Food and Drug Administration

Memokath/Memocath

Through a thermo-sensitive mechanism and nitinol, the Memokath® (Doctors and Engineers, Kvistgaard, Denmark) stent softens before insertion and, once endoscopically implanted, returns to a cone shape which pushes the stent into the urethra in order to keep it open and unobstructed [11]. General anesthetic was normally used for this procedure; however, local anesthetic can also be used [11]. Studies have reported that the Memokath avoids the need for indwelling catheterization [12]. In a 2013 prospective study comparing the Memokath to TURP in 52 patients, 12-month decreases of the International Prostate Symptom Score (IPSS) from 6.8 ± 2.9 to 6.1 ± 3.1 were significant due to improvements in obstructive symptoms [13]. This concluded that the Memokath provides patients with surgical comorbidities with a safe alternative to relieve LUTS. However, the complication rate after insertion was 33.3% due to cases of pain, incontinence, and stent migration [13]. Within 7 years, Memokath had an 86% success rate, and in

unsuccessful cases, migration led to premature removal of the stent [14].

Poly-L-lactic and poly-L-glycolic copolymer spiral stents

Poly-L-lactic and poly-L-glycolic (PLGA) copolymer spiral stent is a self-expandable and self-reinforced device with a lactic/glycolic molar ratio 80/20, typically degrading in 2–2.5 months. It was designed to prevent postoperative urinary retention in patients with prostatic edema and bladder outlet obstruction following interstitial laser coagulation of the prostate (ILCP). In one study, this led to an increase in mean maximum and average flow rates, as well as a decrease in DAN-PSS-1 symptom scores and residual urine volume [15]. At 2 months, the stent was intact in all except three patients, and at 4 months, it had been degraded into small fragments. The stent was fully eliminated by 6 months [15]. However, parts of the stent were found at the bottom of the bladder in 2 patients. Results of these studies have concluded that the stent was

able to lock in place and degrade successfully, leading to voiding in cases of bladder outlet obstruction (BOO).

Braided poly(lactic-co-glycolic acid) urethral stent

In the braided PLGA urethral stent, a pilot study has established the efficacy in treating acute urinary retention (AUR) in patients with BPH [16]. The biodegradable stent was inserted via an insertion device followed by a dutasteride treatment. Insertion was successful in all patients, as all men were able to void afterwards. Five patients voided with a low residual urine volume (< 150 mL) by 1 month. Some experienced high residual urine volume or required a suprapubic or indwelling catheter. By 3 months, 5 patients were voiding. The braided design of this stent acts as a solution against migration and sudden breakage into large portions which is associated with biodegradable spiral stents, acting as a plausible option to treat AUR.

Present stents

Allium TPS

The Allium™ TPS (Allium TPS, Allium Medical, Caesarea) is a nitinol-built polymer-covered stent, preventing tissue growth and avoiding encrustations. The insertion procedure is performed endoscopically with local anesthetic, and studies have recommended it as an effective alternative to indwelling catheterization [17]. The soft proximal segment prevents sphincter dysfunction that may cause incontinence [18]. With various available lengths ranging from 30 to 65 mm with a large calibre, the chances of stent migration are reduced.

The first report of Allium TPS studied 51 men with severe benign prostatic obstruction secondary to BPH [17]. They found that all patients had significant improvement in peak urinary flow and improvement in IPSS at 12 months post-operatively with no intraoperative complications, significant improvements in QoL. Most postoperative complications were graded as mild and eventually resolved. At 12 months, the failure rate was 3.9% ($n=2$). Similarly, another study with 7 high-risk surgical candidates with BPH experienced no postoperative migration or hematuria after stent insertion [19]. While discomfort and urge-incontinence episodes were reported, mean Qmax flow index increased from 8.4 mL/sec to 13 mL/sec across all patients. While these outcomes are promising, attrition has not been reported at follow-up time points. No other included studies reported long-term outcomes, cost, sexual function, or QoL.

iTiND the temporary implantable nitinol device iTiND (Medi-Tate, Hadera, Israel/Olympus Corporation, Tokyo, Japan) is a second-generation FDA-approved nitinol device

[20]. It consists of three nitinol struts, an anti-migration anchoring leaflet and a polyester retrieval suture [6]. The device is inserted through a flexible cystoscope under sedation or local anesthesia in an outpatient setting. Studies have not reported the need for indwelling catheterization postoperatively [21]. The iTiND remodels the prostatic urethra and bladder neck by creating incisions at 5, 7 and 12 o'clock via continuous ischemic pressure [20]. The current Canadian Urological Association (CUA) guidelines do not support the use of iTiND in large prostates (> 75 ml) and in the presence of a large median lobe [22]. This technique is not included in American Urological Association (AUA) guidelines.

Chugtai et al. in a multicenter RCT showed that at 1-year follow-up patients treated with iTiND demonstrated a 9.25 reduction in IPSS, a 3.52 mL/s increase in PFR and a 1.9-point reduction in QoL [23]. The longest follow-up is reported by the MT-02 study at 36 months follow-up: IPSS improved by 58.2%, QoL by 55.6%, Qmax by 114.7%, and PVR by 85.4% [24]. Summary of functional outcomes of iTiND is shown in Online Appendix 5.

No de novo erectile dysfunction was reported 1 year post-treatment with iTiND. In patients with age between 45 and 60 years or no previous ED, sexual function is modestly improved post-procedure (IIEF-5 8.1%) [25]. Overall, sexual and ejaculatory functions were stable at 3 years follow-up [24]. Adverse events occurred in 38.1% of patients post iTiND and were typically mild and transient Clavien-Dindo grade I or II—dysuria occurred in 22.9%, hematuria in 13.6% and urgency in 5.1%. For grade III events, 7 patients (5.9%) presented urinary retention [23]. One case of gross hematuria was reported [26].

Retreatment rate varied from 0 to 8.6% and medical therapy re-initiation was necessary in 6.2% of patients [27, 28]. A long-term follow-up from an international multicenter prospective cohort showed that 2 out of 42 (4.7%) men had treatment failures requiring reintervention 50 months post-procedure (1 TURP and 1 ThuLEP) [29]. Safety and effectiveness of iTiND has been investigated and shown improvement on functional and sexual outcomes. Further studies are required to determine the role of iTiND in patients with an obstructive median lobe, AUR, and large prostate volume. Economic evaluations are not available to determine the cost-effectiveness of this stent.

The Spanner™

The Spanner (The Spanner, AbbeyMoor Medical, Inc., Minnesota, USA) is an FDA-approved temporary silicone elastomer prostatic stent [30]. It is placed under topical anesthesia in an outpatient setting without cystoscope visualization. Candidates must possess an intact reflex detrusor contraction and pelvic floor relaxation for optimal results from this stent. A pivotal study found a mean 42% improvement in

Qmax, a 64% decrease in PVR, and a 68% decrease in IPSS. The device was found to be safe, with no stent migration confirmed radiographically at up to 12 weeks of follow-up [31]. A multicentre RCT showed an 86% patient satisfaction rate with the Spanner stent after transurethral microwave thermotherapy for chronic obstruction due to BPH at an 8-week follow-up [32]. In 2022, a multicentre trial found the Spanner stent to be safe and effective in patients with chronic urinary retention due to BPH who were unfit for surgery, extending FDA approval for this population. Adverse events were predominantly mild, with 23.4% experiencing asymptomatic bacteriuria, 9.4% experiencing pain, and 7.5% experiencing urinary urgency [33].

Future stents

Zenflow™

Currently undergoing clinical trials, the ZenFlow™ Spring (Zenflow, South San Francisco, CA, USA) is a small nitinol-based implant inserted with local anesthetic through a flexible cystoscope to treat BPH symptoms [34]. Designed to be permanent but can be removed, the spring creates internal tension which helps the device incorporate into the wall of the urethra. In an initial study of ZenFlow™ Spring, patients had a significant IPSS improvement at 12 months [4]. As of recently, patients were followed for at least 18 months since the index procedure. Nine of 10 patients who had the device inserted and still had the implant indwelling reported improvements of approximately 6 points on IPSS at 18-month follow-up. The device has been shown to result in a low rate of adverse events, and no studies have reported indwelling catheterization required. Reported adverse events have included post-procedural urgency and minor discomfort, which have been easily resolved [4]. As of 2021, ZenFlow has initiated ZEST CAN, a pivotal randomized control trial to evaluate safety, cost-effectiveness, and overall performance of this device, with expected completion in 2026 [35].

Prodeon Urocross™

The Urocross™ Expander System (Prodeon Medical, Inc. (PMI), Sunnyvale, California, USA; formally branded as the XFLO Expander System) has been developed for use with a flexible cystoscope. It is comprised of a stent and delivery system designed for implantation in the prostatic urethra and its retrieval after implantation for a minimum of one month and up to 12 months. Local or general anesthetic is used, depending on whether the procedure is completed in a cystoscopy suite or operating room [36]. The temporary implant is a nitinol device developed to expand and reshape the prostatic urethra, through gentle mechanical tissue retraction to

alleviate urinary outflow obstruction which leads to LUTS. Most patients in early trials have reported rapid symptom relief and minimal complications, and indwelling catheterization has not been reported. Regarding the EXPANDER-1 trial from 2021, a prospective, three-arm study, several of these stents were successfully used. In this cohort, there were no cases of encrustation and few adverse events were reported. IPSS and QoL were improved over the course of the trial [36].

Proverum ProVee

The ProVee device is a 'stent-like' nitinol expander designed to gently reshape and open the obstructed urethra without heating, piercing, cutting, or removing part of the prostate. The delivery system for the expander is thinner than most treatment options, and the uncomplicated procedure is intended to be performed in an outpatient or doctor's office setting with local anesthetic [37]. Since this device is still in its early stages of exploration as an intervention, the first-in-man study conducted in 2019 has not yet established its results. As of 2022, another prospective trial called the ProVIDE study has been proposed to investigate the effectiveness and safety for the commercial use of this device. It is currently in the recruitment stage and is expected to be completed in 2028 [38].

Butterfly™

The Butterfly™ (Butterfly, Medical Ltd, Yokneam, Yilit, Israel) device is another new metallic implant that retracts the lateral lobes of the prostate and is easily delivered with either a rigid or flexible cystoscope under local anesthesia in an outpatient setting [39]. It is designed to be permanent but can easily be extracted [40]. It avoids invasive techniques such as cutting, ablation, heating, or removing prostatic tissue, as well as the need for catheterization afterwards [5]. A prospective study in 2021 has concluded that this device is effective for the management of LUTS due to BPH [41]. The mean IPSS was 25 at baseline and 15 after 12 months (40% decrease), and the mean improvement of QoL was 1.5 points (38%) [40]. It has been found to be easily removable; however, further study on the effectiveness of the device is underway.

EXIME®

The Exime® catheter (Rocamed; Munich, Germany) is a single-use temporary (up to 30 days) prostatic stent inserted in the prostatic urethra before the sphincter, acting as a substitute for a Foley catheter [42]. It was designed to allow voluntary urination in males with acute or chronic urinary retention due to BPH. Exime is inserted in an office-based setting

under local anesthetic without cystoscopy, sonography, or fluoroscopy guidance. A prospective cohort with 61 patients with a mean prostate volume of 67 ml (30–120 ml) obtained spontaneous urination immediately after the procedure in 90% of the sample [43]. Exime reduced postoperative discomfort after Rezum in patients with a mean operative IPSS of 23 and mean prostate volume of 61 ml, including patients with median lobe. Patients did not have complications or AUR, and the catheter was removed within 8 h [44].

Discussion

The rapidly growing number of men requiring surgical intervention for BPH is overwhelming when combined with the stagnant growth of practicing urological surgeons and undesirable side effects from medical treatment. While evidence for historic and current stents is more abundant, newer prostatic stents are still in development and have few published results, aptly calling for a scoping review. Most studies on new stents were only available in conference abstracts; however, they showed potential of decreasing IPSS scores and improved QoL ratings with few to no adverse events reported.

While historic stents paved the way for today's innovation, most have shown high failure rates. Present day stents, such as iTiND or Allium, offer patients an office-based procedure with improvement in IPSS and no sexual dysfunction. Existing and emerging TMISTs, such as iTiND, Butterfly, Urocross, Zenflow, and Exime, are office based and only require a standard flexible cystoscope without general anesthetic. While MISTs such as iTiND have helped men with BPH avoid invasive surgeries and even forgo daily medication, it remains costly (approximately \$2500 CAD per implant) and requires anesthesia [45]. Furthermore, stents may not be suitable for patients with detrusor hypocontractility due to the stents' reliance on contraction and volitional voiding, which emphasizes the importance of evaluating suitable candidates [46]. MISTs will remain a treatment option for the foreseeable future; however, the transition toward TMISTs will allow both patients and surgeons to benefit from reduced resource waste, favourable patient outcomes, and increased ease and accessibility.

Aside from awaiting long-term outcomes of future stents, it is also crucial to consider the study design and interpretations of results from recent studies. While it is FDA mandated for new innovations to begin with sham-controlled trials, the determination of safety or efficacy must be approached with caution, especially when considering the lack of long-term data and retreatment rates. Further head-to-head randomized trials with continued monitoring are needed to determine the true differences between the

various stent options, especially in a growing market of BPH treatments.

The strength of our study is the comprehensive review of literature on past, present and future prostatic stents. However, we acknowledge that not including studies in languages different from English might have introduced bias to our analysis. Additionally, there was heterogeneity in reporting functional and sexual outcomes from different studies, therefore making comparison between the stents challenging.

Conclusion

The revolution of prostatic stent technology for BPH has been gradually evolving for several years. Early designs of these devices have been shown to result in adverse outcomes such as migration, encrustation, and complications that have resulted in stent failure. Through this overview, it is evident that the shift towards TMIST and prostatic stents serves as an effective bridge between medical and surgical therapies for BPH. Prostatic stents continue to show increasing promise as a safe, effective, and durable intervention for BPH to better QoL and decrease rates of IPSS and LUTS/BOO. As current trials are on the trajectory to investigate the positive long-term implications of prostatic stents, further data are required to support the notion that the development of stent technology is advantageous for this population.

Supplementary Information The online version contains supplementary material available at <https://doi.org/10.1007/s00345-023-04508-7>.

Author contributions AVN contributed to project development, data collection, data analysis, and manuscript writing. IV contributed to data collection, manuscript writing, and manuscript editing. RF contributed to data collection, manuscript writing, and manuscript editing. DDN contributed to project development and manuscript editing. DSE contributed to project development, manuscript editing, and supervision.

Funding None.

Data Availability Scoping review data is available in the Supplementary Material.

Declarations

Conflict of interest Dr. Elterman is a consultant for Boston Scientific, PROCEPT Biorobotics, Olympus, Urotronic and Prodeon. All other authors do not have any relevant conflicts of interest.

Ethics approval Ethics approval was not required for this type of study (review).

Informed consent Formal consent is not required for this type of study (review).

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