State of the art: Advanced techniques for prostatic urethral lift for the relief of prostate obstruction under local anesthesia

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Benign prostatic hypertrophy (BPH) affects an estimated 60% of men over the age of 50 and 90% of men over the age of 80. The prostatic urethral lift (PUL) is a safe and effective office-based procedure that is used worldwide for the treatment of BPH in men who are dissatisfied with medications due to side effects or lack of efficacy or don't want to have a transurethral resection of the prostate due to the side effects and invasiveness of the procedure. In 2012 Barkin et al, published the standard technique for the delivery of the UroLift implant. The objective of this article is to describe the current state of the art advanced techniques for the delivery of the UroLift implant.

Key Words: prostatic urethral lift, PUL, UroLift system, benign prostatic hyperplasia, prostate, LUTS

Introduction

The UroLift (NeoTract Inc., Pleasanton, CA, USA) system is a treatment for benign prostatic hypertrophy (BPH) that has been used in men since 2005. The L.I.F.T. study demonstrates that prostatic urethral lift (PUL) improved the International Prostate Symptom Score (IPSS) by 11 points as early as 3 months.[1] Subsequent reports demonstrated the durability of this result through 5 years.[2,3] Patients rapidly experienced a greater improvement as compared to alpha blockers and 5-alpha reductase inhibitors which have been shown to improve the IPSS score by an average of 3-5 points.[4] By contrast to transurethral resection of prostate which can improve the IPSS score by 14 points, the UroLift does not have any adverse effects on erectile function or ejaculation and offers similar quality-of-life improvement.[5] The PUL technique has been well described previously.[6,7] Since that time, the technique has been refined to address variations in prostate anatomy. In our experience treating over 300 patients, these techniques have proven helpful in optimizing patient comfort and patient outcomes.

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Methods and technique

Patient education and work up

Effective treatment begins with patient education. Most men are aware of the standard surgical options and typically will not elect them until symptoms are severe. We have found that educating patients that PUL can offer

relief from the side effects or daily hassle of medication leads to a different conversation with both established and new patients in my practice. Interested patients are scheduled for a follow up visit to complete the work up and confirm anatomical candidacy for the procedure.

Men are assessed preoperatively using a uroflow, prostate and bladder ultrasound, and flexible cystoscopy. Patients with a normal uroflow have a 30% chance of being obstructed and consideration should be given to treating for overactive bladder. A prostate ultrasound should be used to assess the presence of intravesical prostate protrusion, and lateral lobe width in large prostates. These should be noted in the patient chart and available for procedural planning. The UroLift needle extends 33 mm from the device and is deployed in the anterolateral aspect of the prostate, which is typically not the widest portion of the lobe. Because the gland is compressed with the rigid delivery device, prostates with lateral lobes of 5 cm (10 cm prostate width) can be effectively treated. Use caution in prostate glands with lateral lobes > 5 cm. Patients with significant urinary retention (> 200 cc) should be counseled about the contribution of bladder dysfunction and that he may not do as well as patients who are not retaining urine. We have also incorporated this into my patient education process by making patients aware of the potential bladder health risks associated with delayed treatment or prolonged medical therapy.

Flexible cystoscopy should be performed to measure the intravesical protrusion of the prostate and the presence of an obstructive median lobe. Small median lobe protrusions at the bladder neck are typically not of clinical significance; if lateral lobe distraction can address the primary obstruction, PUL can be an effective treatment. Similarly patients with a high bladder neck can be effectively treated via PUL.

Many elderly patients are on anticoagulation and antiplatelet medications. We do not routinely ask patients to stop aspirin prior to treatment. However, we obtain cardiac clearance to hold Plavix, Coumadin, and Eliquis prior to the procedure. These medications are typically resumed the following day.

Procedural tips: local anesthesia

PUL is well-suited to treatment in the office under local anesthesia as was routinely done in the L.I.F.T. study.[1] Currently, no single anesthesia protocol has emerged as a standard practice. Several approaches have proven effective. Common protocols include a combination of modalities as follows:

1. Local anesthesia with chilled intraurethral lidocaine jelly which can be combined with intravesical lidocaine/sodium bicarbonate solution.
2. Regional nerve blocks using US guided prostate block (identical to the block used for prostate biopsy), or pudendal nerve block.
3. Sedation with benzodiazepines (alprazolam).
4. Narcotic pain medication (hydrocodone).
5. Anti-inflammatory (ibuprofen).

We have found that a combination of a TRUS-guided prostate block utilizing 15 mL of 1% lidocaine and 50 cc of chilled intravesical lidocaine/sodium bicarbonate solution, and intraurethral lidocaine jelly is very effective for most patients. If a patient tolerates a flexible cystoscopy with topical lidocaine only, they will typically tolerate PUL with this regimen. We occasionally add a sedative; though for elderly patients, we avoid using office sedation as the effects of sedation can persist after the patient is home and may present a fall risk.

In addition to the prostate block, clear communication with the patient is important to maintain patient comfort through the procedure. We advise patients and their family prior to the procedure that the patient will feel a tugging sensation and pressure during the procedure. During the procedure, we tell the patient the expected number of implants and the progress we make during the procedure. The few patients who complain about pain during the procedure claim that the pain was present from the moment the scope entered the urethra until the end of the case, not that one step was more painful than another. If the patient cannot tolerate or is exceedingly anxious about a regular office cystoscopy, we recommend that patient undergo the PUL procedure under anesthesia. Specific causes of pain that can be avoided include bladder distention with saline irrigation and scope trauma at the bladder neck that may occur when the cystoscope enters or exits the bladder. For this reason the urologic surgeon should drop his/her hands, thereby maneuvering the device tip anteriorly, when moving the scope into and out of the bladder and avoid over distention of the bladder.

Although uncommon, vasovagal episodes do occur in the office and can occur even after the procedure when the patient is dressed. Our staff maintains a constant line of sight with the patient until they are dressed in an exam room with a family member. We also advise patients to be well hydrated prior to the procedure and eat a light meal. Our staff monitors vital signs when they arrive, during the procedure and in recovery.

Procedural tips: basic surgical technique

The goal of the PUL procedure is to achieve a continuous anterior channel. This may seem counterintuitive given the long successful history of various cavitating procedures. The distinction with PUL is to achieve the benefits associated with a continuous anterior

channel without the complications and recovery period associated with tissue removal and destruction. A continuous anterior channel mimics the lumen created with a Foley catheter and provides meaningful symptom relief.

The required equipment and basic surgical technique have been described previously.[6] This paper will focus on advanced procedural techniques to address anatomical variations.

Prior to starting the procedure it is important to ensure patients are positioned in the highest lithotomy position allowed by the office set up, with the buttocks slightly off of the edge of the table so that there is unrestricted movement of the device during implantation. This position also minimizes the likelihood of the needle contacting the pelvic bone during implant deployment.

Procedural tips: addressing small and large prostates

The UroLift implant should typically be placed in the anterior aspect of the lateral lobes. The tissue should be compressed to form the tissue into the shape of a "B" [for the patients' right lateral lobes, and mirror image on the left] so that 1/3 of the tissue is anterior to and 2/3 of the tissue posterior to the delivery device, Figure 1. As described previously, the implants are typically placed in series from the bladder neck to the verumontanum.[2] During the procedure, landmarks are used to efficiently place the implants. To avoid placing implants at the bladder neck which can cause short term irritative voiding symptoms, start by placing the implants bilaterally, at least 1.5 cm and preferably 2 cm distal to the bladder neck. This is followed in succession by placing two implants bilaterally superior and just proximal to the verumontanum. A visual obturator is used to visualize and confirm proper placement of each of the implants and to identify areas of persistent obstruction requiring additional implants.

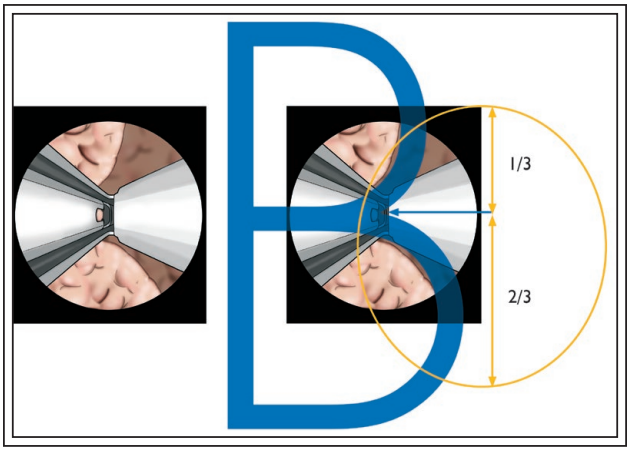

Figure 1. Left: illustration of the delivery device tip invaginating into the right lateral lobe (implant will be delivered to the left side of the image). **Right:** the same image, illustrating the "B" that can be imagined to remember that more bulging tissue should be inferior to the delivery device tip. The blue arrow indicates the needle exit direction and location; the yellow circle indicates the approximate perimeter of the urethra and the yellow lines illustrate positioning the needle 1/3 of the distance from the anterior aspect of the urethra. Courtesy of NeoTract Inc.

Patients with short prostates can present a challenge since positioning 2 cm distal to the bladder neck may appear too distal to have an effect. Instead, omit the bladder neck deployments and begin with the distal deployments, positing the delivery device with the lens tip above the verumontanum in the plane 1/3 of the way from the roof to the floor. Typically very light compression is sufficient and we inspect after the first implant and adjust the second implant slightly towards the bladder if we think the first implant's effect at the bladder neck is insufficient, Figure 2. Since the suture cannot elongate once the needle is retracted, use caution to avoid excess movement during the deployment. Note that while there is an upper size limit of 80 grams in the US (100 grams in Canada, the EU, and Australia) there is no lower size limit. We have treated men with prostates as small as 12 grams and in my experience these men do very well.

For tall prostates, it is important for the urologic surgeon to drop his/her wrists at the verumontanum to

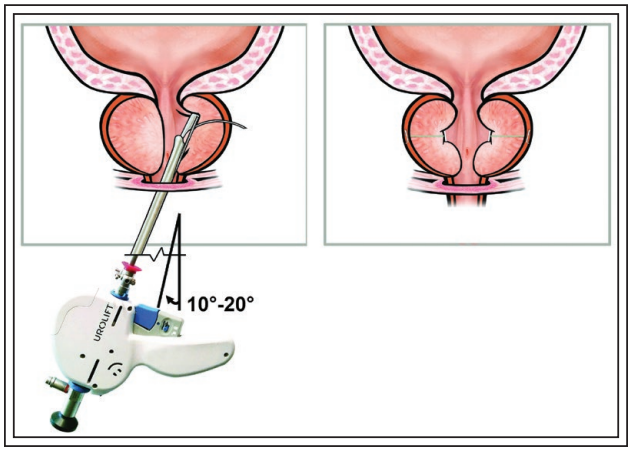

Figure 2. Left: delivery device angle of 10°-20° (versus more typical 20°-30°) is typically sufficient in small prostates (< 30 g). Position the lens tip anterior to the verumontanum to place the implants mid-prostate. **Right:** two implants are often sufficient in men with a short prostatic urethra. Courtesy of NeoTract Inc.

see the anterior and posterior urethra to ensure that the implants are placed approximately 1/3 of the distance from the anterior aspect to the posterior aspect. This technique should be used for all implants to ensure a continuous channel through the entire length of the prostatic urethra.

It is recommended to visualize the full extent of the prostatic urethra as part of the initial procedural cystoscopy since apical tissue can contribute to the obstruction. In particular, obstructive lateral lobe tissue can extend beyond the distal aspect of the verumontanum just proximal to the urethral sphincter. The UroLift implants can be placed to treat the apical obstructing prostate tissue that extends distal to the verumontanum without fear of injuring the urethral sphincter since the needle extends approximately 8 mm closer to the bladder than the telescope lens. Thus, if the scope tip is within the prostatic urethra, the sphincter cannot be compromised, Figure 3. It is important to test for completion of the procedure by visualizing a continuous anterior channel from the apex to the bladder outlet with irrigation pressure turned off at the end of the procedure.

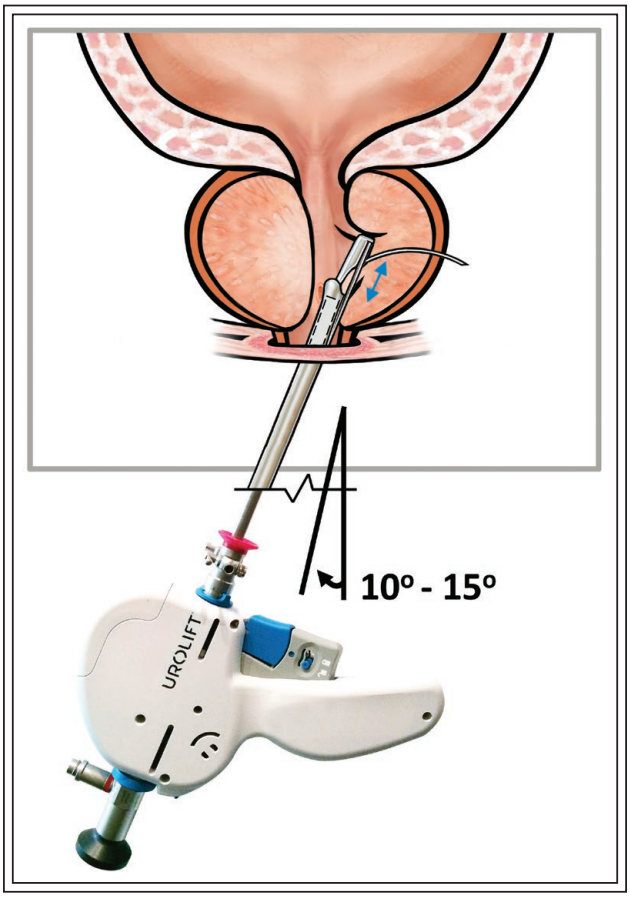

Figure 3. The implants cannot compromise the sphincter if the verumontanum is as long as the telescope (shown as grey rectangle with dashed perimeter) is distal to the verumontanum because the needle exits 8 mm beyond the telescope (blue line). Courtesy of NeoTract Inc.

Procedural tips: prostate-bladder anatomical interaction

Patients with intravesical protrusion of prostate (IPP) can be successfully treated with the UroLift system. The needle from the UroLift delivery device extends at a 20° angle relative to the delivery device and extends beyond the needle exit location approximately 12 mm. In patients with a significant IPP, the length of the IPP must be taken into account to prevent placement of the capsular tab into the bladder. This can be done by deploying further from the bladder neck (e.g. 2.5 cm back from the bladder neck if there is a known IPP of 2 cm) and also by increasing the angulation of the delivery device beyond 30° to route the needle distal to the exit location, Figure 4. Note that the height of the IPP can be measured using the width of a flexible cystoscope as a fiducial – most flexible cystoscopes are 4 mm in diameter. The length of protrusion is calculated by estimating the number of scope diameters and multiplying by 4 mm. It is widely understood that PUL is contraindicated (in the US) in patients with an obstructive median lobe. Some attention must be given to defining "obstructive" because many men with small posterior protrusions visible at the bladder neck or even modest growth

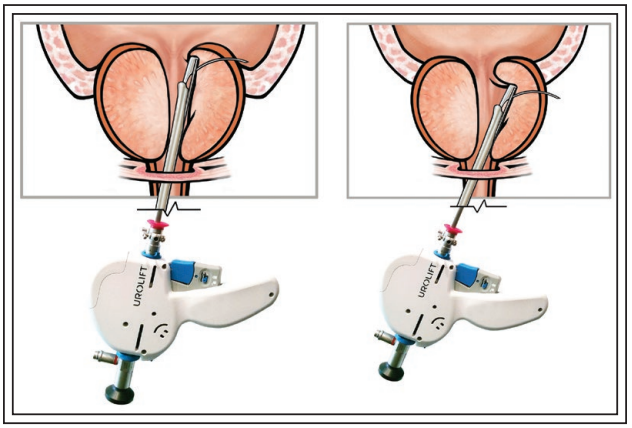

Figure 4. Illustration of prostate with intravesical protrusion of the prostate. **Left:** deploying the needle close to the bladder neck can position the needle tip within the bladder. **Right**: while the recommended 1.5 cm distance from the bladder neck is typically sufficient, we also adjust for a known IPP by increasing the delivery angle and positioning the tip further from the bladder neck. Courtesy of NeoTract Inc.

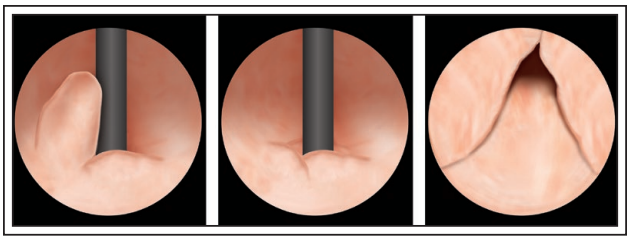

Figure 5. Left: pedunculated ball-value type middle lobe extending into the bladder visualized via retroflexion of the cystoscope – this anatomy is not suitable for PUL using current techniques. **Center:** modest middle lobe and lateral lobes protruding into the bladder – this anatomy can be effectively treated by addressing lateral lobe obstruction via PUL. **Right:** elevated bladder neck with possible middle lobe – this anatomy can be effectively addressed via PUL. Courtesy of NeoTract Inc.

of the middle lobe into the bladder of 6 mm-8 mm can be effectively treated using the PUL technique. Patients with a middle lobe should be excluded from consideration if their middle lobe is the clear primary cause of obstruction or if the middle lobe extends into the bladder and is sufficiently large to be mechanically unstable and therefor mobile, Figure 5. Such middle lobes could move into the bladder outlet and present an obstruction that is not well-treated using current PUL techniques. Techniques to address this type of anatomy are currently being investigated.

Procedural tips: stacking implants near the bladder neck

While four implants are sufficient for many prostates, there are particular anatomical variations that require additional implants. Long prostatic urethras may require three implants along the length of each lateral lobe. Patients with a high bladder neck, a modest non-obstructing median lobe, or protruding anterior tissue may benefit from supplemental implant(s) near the bladder neck. A stacking technique has been developed to address these particular anatomical variations.

The stacking technique is performed after placing the proximal implants in the standard manner: bilaterally 2 cm distal to the bladder neck 1/3 of the way from the roof to the floor. Note that in patients with an elevated bladder neck, these initial implants will likely be in line with the inferior aspect of the bladder outlet. The stacking technique is placing a subsequent pair of implants superior to each of the previous implants, Figure 6. Precise placement is afforded by aligning the needle exit location superior to the distal end of the previous implant. The shaft

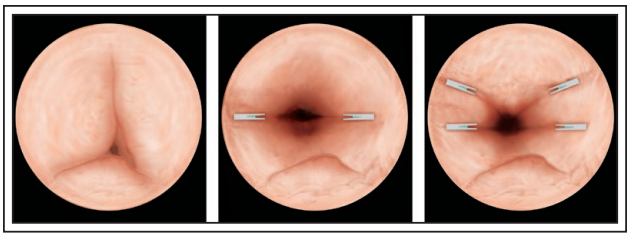

Figure 6. Stacking technique. **Left:** lateral lobe hypertrophy. Center: initial implants result in wide bladder outlet and anterior tissue prolapse. **Right:** stacked implants at the bladder neck restore round bladder outlet. Courtesy of NeoTract Inc.

of the delivery device should also be rotated slightly anteriorly such that the needle trajectory will be in the 2:30 or 9:30 position. This slight angulation will create opposing upward force vectors thereby providing a wide anterior channel. If this technique is used to address prolapsing anterior tissue, the device tip should be used to lift the anterior tissue as the tip is slowly drawn out of the bladder. The use of implants at the 12 o'clock position should be avoided due to the presence of the dorsal veins.

Results

Our single-center results to date have mirrored those published from the L.I.F.T. study.[1] Our initial 30 patients were specifically selected to match the inclusion and exclusion criteria from the L.I.F.T. study. After developing proficiency in the basic technique we expanded into larger prostates, patients with high bladder necks, and patients with modest, but not obstructive middle lobes. Utilizing the techniques described in this paper we have been able to achieve visible anterior channels and maintain visual disobstruction and excellent outcomes as we expanded into a wider range of anatomies. We track outcomes using AUASI at baseline, 2 weeks, 3 months, and annually thereafter. Patients in this expended anatomical range continue to match the L.I.F.T. study in terms of results. Patients with an indwelling catheter have had mixed results (~50% recovered) and so it is important to set expectations appropriately for these patients and only attempt them once the technique is mastered in order to provide them maximum opportunity for recovery.

Discussion

The physical basis for the effectiveness of the UroLift is the compressibility of the prostate adenoma and the presence of a firm capsule. Proper patient selection is

crucial to ensure the success of the procedure. Patients who have had prior prostate surgery or radiation therapy may be candidates for PUL if the prostate tissue is compressible with the rigid cystoscope.

The UroLift system procedure has been used with good results in patients who have been treated with external beam radiation therapy and brachytherapy provided that there is compressible lateral lobe tissue. We have not seen dystrophic calcification or strictures that can occur with energy based treatments like the transurethral resection of the prostate. Fibrous, non-compressible lobes should not be treated with the UroLift system. This area warrants further research.

Current recommendations of prostate size of 80 g or less is based on the approved indication in the United States (100 g or less elsewhere) and not the presence of clinical data that shows a lack of effectiveness. We have successfully treated men with larger than 80 g that have lateral lobe obstruction.

A current contraindication to the UroLift system is an obstructive median lobe or ball valve median lobe. A median lobe refers to either a middle lobe which includes prostate adenoma or a fibrous median bar. The definition of an obstructive median lobe means that the lobe completely fills the prostatic urethra, leaving no anterior channel and only this type of anatomy need be excluded from treatment. A ball valve middle lobe is defined as a middle lobe that is taller than it is wide and can obstruct the bladder during bladder empty by closing the bladder neck with prostate tissue flap. The MedLift study is in progress and is designed to determine if the UroLift system can be used successfully to treat middle lobe obstruction.

Conclusion

The UroLift system has been used worldwide for the treatment of BPH due to its efficacy and favorable side effect profile. It is well tolerated in the office setting using local and regional anesthetic familiar to all urologists. The adoption of advanced techniques can lead to improved visual disobstruction which may provide enhanced symptomatic relief. □

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