

# Current and emerging mechanical minimally invasive therapies for benign prostatic obstruction

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**Abstract:** Transurethral resection of the prostate (TURP) is considered the ‘gold standard’ for the surgical management of lower urinary tract symptoms (LUTS) due to benign prostatic obstruction (BPO). However, during recent years TURP has been challenged by several minimally invasive therapies (MITs). The reasons for the development of these MITs are the need for anesthesia and the rather unchanged morbidity of TURP, including ejaculation disorders. Mechanical MITs may represent an attractive option for treating LUTS/BPO by using mechanical forces to maintain urethral patency without cutting, ablating, heating or removing prostatic tissue. The present paper provides an update on currently available mechanical devices for the treatment of LUTS/BPO including the prostatic urethral lift (PUL), the temporary implantable nitinol device, and new intraprostatic implants. It analyzes the evidence for their safety, tolerability, and efficacy in clinical practice and aims to define those subpopulations of patients who will benefit from these MITs. It is obvious that there is a wide variation in the degree of maturity of the available mechanical MITs. Time and high-quality long-term studies will decide which of these therapies will be accepted by patients and urologists. At the moment, PUL is claiming its position in the armamentarium of BPO treatment.

**Keywords:** transurethral resection of the prostate, LUTS, benign prostatic obstruction, minimally invasive therapies

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## Introduction

A variety of minimally invasive therapies (MITs) have been developed to address the limitations and shortcomings of surgery and medical therapy for the management of lower urinary tract symptoms (LUTS) due to benign prostatic obstruction (BPO). Indeed, despite the variety of surgical procedures for BPO, there still exists a large population of men who are not convinced to pursue these options and desire a therapy with minimal surgical risks and fast recovery. The sexual side effects of surgical treatment of BPO, mostly ejaculatory disorders (EjDs), are certainly the more concerning and the ones that mostly discourage patients from opting for surgical treatment.<sup>1</sup> Moreover, living in the era of aging men, there is a substantial population of men bothered by LUTS not responsive to pharmacotherapy who are

medically fit for surgery. MITs aim to offer an alternative solution to these men by providing sustainable improvement in LUTS/BPO while minimizing the risks, complications and adverse events associated with surgery

The hallmarks of a successful MIT include (a) rapid and durable relief from symptoms, (b) fast recovery (c) minimal adverse events, (d) ambulatory setting procedure with minimal anesthesia requirements, which are important determinants for quality of life.<sup>2</sup>

Recently the concept of mechanical devices for the management of LUTS due to BPO has attracted renewed interest with innovative mechanical concepts for de-obstruction of the prostatic urethral lumen while preserving ejaculatory function being introduced with promising early clinical

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results. Mechanical MITs mechanically retract the obstructing lateral prostatic lobes to keep prostatic urethra open without cutting, ablating, heating or removing prostatic tissue and include intraprostatic stents and new devices such as the prostatic urethral lift (PUL; Urolift®) and the temporary implantable nitinol device (TIND®). The present paper reviews the mechanical devices for the treatment of LUTS/BPO and presents the available data for their safety, tolerability, and efficacy in clinical practice.

## Mechanical devices

### *Prostatic urethral lift*

PUL (Urolift®, NeoTract, Pleasanton, CA, USA) compresses the obstructing lateral lobes using small permanent suture-based tissue-retracting implants loaded on a dedicated delivery device. The implants are placed anterolaterally at the 2 o'clock and 10 o'clock positions under cystoscopic control resulting in the creation of a continuous anterior channel through the prostatic lumen extending from the bladder neck to the verumontanum.<sup>3</sup>

*Device-related side effects.* By mechanically opening the prostatic urethra without requiring a response to tissue injury or ablation, the most common adverse events include dysuria, hematuria, pelvic discomfort, and urgency that are mild and typically resolve within 2–3 weeks.<sup>4</sup> As implants hold the prostatic urethra open during the period of expected postoperative edema, urinary catheterization rates have been shown to be as low as 20% for an overall mean duration of 1 day.

The absence of ejaculatory or erectile dysfunction (ED) is a major advantage of the PUL procedure uncovered from available clinical trials. Up to now no *de novo*, sustained ejaculatory dysfunction or ED has been reported following treatment with PUL.<sup>5–8</sup> The procedure does not affect the integrity of the bladder neck, therefore normal antegrade ejaculation is maintained and in the absence of thermal tissue damage, the risk of ED is minimal.<sup>9</sup>

*Evidence from meta-analyses and randomized controlled trials.* Perera and colleagues performed a systematic review and meta-analysis of symptomatic, functional, and sexual outcomes following the PUL procedure.<sup>10</sup> Pooled estimates from between 452 and 680 patients suggested

overall improvement following PUL, including symptoms [International Prostate Symptom Score (IPSS) difference of –7.2 to –8.7 points], peak urinary flow rate (Q<sub>max</sub>; 3.8–4.0 ml/s), and quality of life (QoL; 2.2–2.4 points). Sexual function was preserved at 12 months with an estimated small improvement (standardized mean gain range of 0.3–0.4).<sup>10</sup>

In 2015, Shore performed a systematic review of available PUL studies. Reviewers reported that, from 0.5 to 1.5 months to 2 years, Q<sub>max</sub> increased from 3.3 to 4.15 ml/s, IPSS improved from –4.5 to –9.2, QoL improved from –1.2 to –2.2 and benign prostatic hyperplasia (BPH)-II scores improved from –0.1 to –3.8 compared with baseline.<sup>11</sup>

In 2016, Jones and colleagues performed a systematic review of the PUL studies with at least 12 months of follow up including 440 patients from seven series.<sup>12</sup> The authors reported that Q<sub>max</sub> increased from 8.4 ml/s to 11.3 ml/s, mean IPSS dropped from 24.1 to 14, mean QoL improved from 4.5 to 2.3, while the mean 5-item International Index of Erectile Function score remained stable (from 17.7 to 18.2).<sup>12</sup>

The United Kingdom National Institute for Health and Care Excellence (NICE) performed a literature search in order to publish a technical guidance on PUL.<sup>13</sup> Comparators with PUL were transurethral resection of the prostate (TURP) and holmium laser enucleation of the prostate (HoLEP). As at the time the literature search was performed there were no studies directly comparing PUL with either TURP or HoLEP; NICE extracted data from a TURP *versus* HoLEP systematic review to perform a 'pragmatic indirect comparison' with PUL. Reviewers concluded that while PUL provided a significant improvement in IPSS, BPH-II and QoL. Those improvements were smaller than those seen with TURP or HoLEP; however, the PUL procedure was associated with a slight improvement in erectile or ejaculatory function.<sup>13</sup>

In 2015, Sonksen and colleagues published the results of a randomized controlled trial (RCT) of 10 European centers comparing PUL with TURP among men >50 years of age with LUTS/BPO. Eligible patients had an IPSS > 12, Q<sub>max</sub> < 15 ml/s, post-void residual (PVR) < 350 ml, and prostate volume of <60 ml without an enlarged median lobe.<sup>7</sup> The study used a novel endpoint, referred to as the BPH6, composed of

the following six domains of efficacy and safety: relief from LUTS, recovery experience, erectile function, ejaculatory function, continence preservation, and safety.<sup>7</sup> A total of 80 patients randomized to TURP or PUL were available for analysis over a 12-month period. Significant improvement in LUTS was achieved with both procedures. Improvement in IPSS, Qmax, and PVR was considerably better after TURP ( $p < 0.05$ ), whereas PUL was superior to TURP in terms of recovery ( $p = 0.008$ ) and preservation of ejaculation ( $p < 0.0001$ ). No relevant difference was reported for erectile function, incontinence, and safety. The number of patients experiencing grade 2 and 3 adverse events was similar between groups. Re-interventions due to insufficient treatment response were necessary in 6.8% and 5.7% of patients after PUL and TURP, respectively.<sup>7</sup>

In 2017 the 2-year results from the BPH6 study were published and PUL demonstrated measurable improvements in urinary symptoms and flow rates. However, TURP achieved superior improvements in IPSS and Qmax compared with PUL, whereas PUL showed sustainable benefit over TURP for quality of recovery and ejaculatory function.<sup>14</sup> Throughout the 2-year follow up, 6 (13.6%) PUL patients and 2 (5.7%) TURP patients had secondary intervention for refractory LUTS.<sup>14</sup>

The BPH6 trial was limited by unequal dropout rates between groups, mid-term follow up and uncertainty about the validity of its composite outcome measure, as it was composed mostly of safety items raising criticism that it may have favored the PUL group.

*Long-term results of PUL.* The LIFT study was a prospective, randomized, controlled and blinded study of 206 patients at 19 centers in North America and Australia who were 2:1 randomized between PUL ( $n = 140$ ) and a sham procedure ( $n = 66$ ).<sup>15</sup> Roehrborn and colleagues published the 3-year results from patients randomized to PUL in the LIFT study, including 93 (66%) of the original 140 patients.<sup>16</sup> At 3 years, the mean IPSS was significantly improved by 41.1% (8.8 points), QoL by 48.8%, and Qmax by 53.1%. There were no *de novo* cases of EjD (retrograde or anejaculation) or ED, with sexual function assessments showing average stability or improvement.<sup>16</sup>

The 5-year results of the LIFT study were recently published confirming the good results and durability of the procedure.<sup>8</sup> In the analysis, change in IPSS was  $-7.85$  at 5 years ( $p <$

$0.001$ ). Significant improvements, compared with baseline, continued to be seen for QoL (50% QoL; 52% BPH-II) and Qmax (44%). Almost 82% of PUL patients reported (IPSS, QoL) some level of satisfaction with their urinary symptoms at 5 years. Of the 18% who were not so satisfied with their symptoms (QoL  $> 3$ ), 10 (77%) had severe LUTS (IPSS  $\geq 20$ ) at baseline.<sup>8</sup>

Over the 5 years, 19 (13.6%) of the 140 PUL patients had a surgical procedure for refractory LUTS with 13 (9.3%) undergoing TURP or laser ablation accounting for a retreatment rate of 2–3% per year. In comparison, the reported retreatment rates for TURP at 5 years are 5.8%–7.0% (often quoted as 1–2% per year).<sup>17</sup> Of note, 18 of the 19 retreated patients had severe baseline LUTS (IPSS  $> 20$  or greater). Overall, 10 patients underwent removal of encrusted implants that had been deployed too proximally and protruded into the bladder.<sup>8</sup> Sexual function was stable over 5 years with no *de novo*, sustained erectile or ejaculatory dysfunction. Both due to ejaculatory function improved rapidly and remained modestly improved at 5 years ( $p = 0.02$ ).<sup>8</sup>

*Position and future perspectives.* In 2018, the European Association of Urology (EAU) guidelines on male LUTS included PUL in the established therapies.<sup>18</sup> It is recommended in patients with LUTS who are interested in preserving ejaculatory function and have prostates smaller than 70 ml with no middle lobe. It was clearly noted that long-term effects have not been evaluated as studies with long follow-up time are needed to evaluate the duration of the effect in comparison with other techniques.<sup>18</sup>

Similarly the American Urological Association Guidelines consider PUL as an option for patients with LUTS attributed to BPH, provided the prostate volume is less than 80 g and there is a verified absence of an obstructive middle lobe, and may be offered to eligible patients concerned with erectile and ejaculatory function for the treatment of LUTS attributed to BPH.<sup>19</sup> However, patients should be informed that symptom reduction and flow rate improvement is less significant compared with TURP.

The principle concern about PUL is the lack of data to support its long-term efficacy, although recent updates of the LIFT study with a 5-year follow up are encouraging. The reason for this

concern lies in the fact that as experience has shown, the long-term efficacy of any mechanically BPH treatment will rarely compete that of cavitating surgery. It is well known that men with a larger baseline prostate volume will be more likely to experience clinical BPH progression and there is no evidence regarding the effect of the PUL procedure in the natural history of BPH. It could be argued that men with smaller prostates will be less likely to have subsequent prostate growth and may well represent the cases where long-term efficacy can be realistically anticipated. There are currently few data on the effect of retreatment with further PUL or conventional cavitating surgical treatment.

### Stents

Stents are used to maintain urethral patency in males with BPO and have been tested in urology for many years. Initially, they were designed as an alternative to indwelling catheters, but nowadays there is a new interest in stents as an option for the management of BPO.

Ideally, the perfect prostatic stent should be placed easily and accurately under local anesthesia while migration, any local reaction or encrustation should not occur. Endoscopy through the stent lumen should remain possible and the stent should be easily removable if needed.

Prostatic stents are classified into two categories: permanent/epithelializing and temporary/non-epithelializing stents. Temporary stents are made of material that prevents epithelial ingrowth thereby facilitating removal. Temporary stents can be either biostable or biodegradable. Permanent stents are biocompatible, allowing for epithelialization.

Relative contraindications for intraprostatic stents may be meatal or urethral strictures, urinary tract infections, bladder stones, neurogenic bladder dysfunction, a large median prostatic lobe, a prostatic urethra less than 2 cm long and the presence of bladder neck contracture.<sup>20</sup>

Overall, there is a diversity of stents design in terms of length, lumen diameter and material. In addition, the available studies are very small with short follow up, significant attrition rate and different definitions of efficacy. Therefore, there is a lack of robust data.

The main representative of the epithelializing/permanent stents is the Urolume Wallstent® (American Medical Systems, Minnetonka, MN, USA). A systematic review pooled data from 20 case series with 990 patients in total.<sup>21</sup> It was found 84% of patients (148/176) who were catheter-dependent regained voiding ability after UroLume treatment. A total of 10 studies assessed symptoms and reported relevant improvement in symptoms scores while Qmax increased by 4.2–13.1 ml/sec. However, in 1 in 6 men (104/606), the stent was removed within 1 year because of malpositioning, migration, penile pain, and symptoms of irritation.<sup>21</sup>

Memokath® (Doctors and Engineers, Kvistgaard, Denmark) is a thermoexpandable, nonepithelializing stent with several small studies. It is a nickel-titanium spiral stent with the main advantage of ease of removal based on its physical properties at different temperatures. Armitage and colleagues performed a systematic review of 14 studies on 839 men with Memokath.<sup>22</sup> In terms of efficacy, IPSS was decreased by 11–19 points (assessed in 5 studies) and Qmax was evaluated in 8 studies and was improved by 3–11 ml/s. Migration was reported as the main reason for late failure. Adverse events also included hematuria, incontinence and infection. It was concluded that Memokath could be a good alternative for BPH treatment for patients unfit for surgery, but no estimation was made regarding the durability of the stent.<sup>22</sup>

Refinements and advances in prostatic stents resulted in the development of biodegradable and polyurethane stents. Biodegradable stents are made with materials as polylactic acid, polyglycolic acid, and copolymers of lactide and glycolide and spontaneously biodegrade and hence do not require removal, since small pieces are excreted through the urethra over time.

The Spanner® (Abbey Moor Medical, Parkers Prairie, MN, USA) is a temporary, polyurethane prostatic stent. A study in 30 men showed an improvement in mean Qmax and IPSS after the Spanner® implantation.<sup>23</sup> The lack of migration was remarkable (0%). Patients with Spanner® *in situ* had increased sexual activity, and erections without significant pain.<sup>23</sup> In another observational study, Spanner® was used in 43 men unfit for surgery and the stent was replaced every three months.<sup>24</sup> Overall, 63% of the patients had an unsatisfactory outcome due to immediate or

delayed retention or elective stent removal because of severe symptoms. The authors concluded that this stent was indicated only for short-term use.<sup>24</sup>

Based on all the above, EAU guidelines on male LUTS recommend the use of prostatic stents as an alternative to catheterization in men unfit for invasive procedures requiring spinal or general anesthesia.<sup>18</sup>

#### *Temporary implantable nitinol device*

The temporary implantable nitinol device (TIND<sup>®</sup> Medi-Tate Ltd., Or Akiva, Israel) is a temporary implantable nitinol device consisting of nitinol struts which is positioned endoscopically into the prostatic urethra in order to remodel the bladder neck and prostatic urethra and provide relief from bothersome LUTS/BPO. Monitored anesthesia care including sedation and analgesia is employed with the patient maintaining spontaneous breathing. The nitinol struts of the implant expand within the prostatic fossa exerting outward pressure on the obstructive prostatic lobes. The intended mechanism of action is compression of the obstructive prostatic tissue as the expanded struts exert radial force resulting in local ischemic necrosis of the urethral mucosa with a progressive effect: after 5 days, the nitinol wires reach their complete expansion, sinking into the peri-urethral tissues and allowing a decrease of bladder neck tension, thereby alleviating bladder outlet obstruction.<sup>25</sup> After removal of the device in 5 days, it is intended that a pattern similar to transurethral incisions of the prostate remains, thus creating durable relief of BPO.

*Device-related side effects.* Device-related symptoms may occur including discomfort, burning during voiding, pressure around the area of perineum, increased urgency and frequency, and mild hematuria. The symptoms are self-limited and respond well to standard symptomatic treatment.

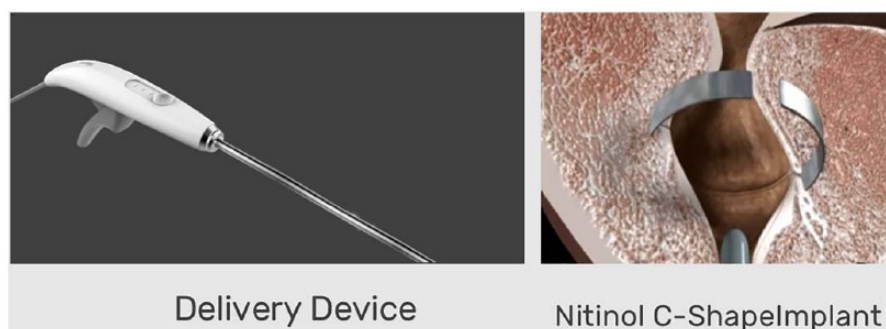
*Clinical outcomes.* A single-arm pilot study was conducted to evaluate the safety and preliminary impact of the procedure.<sup>25</sup> A total of 32 patients aged >50 years with LUTS due to BPH, IPSS > 10, Qmax < 12 ml/s, and prostate volume <60 ml, were treated. All cases were done in the outpatient setting under light sedation within a mean operative time of 5.8 min. The median postoperative stay was 1 day. After the 20th procedure, patients

were discharged on the same day. At 12 months there were statistically significant differences in the IPSS, QoL score and Qmax compared with baseline. Median IPSS reduced from 19 at baseline to 9 (53% improvement), while the mean Qmax increased from 7.6 to 11.9 ml/s (67% improvement). Median IPSS QoL improved from 3 to 1. The improvement in symptoms occurred early, within 3 weeks of the procedure, presenting an important positive aspect of this procedure. Retrograde ejaculation was not seen in any of the preoperatively sexually active patients. There were 4 postoperative complications in the TIND pilot study (4 of 32 patients, 12.5%) including prostatic abscess, urinary retention, urinary tract infection, and temporary incontinence. Urinary retention occurring while the device was still in place was best managed by drainage of the bladder with a Tiemann 10 F catheter.<sup>25</sup> No patient required medical therapy or additional surgical procedures for BPH during the 12-month follow up and no implants required removal for migration or incorrect placement. No late complications or adjunctive re-interventions were documented at the 12-month follow up.<sup>25</sup>

The same group recently reported the 3-year follow up data.<sup>26</sup> The authors confirmed that, at 3 years, the change from baseline in IPSS, QoL score, and Qmax was significant. After 36 months of follow up, a 41% rise in Qmax was achieved (mean 10.1 ml/s), the median IPSS was 12 (6–24) and the IPSS QoL was 2 (1–4).<sup>26</sup>

Recently, a second-generation implant was introduced, the i-TIND which is comprised of three nitinol elongated struts and an anchoring leaflet and it is again preloaded by crimping it into the delivery system. Preliminary results were presented as an abstract and showed a statistically significant improvement in terms of IPSS score (–15.33), and Qmax (6.2 ml/s) between baseline and 6 months postoperative results in 40 patients treated with iTIND.<sup>27</sup>

*Current position and future perspectives.* The first and only available small cohort of patients who were treated with TIND demonstrated that TIND is a well-tolerated and safe minimally invasive option for the treatment of LUTS due to BPH with durable results up to 3 years.<sup>25,26</sup> The functional results are encouraging and the treatment significantly improved QoL although the observed trend towards a worsening of functional outcomes at 36 months in the recently published follow-up



**Figure 1.** The ClearRing device (with permission from ProArcMedical).

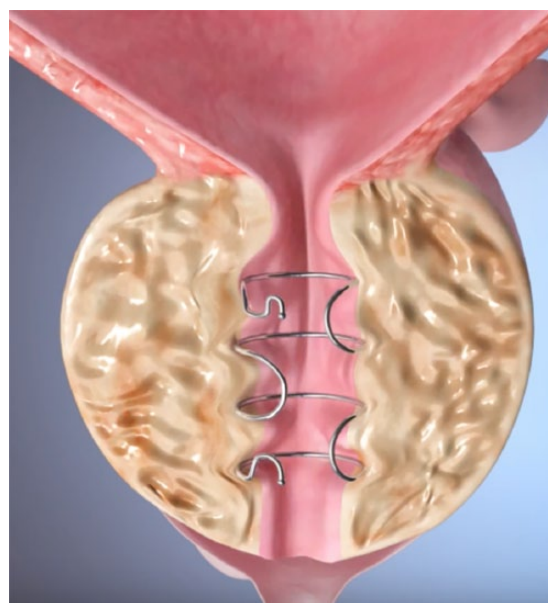
study could represent a future need for re-intervention. The company recently introduced the second-generation implant (iTIND) to further optimize outcomes.

Obviously, further larger studies are required to reproduce the results, assess the efficacy and durability of (i)TIND functional outcomes and compare (i)TIND with TURP or other MITs.

#### *New implants*

**ClearRing.** The ClearRing device (implantable compressive ring; ProArc Medical, Pardes Hana/Karkur, Israel) is a device used to refashion the prostatic urethra (Figure 1). This nitinol C shape ring is deployed in a circular incision in the prostatic tissue, surrounding the urethra, done by electrocuting blade over a dilatation balloon that are using local anesthesia. The mechanism of action of the ring placement is to compress prostatic transition zone tissue. A phase I animal trial demonstrated that implantation of the ClearRing device is a feasible procedure.<sup>28</sup> A multicenter single-arm study has been published very recently.<sup>29</sup> Overall, 29 patients with severe symptoms (mean IPSS 21.6, mean Qmax 8ml/s) and prostates between 35 and 50 cc were treated using the ClearRing device. The delivery device was modified after the first 13 patients and the success rate for implant positioning improved from 5/13 patients to 13/16 patients. Mean IPSS, and Qmax improved by 45%, and 40% by 3 months, and 53%, and 49% by 12 months, respectively. Adverse events were mild and transient. Ejaculation was preserved while no effect on erectile function was reported.<sup>29</sup>

**Spring.** The Spring system (Zenflow, South San Francisco, CA, USA) includes a low-profile nitinol implant and a flexible cystoscopy system

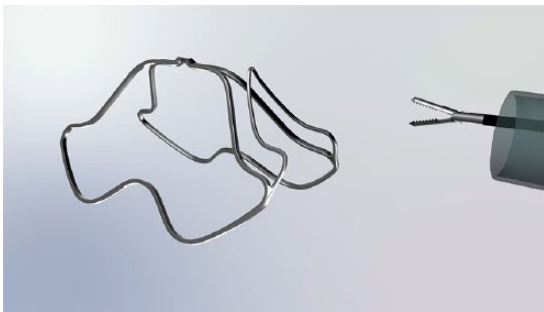


**Figure 2.** The Spring system (with permission from Zenflow).

designed to easily and accurately place the implant in the prostatic urethra (Figure 2). The implant is designed to be permanent, but can be removed at any time if needed through a flexible cystoscope using a custom retrieval tool. The nitinol composition creates internal tension that imbeds it into the wall of the prostatic urethra. In a small first-in-man study with an early prototype device, patients had a significant IPSS improvement at 12 months. All patients have now been followed for at least 18 months since the index procedure, and 9 of 10 patients who had an implant deployed into the prostatic urethra still have the implant indwelling and reported at least 6-point IPSS improvements at the most recent follow up. Adverse event frequency and severity has been low, with the most common adverse events (AEs)

being post-procedural urgency and minor discomfort, which typically resolved quickly. No long-term adverse events have been recorded (unpublished data, personal communication). Zenflow is now initiating a larger clinical study to evaluate safety, effectiveness, and performance of an improved implant and delivery system (the Zenflow Spring System Safety, Performance and Effectiveness Study, ZEST2, ClinicalTrials.gov identifier: NCT03595735).

**Butterfly.** The Butterfly Prostatic Retraction device (Butterfly, Medical Ltd, Yokneam, Yilit, Israel) is a metallic implant designed to reside in the prostatic urethra without extensions into the bladder or into the urethra, retract the lateral lobes of the prostate and restore urine flow in BPO patients (Figure 3). The Butterfly device is folded into a thin, flexible delivery tube and can be delivered with either rigid or flexible



**Figure 3.** The Butterfly device [with permission from Butterfly Medical].

cystoscope under local anesthesia. The ribs of the Butterfly device are all in contact with the prostatic urethra tissue and that will lead to coverage by the mucosa tissue after several months. Though designed as a permanent solution, the Butterfly device can be easily extracted when needed.

The Butterfly device is CE marked and initial clinical data are very promising with good IPSS improvement and patients on a permanent catheter not needing the catheter anymore after the Butterfly procedure (personal communication). A multicenter single-arm study to assess safety and efficacy of the Butterfly device is underway.

### Conclusion

The rise in MITs aims to address current unmet needs in the management of patients with LUTS/BPO. The new mechanical devices strive to effectively treat LUTS, lower surgical and anesthetic risk, and minimize sexual side effects common to both medical BPH therapy and prostate cavitating surgery. Mechanical MITs represent ‘middle-ground’ therapies covering an area between medical therapy and invasive surgical intervention and ideally can be performed in an office or outpatient setting, with minimal recovery time and morbidity to the patient. Mechanical MITs are indicated in selected patients with LUTS/BPO. Patients who want to preserve ejaculation or patients at high risk for the classic surgical therapies seem to be the best candidates. In

**Table 1.** Current status of mechanical minimally invasive therapies.

MIT	Evidence	Anesthesia	Selection criteria	Recommendation
PUL	Systematic review of two RCTs and seven prospective cohorts	General or spinal or sedation	Prostate volume less than 80 cc, No middle lobe	Men who want to maintain ejaculation (EAU <sup>18</sup> -AUA <sup>19</sup> )
Intraprostatic stents (several devices)	Several small case studies	Local or Regional	Prostatic urethra >2 cm, No middle lobe	Men unfit for surgery (EAU <sup>18</sup> )
TIND	One single-arm study with 32 patients	Sedation	Prostate volume less than 80 cc, No middle lobe	No EAU/AUA recommendation
ClearRing	One single-arm study with 29 patients	Spinal as part of the feasibility study	Prostate volume less than 80 cc, No middle lobe	No EAU/AUA recommendation

AUA, American Urological Association; EAU, European Association of Urology; PUL, prostatic urethral lift; RCT, randomized controlled trial; TIND, temporary implantable nitinol device.

addition, anatomical factors such as the prostate volume and presence of middle lobe can guide treatment selection (Table 1).

Obviously mechanical MITs constitute a heterogeneous group of devices that continue to grow and have a wide variation in the degree of mature (Table 1). PUL has been the best studied mechanical MIT and is claiming its position in the armamentarium of BPO therapies while other mechanical options are still experimental. Durability is another critical factor for a successful BPO invasive therapy and in the past we had a bitter experience from promising MITs which did not stand the test of time. It will be prudent to wait for further validation of the performance of these novel MIT options for LUTS/BPO in future well-designed studies.

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### Conflict of interest statement

The authors declare that there is no conflict of interest.

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