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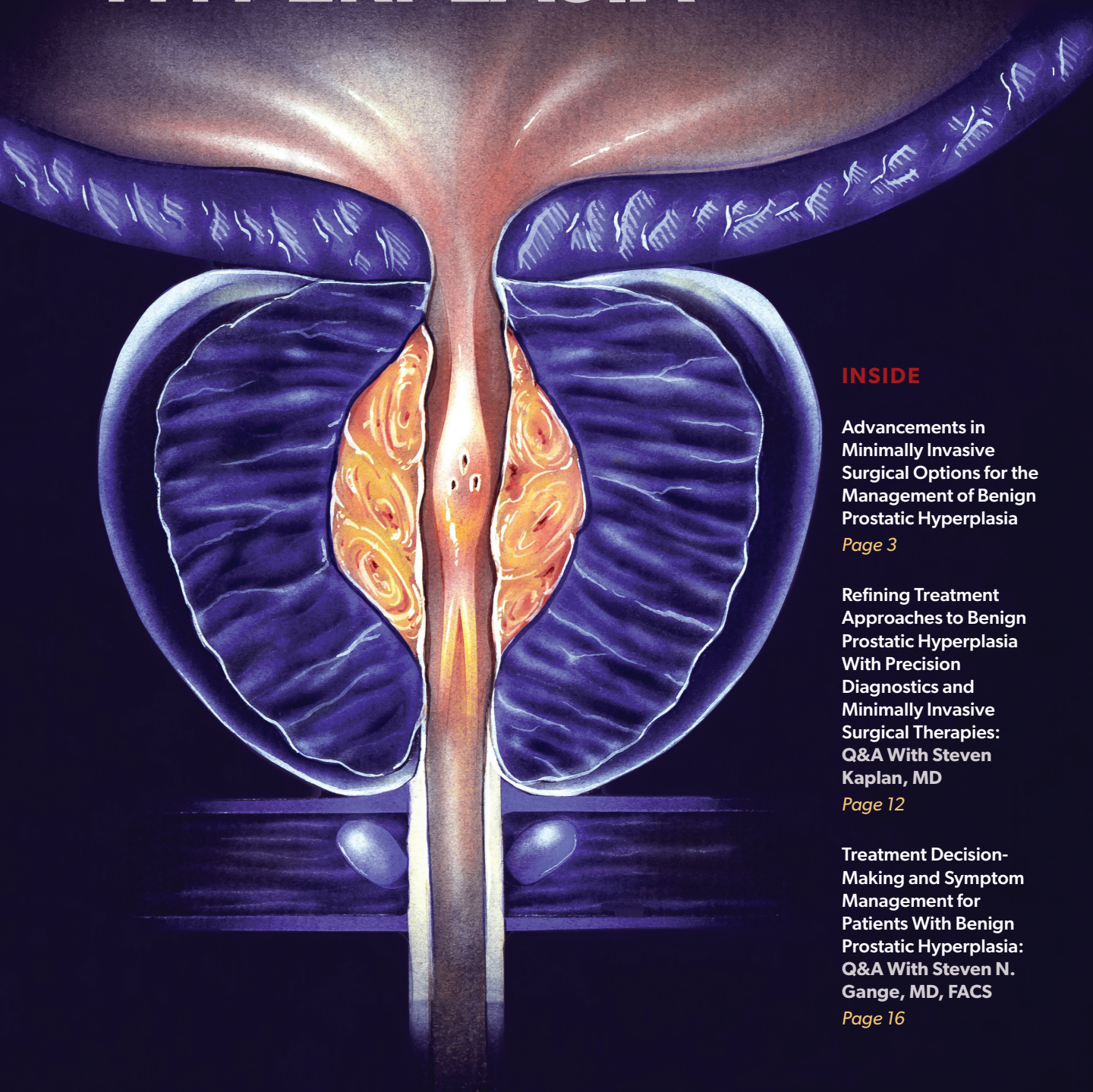

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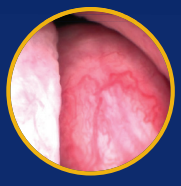

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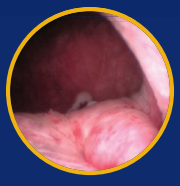

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*Individual results may vary. Most common side effects are temporary and include hematuria, dysuria, micturition urgency, pelvic pain, and urge incontinence.[1] Rare side effects, including bleeding and infection, may lead to a serious outcome and may require intervention. Refer to the Instructions for Use for a complete listing of the indications, contraindications, warnings and precautions.

1. Roehrborn, J Urol 2013

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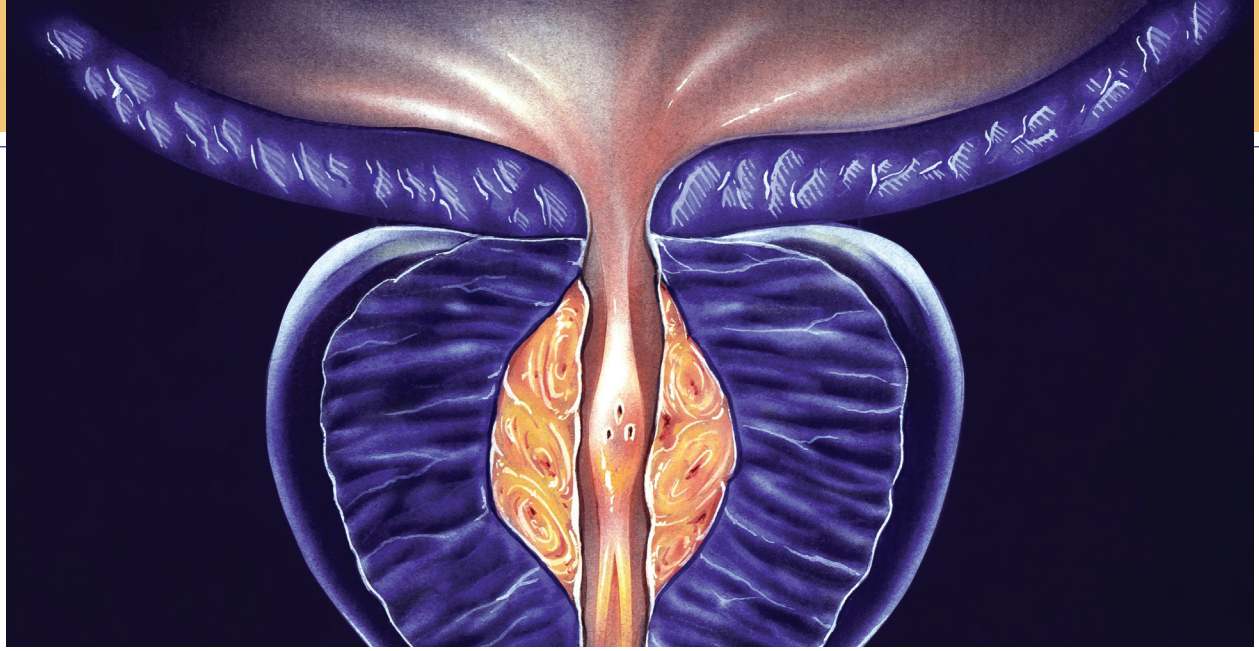

Advancements in Minimally Invasive Surgical Options for the Management of Benign Prostatic Hyperplasia

Benign prostatic hyperplasia (BPH) is a noncancerous enlargement of the prostate affecting more than 40 million men in the United States with an associated prevalence that increases from 40% to 80% among men 50 to 70 years of age, respectively.[1,2] Progression of BPH leads to the subsequent development of lower urinary tract symptoms (LUTS), which most commonly include frequent urination accompanied by urgency and a weak urinary stream.[3] Continued, chronic LUTS can have a significant impact on the quality of life for patients by causing a loss of sleep, reduced productivity, impaired sex life, social isolation, and clinical depression.[1]

CONSIDERATIONS FOR EARLY INTERVENTION IN THE PATIENT CARE PATHWAY

Treatment options for BPH encompass a range of pharmacologic and surgical options. Studies have suggested that therapy failures may be a result of late treatment initiation, which could suggest that earlier intervention may be warranted for some patients.[4] The establishment of a validated grading system for bladder trabeculation provides a useful method that may be helpful to identify patients who may benefit from an earlier intervention.[4,5] Within the current patient care pathway, there is an opportunity for the earlier identification of patients who may be candidates for surgical treatments. There may be an important window of opportunity for effective treatment by considering surgical interventions sooner in the decision-making process.

Pharmacotherapy options are a first-line approach for some patients, particularly in mild to moderate cases in which invasive surgical options are not appropriate. However, barriers to long-term management with pharmacotherapies include adherence challenges, treatment-related adverse effects, and limited effectiveness. Current data demonstrates that up to 70% of patients are nonadherent to their pharmacologic regimens. Moreover, up to 26% of patients discontinue their medications because of insufficient treatment efficacy or adverse effects, including sexual dysfunction, headaches, and dizziness.[2,6,7] Numerous large-scale studies have reported modest effects on LUTS with traditional medical treatment. Additionally, long-term use of pharmacotherapy for LUTS in patients with BPH at very high risk for disease progression has been shown to potentially mask progressive increases in post void residual (PVR) volume and lead to further deterioration of detrusor muscle function.[8]

Surgical interventions become the primary strategy when first-line pharmacologic treatments fail to improve symptoms or prevent progression of BPH, according to evidence-based recommendations from the 2021

TABLE. INDICATIONS FOR BPH MINIMALLY INVASIVE SURGICAL THERAPIES[9,12-14]

Treatment	Indication	2021 AUA recommendations for use	Contraindications
Prostatic Urethral Lift (UroLift)	• Men ≥ 45 years of age • Prostate volume ≤ 100 cc • Lateral and median lobe hyperplasia	30-80 cc	• Prostate volume >100 cc • Urethral conditions that would prevent insertion of delivery system into the bladder • Urinary incontinence due to incompetent sphincter • Current gross hematuria • Active UTI
Water Vapor Thermal Therapy (Rezum)	• Men ≥ 50 years of age • Prostate volume of 30-80 cc • Central zone and median lobe	30-80 cc	• Urinary sphincter implant • Penile prosthesis • Active UTI
Robotic Waterjet Treatment (Aquabeam Robotic System)	• Resection and removal of prostate tissue in men with LUTS due to BPH	30-80 cc	• Known allergy to device materials • Inability to stop anticoagulants or antiplatelet agent perioperatively • Diagnosed or suspected cancer of the prostate • Active UTI

AUA, American Urological Association; BPH, benign prostate hyperplasia; LUTS, lower urinary tract symptoms; UTI, urinary tract infection.

American Urological Association (AUA).[9] Transurethral resection of the prostate (TURP) has been a mainstay among surgical therapies for the past 6 decades.[6,10] Historically, TURP has been considered a standard for surgical treatment of BPH based on its demonstrated efficacy; however, it is associated with long-term complications. Ejaculatory dysfunction occurs in approximately 65% of patients with TURP.[11] TURP-related complications may also affect utilization, as only about 2% of patients with moderate to severe BPH elect to undergo these procedures.[6]

Compared with initiation of treatment with pharmacotherapy in the first-line, patients who are considered for surgical intervention have added considerations and risks. Patients who undergo surgery are older, as they have progressed or not achieved symptom resolution, patients are more anticoagulated, and present with an increased presence of comorbidities.[8] Thus, it's possible that a window of opportunity could be missed by not considering surgery earlier.

In recent years, technological advancements in surgical procedures have introduced minimally invasive surgical therapy (MIST) options, offering patients and clinicians an additional treatment path to consider (**Table**).[9,12-14] MISTs, which include the prostatic urethral lift (PUL) procedure, water vapor thermal therapy (WVTT), and robotic waterjet treatment (RWT), are associated with faster recovery times than traditional surgical options and may be ideal in treating LUTS in patients with BPH who are younger, sexually active, precluded from other surgical procedures, or have failed medical therapy.[1,15]

The addition of several MISTs to the AUA guidelines offers patients and clinicians additional treatment avenues for the management of BPH, particularly for patients who may not require invasive surgery but for whom medical therapy has failed or those who wish to avoid long-term adverse effects associated with medical therapy. Consideration of patient preferences and a shared decision-making approach when selecting a treatment is increasingly important. Factors that may affect the patient experience

include the preservation of sexual function and quickness of recovery from treatment. Also worth considering with respect to medications, TURP, and other invasive options, are long-term complications, adverse effects, and patient factors (eg, adherence, utilization rates, patient preference).

This article explores the data and utility of MISTs and their role in the treatment spectrum for BPH. It will also review the implications of the rapidly evolving treatment spectrum and the increased importance of shared decision making when making treatment decisions.

MINIMALLY INVASIVE SURGICAL TREATMENTS

The 2021 AUA guidelines provide evidence-based recommendations for several MISTs (Table). The PUL procedure using the UroLift system received a moderate recommendation for patients with LUTS or BPH, where prostate volume is 30 to 80 cc, excluding patients with a verified obstructed median lobe (OML). WVTT using the Rezum system was also given a moderate recommendation for patients with LUTS or BPH, where prostate volume is 30 to 80 cc, with the PUL recommendation excluding patients with a verified OML.[9] Additionally, the guidelines conditionally recommend PUL and WVTT as treatment options to patients who wish to preserve erectile and ejaculatory function. RWT is another MIST that is included in the recent guidelines, with a conditional recommendation for patients with a prostate volume of 30 to 80 cc.

Prostatic Urethral Lift

The PUL procedure (UroLift system) is an office-based MIST that involves the transurethral installation of permanent, mechanical implants via endoscopic guidance to lift apart lateral lobes and relieve BPH-associated bladder outlet obstruction.[1,16] The UroLift system received FDA approval in 2013 for the treatment of symptoms due to urinary outflow obstruction secondary to BPH, including lateral and median lobe hyperplasia, in men 45 years of age or older with a prostate volume of 0 cc to 100 cc. Like other MISTs, the UroLift system was developed to address shortcomings with both medical treatment and traditional, more invasive surgical techniques such as TURP and simple proctectomies.[1] PUL offers a less invasive surgical treatment option for potentially underserved patients who are noncompliant or discontinue medical treatment.[16]

Many previous MISTs have utilized thermal energy to induce tissue necrosis and reabsorption to relieve urinary obstructions.[1] Because such techniques require tissue ablation, a significant amount of postoperative edema occurs, which can require a longer recovery time and/or period requiring catherization.[1]

Consideration of patient preferences and a shared decision-making approach when selecting a treatment is increasingly important.

The UroLift system relieves prostate obstruction without cutting, heating, or removing any prostate tissue.[1,17] Consequently, PUL has been shown to provide more rapid relief of LUTS and a quicker recovery with mild to moderate perioperative adverse effects that typically resolve within 2 weeks, which allows patients to return to their normal routines with minimal downtime.[1,17,18]

Evidence Supporting the Utility of PUL

Recovery rates and quality of the recovery are important considerations for patients in their overall care experience with a given surgical intervention. Findings from the BPH6 study provide evidence supporting that patients who underwent PUL when compared with TURP experienced significantly faster rates of recovery (82% vs 53% at 1 month, $P = .008$). Compared with TURP, fewer patients who received PUL intervention required catheterization for more than 24 hours (45% vs 74%), had a lower average number of days to discharge (1.0 vs 1.9 days), and experienced a faster return to preoperative activities (11 vs 17 days), respectively.[11] PUL has also been shown to preserve both erectile dysfunction and ejaculatory dysfunction, with BPH6 study data reporting significant improvements in average ejaculatory score at 12 months for patients receiving PUL ($P = .03$) vs significant decline in patients who received TURP ($P < .0001$).[11] Additionally, 2-year follow-up data from the BPH6 study further demonstrated a sustained effect in preserving ejaculatory function in 100% of patients who received the PUL procedure vs 66% of those who received TURP.[19] A Cochrane analysis provides further validation for this observation, reporting a superior ability to preserve ejaculatory function for PUL relative to TURP (mean difference: 4.30; 95% CI, 2.17-6.43).[20]

Several clinical trials, including 2 separate 5-year follow-up studies, offer additional insight regarding the clinical and practical utility of PUL. The results from the L.I.F.T Study were published in 2013, which demonstrated the efficacy of PUL in the treatment of BPH. [18] This data was further validated in a 5-year, prospec-

tive, randomized, sham controlled, blinded study that investigated the safety and efficacy of the PUL procedure across 19 centers in the United States, Canada, and Australia.[1] The study included 206 patients with the following inclusion criteria: age 50 years or more, International Prostate Symptom Score (IPSS) 13 or higher, peak urinary flow rate (Qmax) 12 mL/s or less with a 125-mL voided volume, and a 30 to 80 cc volume prostate as measured via transrectal ultrasound.[1] Notably, patients with the presence of an OML or an active urinary tract infection were excluded from the study.[1] Primary endpoints were evaluated at 3, 12, 24, 36, 48, and 60 months and included the following: symptom response IPSS, quality of life (QOL) and BPH Impact Index [BPHII]), Qmax, sexual function, and safety.[1]

At the 3-month timepoint, all primary and secondary end points were achieved. 88% greater reduction in IPSS for PUL vs sham (PUL, –11.1 ± 7.7; sham -5.9 ± 7.7; $P = .003$) and greater improvement in QOL and Qmax for PUL vs sham (PUL, 4.28 ± 5.16; sham 1.98 ± 4.88; $P = .005$). Associated efficacy for IPSS, QOL, Qmax, and BPHII remained durable through 5 years with reported rates of 35%, 44%, 50%, and 47%, respectively.[1] Surgical retreatment following PUL occurred at an overall rate of 13.6% at 5 years (2%-3% per year) with 4.3% of patients receiving additional implants and 9.3% undergoing TURP or laser ablation.[1] Over 5 years of patient follow up, sexual function remained preserved for all patients receiving PUL treatment with no significant decrease in erectile function (determined by the International Index of Erectile Function [IIEF] 5) or ejaculatory function (determined by the Male Sexual Health Questionnaire for Ejaculatory Dysfunction [MSHQ-EjD).[1]

There were no serious adverse effects of traditional BPH surgery, such as stress urinary incontinence and requirement for blood transfusion, reported in the study; the most common adverse effects during the first 3 months postprocedure were pelvic pain (6%), hematuria (4%), dysuria (9%), and incontinence (3%).[1] In regards to durability of PUL, rates of surgical retreatment at 5 years are higher (13.6%) relative to TURP (5.8%-7%); however, retreatment rates associated with PUL are similar to those with other surgical interventions such as photoselective vaporization of the prostate (6.1%-17.7%), transurethral microwave therapy (9% to 21%), and transurethral needle ablation (TUNA) (14% to 15%).[1] Investigators also reported the lowest rates of postprocedure catherization of any currently available BPH treatment.[1] This aligns with other findings demonstrating that 80% of patients did not need postoperative catherization, and for patients who did, catheter duration averaged 16 hours.[21]

Given the variety of factors that affect treatment success, including the patient experience, understanding the real-world utility of BPH treatments can help to inform treatment decision-making.

Water Vapor Thermal Therapy

Water vapor thermal therapy, another MIST known as the Rezum System, harnesses the high energy potential of steam delivered through a cystoscopic probe to illicit local tissue cellular death.[17,22] The resultant prostatic cellular apoptosis and subsequent local tissue reabsorption effectively relieves LUTS and bladder outlet obstruction.[17,22] Like PUL, WVTT is a viable MIST option for eligible patients that allows for preservation of erectile and ejaculatory function and can be performed as an office or clinic-based intervention using local anesthesia.[16,23,24] A multicenter, randomized, controlled trial investigated the efficacy and safety of WVTT for the treatment of BPH. Investigators followed 197 patients over 12 months, including patients with a median lobe or elevated bladder neck.[25] Findings demonstrated an 8-point or greater improvement in IPSS in 74% of patients at 3 months, which was sustained for a period of 12 months.[25] Significant improvements in flow rates (Qmax) and QOL were also observed at 3 and 12 months with preserved erectile and ejaculatory function.[25] Unlike PUL, a high percentage (90.4%) of patients required catherization for an average of approximately 3 days; 68% of catheterizations were discretionary, and 32% were due to the patient's inability to void prior to discharge.[25] Two patients also experienced 3 adverse events related to the procedure including extended urinary retention and hospitalization due to nausea.[25] Similarly, another study demonstrated an improvement in IPSS of 11.6 points at 12 months that was sustained over a 4-year period (10.1 points).[26] Data from this study further verified that WVTT preserved both erectile and ejaculatory function, with associated IIEF and MSHQ-EjD scores remaining constant and reported improvements in the ejaculatory bother score for 3 years.[26]

Robotic Waterjet Treatment

RWT is a novel therapeutic option previously introduced in the 2019

AUA guidelines.[27] RWT employs the AquaBeam robotic system, which uses real-time ultrasonographic imaging, and robotically guided water jets for prostatic resection.[28] In contrast to other MISTs, RWT requires the use of general anesthesia, and therefore procedures cannot be conducted in an office-based setting.[29] A small, prospective, multicenter trial published in 2017 investigated the efficacy and safety for RWT in the treatment of LUTS/BPH in 21 patients.[28] Resulting data reported significant improvements in mean IPSS (16.2 points; *P* <.01), QOL (3.3 points; *P* <.01), Qmax (9.7 mL/s, *P* <.01), and PVR volume (89 mL, *P* <.01).[28,30] All patients were catheterized with removal occurring after day 1 for 20 of 21 patients.[28] Improvements in sexual function did show some improvement; however, the only statistically significant improvement was regarding sexual intercourse satisfaction.[28] When considering RWT, clinicians should take into consideration that long-term evidence regarding outcomes and retreatment rates remains limited relative to other MISTs.[31]

REAL-WORLD EVIDENCE AND THE IMPORTANCE OF THE PATIENT PERSPECTIVE

Given the variety of factors that affect treatment success, including the patient experience, understanding the real-world utility of BPH treatments can help to inform treatment decision-making. Although double-blinded, randomized, controlled trials (RCTs) provide the most reliable way to evaluate efficacy, they may not always reflect the real-world conditions of medical treatments, particularly for office-based procedures such as the majority of MISTs.[6] In recent years, UroLift and Rezum have become more widely used than many previous MISTs and it can be helpful

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to compare data from RCTs with real-world studies to provide a more complete picture regarding the efficacy and utility of each therapy.[6]

Real-world data from a 2-year, multicenter, retrospective study evaluating PUL in 1415 patients in an office setting demonstrated similar efficacy and safety data relative to previous trials, with several notable findings favoring a real-world vs trial setting: fewer patients required removal of implants, and fewer patients required postoperative catherization (16% vs 20%).[16] Notably, 83% of the patients with baseline urinary retention became catheter-free at 1 month, and a total of 87% of patients achieved catheter independence by the end of the study.[16] Additionally, subgroup analyses across all cancer therapy cohorts reported symptom relief without an increase in postoperative adverse effects; this is favorable relative to TURP, which has reported increased rates of stress incontinence (18% to 70%).[16] These results suggest that clinic- or office-based treatment using PUL may be associated with better outcomes relative to other treatment settings.[16]

WVTTs have also been evaluated in the real-world setting, including data published in a recent, retrospective review including 129 patients from a single office setting.[32] Patients either had a Spanner Prostatic Stent placed or were catheterized post procedure, which were continued 2 to 5 weeks and 1 week, respectively.[32] Findings showed a slightly lower IPSS improvement relative to the Rezum pilot and Rezum II trials, reporting an improvement of 11.6 vs 13.1 and 12.2, respectively.[32] The greatest improvements were observed 91 to 180 days post procedure, with greater reductions reported for voiding symptoms vs storage symptoms (73.6% vs 48.6%, respectively).[32] The most common adverse effect was urinary tract infection, which occurred at a higher rate than standard catheters (23.7% vs 14.6%); additionally, 14% of patients experienced episodes of urinary retention after catheter or Spanner removal, and 4 patients required an anesthesia event post procedurally.[32] Sixty-four percent of patients responded in a follow-up survey, which demonstrated a mean procedural satisfaction of 4.2 out of 5, with 40% of patients reporting that they were very satisfied vs 10% very dissatisfied. Moreover, 86% of patients said they would recommend the procedure to a friend.[32] Overall, real-world data from this study parallels data reported in previous RCTs and supports WVTT as a well-tolerated, viable option for BPH treatment.[32]

Evaluating the Patient Experience: Head-to-Head Studies

In addition to these real-world studies evaluating PUL and WVTT individually, analysis of data from RCTs and real-world practice settings using WVTT and PUL has helped to shed further insight regarding the effectiveness, retreatment rates, and patient experience associated with

these minimally invasive procedures. A head-to-head study published in 2020 followed outcomes in 53 patients who underwent treatment with either procedure.[17] Resulting data demonstrated a significantly better IPSS and QOL outcome for the PUL group vs the WVTT group (8.6 vs 15.6, *P* = .001; 1.5 vs 2.5, *P* = .04, respectively).[17] Catheterization rates were significantly higher for the WVTT group vs the PUL group (87% vs 57%; *P* = .03). The WVTT group reported significantly longer catheterization duration vs the PUL group (4.5 ± 3.8 days vs 1.2 ± 2.3 days; *P* = .0004). Additionally, a significantly greater percentage of patients in the WVTT group vs the PUL group reported interference with community activities (40% vs 12%; *P* = .04) and dissatisfaction with treatment results (22% vs 3%; *P* = .07.[17]

A recent meta-analysis also demonstrated higher rates of catheterization in patients receiving WVTT (55% to 100%) versus PUL (32% to 68%).[33] These observed differences may be due to the inherent nature of each procedure and the associated time to healing and relief of LUTS, as PUL does not require tissue ablation.[17]

Return Procedures and Retreatment

Additional real-world data of relevance to the patient experience include return and retreatment rates among the interventions available. Results from a real-world study evaluating retreatment and return procedures were recently presented at the 2021 AUA Annual Meeting (**Figure**). The rates of return procedures were lowest for PUL (17%) compared with WVTT (23%), GreenLight laser surgery (22%), and TURP (21%). Retreatment rates were similar for GreenLight laser surgery (5.2%), TURP (5.3%), and PUL (5.4%).[34]

Lack of consensus for reporting retreatment associated with BPH treatment has led to a call for change in how the reintervention rate is defined, with some proposing a composite value and others suggesting an annual intervention rate that accounts for patients lost to follow-up.[35] BPH studies have historically suffered from a substantial number of patients lost to follow-up, which has prompted questions surrounding the best method for assessing treatment durability.[6,16] Evaluating study data using Intent to Treat and Per Protocol analysis, as conducted in the L.I.F.T. study, may be helpful in comparing outcomes between different clinical trials and improve information for clinical and shared decision making. Additionally, there is a lack of consensus regarding criteria for defining retreatment for BPH. TURP studies often report 10-year retreatment rates using retrospective vs prospective data and older clinical trials do not include medical therapy as a retreatment in the reported data.[9] Recently, a large Canadian study evaluating 58,038 patients who received TURP over a period of roughly 5 years reported a surgical retreatment rate of 10.9%, however, continued use of BPH medications was strikingly much higher at 27%, which brings into question the current understanding regarding TURP-associated treatment durability.[16]

FIGURE. RETREATMENT RATES FOR BPH SURGICAL INTERVENTIONS[34]

- **1-year return procedure rate**
  - » Lowest for PUL patients (17%)
  - » Similar risk associated with Rezum (23%), GreenLight (22%), and TURP (21%)
- **1-year surgical retreatment rate**
  - » Similar between PUL (5.4%), TURP (5.3%), and GreenLight (5.2%)
  - » Adjusting for available population variables using hazard modeling: PUL (using UroLift) was associated with a lower risk of undergoing a return procedure compared to Rezum, GreenLight, and TURP

PUL, prostatic urethral lift; TURP, transurethral resection of the prostate.

The Value of Shared Decision-Making

Given the increasing number of options for the treatment of BPH, as well as the variety of factors that may affect treatment success, emphasis should be given to the patient perspective in the treatment selection process. To that end, updates to the 2021 AUA guidelines place an emphasis on the importance of using a shared decision-making model, wherein clinicians discuss key treatment classes (eg, medical, minimally invasive, endourologic, open/robotic assisted surgery) and thoroughly review risks and benefits for all treatment options.[36] Through a shared decision-making process, patients can feel a sense of empowerment to make an informed decision on their treatment selection that is more likely to result in a higher level of satisfaction, better treatment adherence, improved quality of life, and less decisional regret.[37]

CONCLUSIONS

For patients seeking to preserve sexual function, prefer to forego invasive surgery, or for whom medical

therapies have failed, MISTs provide an alternative to traditional medical and surgical therapies, particularly for patients who may benefit from earlier surgical intervention. With the ability to fill unmet needs, MISTs also allow clinicians and patients greater flexibility when pursuing a shared decision toward optimal treatment. Finally, the addition of MISTs to the AUA guideline recommendations coupled with increasingly robust clinical trial data and real-world findings suggest that MISTs play an important role in the treatment landscape for BPH. ●

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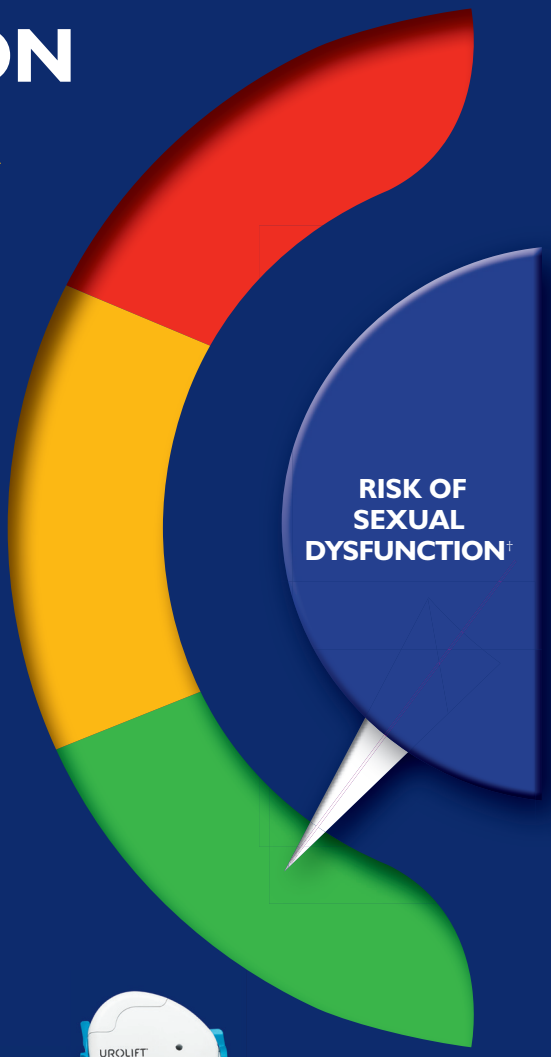

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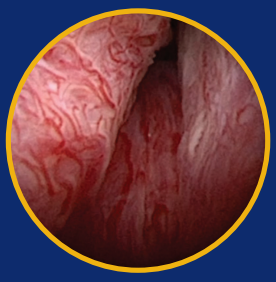

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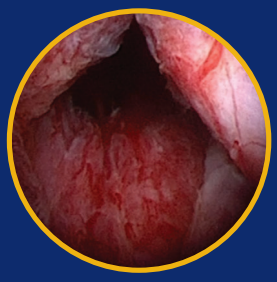

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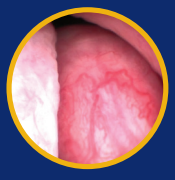
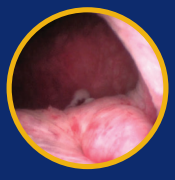


Obstructive Median Lobe Before



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Refining Treatment Approaches to Benign Prostatic Hyperplasia with Precision Diagnostics and Minimally Invasive Surgical Therapies

STEVEN KAPLAN, MD

Professor and Director,
Men's Wellness Program,
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Mount Sinai, New York, NY

***Urology Times*®: How have treatment goals for benign prostatic hypertrophy (BPH) changed in recent years, particularly with the growing number of available and minimally invasive surgical therapies (MISTs)?**

Kaplan: People are looking for a more sustainable improvement, perhaps [one that doesn't involve taking] a pill every day. In the past, there were fewer options, and people are looking at things like [having] sustainable success, being able to have reasonable improvement in quality of life, and not [having] potential [adverse] effects of some of a medication.

We have recognized that while medications remain the number 1 treatment that urologists and probably most health care [providers] advocate for, [many people] may not want long-term use of a medication, [particularly considering] long-term [adverse] effects. With the ability to do procedures in the office and improvements in surgery, there may be a swing in what patients would like to do, advocate to do, or tolerate.

***Urology Times*®: What is the role of shared decision-making in the treatment of patients with BPH?**

Kaplan: Patients are becoming more versed—given the internet, marketing, advertising—but it doesn't mean they understand it well, unfortunately. Sometimes, we spend a good portion of our interaction with patients dissuading them or disabusing them of some of the notions that they may have. That being said, in general, the consumer, or the patient, is becoming a little bit more aware and a bit savvier about what's out there. There's a visceral appeal to be able to have procedures that may be relatively easy to do, to not [have] to take a therapy every day, and to not [have] sexual function affected.

Patients will come in, and, based on an evaluation, I try to have a conversation with them about why certain things may work and certain things may not work. They may come in [wanting a certain procedure], but we have to go through the process of explaining why that may not be best for them. In my experience, most patients come to me for my advice, and they will accept it. That doesn't mean they're going to do the procedure or therapy right away, but at least they'll understand.

***Urology Times*®: What are the long-term implications of medical therapy for the treatment of BPH?**

Kaplan: Data [have] emerged about long-term use of medications, in particular long-term use of certain classes of agents, such as 5-alpha-reductase inhibitors (5ARIs) and antimuscarinics, [which] have been associated with cognitive changes, dementia, and depression. While we know this more definitively with a medication such as oxybutynin, the jury is still out on 5ARIs. In addition, conflicting reports about the long-term use of alpha blockers and in particular tamsulosin and depression / dementia remain.

Most BPH medications, probably more than half of BPH medications, are prescribed by [doctors other than] urologists. Those physicians don't have access [to surgical treatment] and don't do minimally invasive procedures. So if you go to your primary care physician and say, "I get up at night with the need to urinate," or, "I want to run to the bathroom," they're not going to offer a procedure, because they don't have access. They're going to give medications. So that's a whole group of patients who we don't even see unless they fail therapy and/or they have [adverse] effects of therapy, and then they're referred to a urologist. So, that's 1 group, and, frankly, that's probably the majority of patients.

Then you have the group treated by urologists. There's a balance, because some urologists

don't do procedures and/or [they] believe that medication should be the first at-bat. Could those algorithms change? Sure, but at least the traditional teaching has been, let's try some medications and see how you do. I like to try medication first just to see the patient's response. If I see a patient respond to a medication, and then, for whatever reason, he doesn't want to take it long term, I can have another conversation to say, "Hey, at least I know that you're probably somebody who will get better with a minimally invasive therapy, because I see how you did with medications."

***Urology Times®*: What is the role of transurethral resection of the prostate (TURP) in the evolving treatment spectrum for BPH?**

Kaplan: One of my colleagues, [Kellogg Parsons, MD, MHS, FACS], says it best [when he comments], "I don't think the TURP is the gold standard. I think TURP is a historical standard." That's a better way of looking at it, and I think it's a good term. I now do Aquablation; we're doing among the most [of that treatment] in the country right now, and that's a surgical procedure. It's not a TURP, per se; it's a water TURP. For me, the GreenLight Laser Therapy, holmium laser, electrosurgical TURP, [and] Aquablation are surgical technologies. Some patients with large prostates who are in retention [are] going to have one of those procedures.

***Urology Times®*: What factors shape your decision to recommend minimally invasive surgical therapies?**

Kaplan: If patients come in with urinary retention, they can't urinate, or they've failed multiple voiding trials, in general, I've not used minimally invasive therapies. Some data are emerging that you could use [them] in retention, but the data are really stronger for patients who come in with symptoms.

I evaluate all patients before I make a recommendation. I want to do diagnostic procedures, including cystoscopies, transrectal ultrasounds, and bladder function measurements. I'm very data driven and precision driven. At a minimum, they have to have a measurement of their prostate size and determination of their prostate configuration if they're going to have a minimally invasive procedure. Being very data- and diagnostic-oriented, [I use that information] to decide whether I want to [use] a UroLift or Rezum [device] or an iTIND [second-generation temporary implantable nitinol device]. For me, it's about prostate size and configuration. So if a patient has a prostate that [weighs more than] 80 g or 100 g, I tend to not do minimally invasive therapies. There's data that they may work, but I'm not as enthusiastic about [using them on] such large prostates.

"We have recognized that while medications remain the number 1 treatment that urologists and probably most health care [providers] advocate, [many people] may not want long-term use of a medication."

So where do I use the UroLift, and where I do Rezum? It depends [upon] whether or not they have what's called an intravesical or middle lobe or [a] large middle lobe. If patients have what's called bilobar hypertrophy, and their prostate [weighs] less than 80 g, even though [UroLift] is approved [for use in prostates weighing] 80 to 100 g, I'm not a big believer [of using it] in prostates [of that size]. If they have bilobar hypertrophy, I tend to favor [use of] the UroLift. But if they have a middle lobe, I tend to favor [use of] the Rezum.

With the Rezum procedure, I put a catheter in patients for 2 or 3 days; in the UroLift procedure, I only put a catheter in about 10% or 15% of patients. If I was a patient, I would rather not go home with a catheter. So if I had a prostate that [weighed] 40, 50, [or] 60 g, and I didn't want to take medication with added [adverse] effects, I'd rather have a [procedure involving] UroLift or Rezum.

The testing really helps us nail down which is a more preferable procedure. I try to be very diagnostic-oriented—that helps me pick the right procedure. Does that mean I always get it right? No. Does that mean a patient always does well? No. But I think I increase the odds by doing the right thing for the right patient.

***Urology Times®*: What does the next several years look like when it comes to the treatment of BPH?**

Kaplan: There are a lot of new technologies that are in clinical trials, so I expect it to be more [and] not less for a while. As the reimbursement and economic structures change, that will continue to be the trend. I don't see them decreasing. I still see a significant increase in these for the short term, over the next 5 years.

With all of these advancements, I'd like to see better diagnostics so that we can answer the questions of why certain therapies, even TURPs, [fail in some patients]. It's not in an insignificant [number] of patients. We just presented data at [the annual meeting

of the American Urological Association] last year, where even with a TURP, the retreatment rate at 1 year was approximately 5%. Sometimes, it's the wrong diagnosis. For example, if you have a patient who just gets up a lot of night to urinate, how much is a TURP going to help them? They have another reason why they may be having their symptoms. And they're almost doomed to [have failure of] even medical therapy, quite frankly, if they just get up a lot at night to urinate but don't have a lot of daytime symptoms.

I would like to see us do a better job with diagnostics, frankly. If we're more precise with diagnostics, and we know the patient has bladder obstruction as the cause of their symptoms, they're more likely to do better [after prostate therapy], regardless of who does it. But if you're going to do a therapy on a prostate in a patient whose primary reason for having their problem is not their prostate, [the therapy is more likely to fail, and the problem is] more likely to recur.

"Let's make the precise diagnosis of why patients have their symptoms, and we'll be more likely to use the precise therapy that will create good, more sustainable results."

If I would like to see us do something better as a community, [it would be] doing a better job at more precisely diagnosing why patients have problems in urinating. That, overall, would be the best thing to help clinicians do the right procedures.

In short, better diagnostics, more precise diagnostics, [and] more precision-driven therapies will improve the field. Let's make the precise diagnosis of why patients have their symptoms, and we'll be more likely to use the precise therapy that will create good, more sustainable results. That's where the field needs to go.

VIEWPOINTS

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Urology Times®

Treatment Decision-Making and Symptom Management for Patients With Benign Prostatic Hyperplasia

STEVEN N. GANGE, MD, FACS

Director of Education,
Summit Urology Group,
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Principal Investigator,
JBR-Utah
Salt Lake City, UT

***Urology Times®*: With the range of treatment options available for benign prostatic hyperplasia (BPH), how do you work with a patient to arrive at the most appropriate therapeutic approach?**

Gange: First of all, we try to quantify the symptoms. For starters, we rely on the validated IPSS (International Prostate Symptom Score), the bladder scan postvoid residual, and urinalysis; in our office, IPSS is administered to every man aged 40 years and over, every visit. In patients who present with bothersome LUTS (lower urinary tract symptoms), their symptoms are typically significant enough that the patients want to initiate therapy, and this is a reasonable starting point for further evaluation. I have a good experience with minimally invasive surgical therapies (MISTs), especially with UroLift, and many patients come to me with that already in mind; this prompts a more comprehensive evaluation (obviously including PSA [prostate-specific antigen] measurement and prostate cancer exclusion).

Certainly, some patients prefer a trial of medical management, but others are inclined to move to a definitive intervention. Insurance requirements may dictate a period of trial and failure, or trial and adverse effects (AEs), related to drug usage. In reality, as I step back and look at the big picture, I'm not always sure that drug therapy is the right thing for many patients. Efficacy can be suboptimal, and I have increasing concerns about long-term AEs and negative or at least neutral impact on bladder health. We will try drug therapy when a patient requests it and when insurance requires it, but in most of our patients on straight or managed Medicare, there are no such requirements. If a patient has CMS (Centers for Medicare & Medicaid Services)-governed care, we can make the choice together to not try BPH drug therapy but instead move on to an evaluation for a definitive intervention. For me, this evaluation always consists of TRUS (transrectal ultrasound), flexible cystoscopy with retroflexion, and UroCuff PFS (pressure flow study); I perform these on the same day in order to maximize patient efficiency and office flow.

The 1-stop BPH evaluation has been very helpful. Often, we find that there is enough evidence of significant outlet obstruction and even early demise of bladder function, such that drug therapy wouldn't have been in the patient's best interest anyway. I work with patients to understand this dynamic; I provide to them a very detailed written overview of BPH and available options as required reading. Patients have preferences, and we acknowledge their preferences. Then we decide, with them, where to go next; I mostly rely on my experience and share my patients' aversion to surgery, so after a complete evaluation, we move towards a minimally invasive option whenever possible.

***Urology Times®*: What challenges emerge as you are working with patients to arrive at a suitable treatment plan? How might the urologist address some of these obstacles?**

Gange: Right off the bat, many of the drugs have tolerability issues. The α-blockers are associated with dizziness, headaches, rhinitis, and ejaculatory dysfunction; some evidence also suggests a risk of dementia and ischemic CVA (cerebrovascular accident). The 5-α reductase inhibitors (5ARIs) particularly are associated with short- and long-term sexual AEs, and a study done by Veterans Affairs found an increased risk of prostate cancer.

On the other hand, I've become comfortable with tadalafil, which is dosed daily and is a very reasonable entry-level BPH drug therapy from an efficacy and safety standpoint. When patients tell me they want to try a drug because they are not ready to jump into procedural management, I often choose tadalafil. It's now inexpensive and is very well tolerated with no known long-term consequences, and it also improves their erections. I like tadalafil for my patients with BPH. Yet even with this most tolerable option, many patients have

no interest in drug therapy. Many men are on a number of other pills and have appropriate concerns about AEs and polypharmacy.

The other issues are related to insurance coverage. Some insurance companies require patients to use conventional drug therapies, even when patients really resist a trial, prior to allowing a patient to undergo a MIST. There are some notable insurance companies that have 3-month or even 6-month medication rules before they allow us to move on to what the patient really came in looking for and would be best served by, which is the minimally-invasive procedural option. Additionally, some carriers won't allow MISTs based on some anatomical issues, despite FDA clearance. We counsel patients about their prostate size and shape and evidence of deteriorating bladder health as we perform the workup; having a monitor in the procedure room really helps in this.

***Urology Times®*: Can you describe the potential risks of opting for a "watchful waiting" approach or traditional medications rather than procedural interventions for BPH?**

Gange: Some of the problem has to do with follow-up patterns; I prefer close follow-up for men with LUTS who are initiating drug therapy. Even pre–COVID-19, men sometimes delayed follow-up appointments. If someone gets started on an α-blocker for their BPH but doesn't show up for a year or longer, by the time they come back, they may have discontinued the drug for AEs, and/or they may have progressed through the α-blocker and developed some degree of detrusor dysfunction with urinary retention. Even if there is no retention, the bladder dysfunction that comes from ongoing obstruction can leave them with storage symptoms that they didn't have at the outset. Generally, I think one of the risks is related to how some men approach their health care: they don't always present when they have issues. If we don't routinely quantify symptoms with IPSS, we may not appreciate what's really going on.

Then the other risk, of course, is that with the passage of time and even with compliance, LUTS and detrusor dysfunction can progress. We are not always diligent as urologists in terms of monitoring our patients with BPH. Maybe we are not doing IPSS or postvoid residuals routinely. We might just ask how they are doing, and they'll sometimes tell us that they are doing fine, when, in fact, they may have undisclosed complaints. If we don't go any further, we might miss an opportunity to intervene when it's appropriate. Historically, when TURP (transurethral resection of the prostate) was the only way to treat LUTS, men did fairly well. These days, TURP is often delayed until the point of urinary retention, and outcomes suffer.

"I prefer close follow up for men with LUTS who are initiating drug therapy. Even pre–COVID-19, men sometimes delayed follow-up appointments ...With the passage of time and even with compliance, LUTS and detrusor dysfunction can progress."

***Urology Times®*: The 2021 American Urological Association guidelines for BPH treatment recommend the use of IPSS at a visit during the 4- to 12-week follow-up period after treatment initiation. What is the role of IPSS tracking at your practice?**

Gange: Although the recommendations do not specify it be done at every follow-up visit, for me, IPSS is an every-visit thing. I think that can feel redundant, but it's essentially a urologist's BPH blood pressure. We don't have any real objective way, short of the PFS, to monitor a patient's progress on their therapy or posttherapy. I like IPSS a lot. IPSS implementation might seem cumbersome, but it isn't. We just hand it to the patients, they fill it out in the waiting area, and a medical assistant imports everything into the medical record. We also leave the paper copy available, so when I walk into the room, I can get a general sense for where the patient is. I think it is an invaluable assessment tool and don't know how I would practice without it.

By the way, IPSS is not the only way to do this; I also like the BPH Impact Index (BII).[1] I think it's a little more general and qualitative; I use the BII in tandem with IPSS for my MIST patients to enhance my understanding in their recovery period.

***Urology Times®*: If a patient is dissatisfied with their treatment or no decrease in IPSS is shown, what are the implications for therapy?**

Gange: Occasionally, I think we have to talk to the patient to learn what they are really complaining about. I look not just at the assessment, the symptom score itself, but also at the quality of life (QOL) score. It's interesting that sometimes we see the QOL score improve while the numbers they are circling at the top of the score sheets don't seem to improve. Possibly, men are circling numbers out of habit or impatience. In other words, an accurate assessment does require a little qualification by a conversation with the patient.

This has also been where I have found the BII to be useful. I'll see patients whose IPSS scores don't

move much, but if we have that other score, that other opportunity to ask these questions alongside the IPSS, sometimes we'll see improvement in that score; it's a matter of interpretation. In the long run, I do acknowledge a patient's elevated score. If it's not improving, I have to get into that with them and determine what's really going on. There are times when we perform MIST and don't decrease the score much but have been successful in discontinuing a twice-daily α-blocker, a 5ARI, and even a bladder drug; in my book, that's a home run. Other times, we will substantially improve the patient's voiding symptoms and essentially uncover the storage symptoms, which now become the predominant complaints. We have to see where the scoring has shifted. Overall, I still continue to like the tool. I don't make treatment decisions solely based upon it, but it's an indispensable adjunct to our overall assessment.

***Urology Times*®: What are some unmet needs in the ways that BPH is currently managed? What kinds of adjustments to the current treatment paradigm might need to occur to address these issues?**

Gange: I think it's time for broad-based patient education, whether by industry-funded DTC (direct-to-consumer) campaigns or a source potentially less "biased." Men (and their caregivers) need to know that untreated BPH can have a significant impact on overall health, hopefully prompting earlier engagement with health care providers.

We can't forget that at least 50% of patients with BPH are managed by primary care providers who have nothing in their toolbox other than stacking medications for these men. Urologists could have a huge impact by educating primary care providers to consider earlier referrals.

The minimally invasive therapies that exist are in many ways less toxic than traditional BPH medications, and "non-user" urologists might want to give these treatment options a closer look. Approaching everything in a stepwise fashion doesn't always serve our patients well. They have to "try and fail"—what does that even mean? How long are we going to let them try and fail drugs while detrusor dysfunction may be progressing? Which drugs? How many months of each drug? Sometimes, we just have to use our seasoned expertise about how best to manage these men. We also really need to begin to pay better attention to the long-term AEs of traditional BPH drug therapy, which have become really concerning to me. Many of us have very little hesitation about moving from drug therapy that's not totally hitting the mark and maybe predisposing to worrisome AEs to a minimally invasive therapy with few downsides that is really a definitive way of managing BPH.

In-office procedures offer patients clear advantages (reduced risk and cost) while maximizing the urologist's efficiency. Self-administered nitrous oxide is a safe and effective adjunct for in-office MISTs.

Finally, our current BPH guidelines emphasize the importance of PFS as a part of the accurate assessment of BPH. Cystoscopy and volume assessment are just not enough, and it is conceivable payers might begin to add this requirement to prior authorization for MISTs or more invasive BPH therapies. ●

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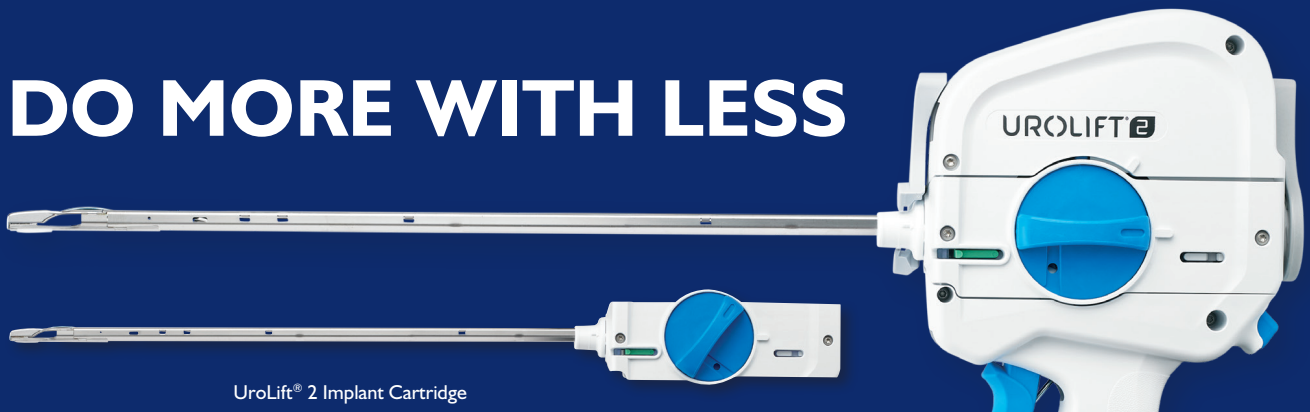

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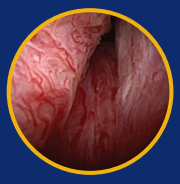
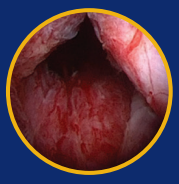
- ✓ Delivers the proven UroLift® System Implant[2,3]

TREAT A BROAD SPECTRUM OF ANATOMIES

Including lateral and median lobe hyperplasia with prostates <100 cc



LATERAL LOBE OCCLUSION BEFORE



LATERAL LOBE OCCLUSION AFTER*

Visit **UroLift.com/UL2** to learn how the UroLift 2 System works, how to get trained, and access education and patient resources.

*Individual results may vary. Most common side effects are temporary and include hematuria, dysuria, micturition urgency, pelvic pain, and urge incontinence.[4] Rare side effects, including bleeding and infection, may lead to a serious outcome and may require intervention. Refer to the Instructions for Use for a complete listing of the indications, contraindications, warnings and precautions.

1. Compared to the current generation UroLift device per average case. Calculations on file.; 2. Roehrborn et al. Can J Urol 2017; 3. Eure et a. J Endouro 2019; 4. Roehrborn, J Urol 2013

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

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INTERVENTIONAL UROLOGY