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Surgery in Motion

Minimally Invasive Prostatic Urethral Lift: Surgical Technique and Multinational Experience

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Abstract

Background: Many men with benign prostatic hyperplasia (BPH) are dissatisfied with current treatment options. Although transurethral resection of the prostate (TURP) remains the gold standard, many patients seek a less invasive alternative.

Objective: We describe the surgical technique and results of a novel minimally invasive implant procedure that offers symptom relief and improved voiding flow in an international series of patients.

Design, setting, and participants: A total of 102 men with symptomatic BPH were consecutively treated at seven centers across five countries. Patients were evaluated up to a median follow-up of 1 yr postprocedure. Average age, prostate size, and International Prostate Symptom Score (IPSS) were 68 yr, 48 cm³, and 23, respectively. **Surgical procedure:** The prostatic urethral lift mechanically opens the prostatic urethra with UroLift implants that are placed transurethraally under cystoscopic visualization, thereby separating the encroaching prostatic lobes.

Outcome measurements and statistical analysis: Patients were evaluated pre- and postoperatively by the IPSS, Quality-of-Life (QOL) scale, Benign Prostatic Hyperplasia Impact Index, maximum flow rate (Q_{max}), and adverse event reports including sexual function.

Results and limitations: All procedures were completed successfully with a mean of 4.5 implants without serious adverse effects. Patients experienced symptom relief by 2 wk that was sustained to 12 mo. Mean IPSS, QOL, and Q_{max} improved 36%, 39%, and 38% by 2 wk, and 52%, 53%, and 51% at 12 mo ($p < 0.001$), respectively. Adverse events were mild and transient. There were no reports of loss of antegrade ejaculation. A total of 6.5% of patients progressed to TURP without complication. Study limitations include the retrospective single-arm nature and the modest patient number.

Conclusions: Prostatic urethral lift has promise for BPH. It is minimally invasive, can be done under local anesthesia, does not appear to cause retrograde ejaculation, and improves symptoms and voiding flow. This study corroborates prior published results. Larger series with randomisation, comparator treatments, and longer follow-up are underway.

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1. Introduction

Moderate to severe lower urinary tract symptoms (LUTS) due to benign prostatic hyperplasia (BPH) affect 30% of men >50 yr of age including 26 million men in Europe and 8 million in the United States [1,2]. Medical therapy provides a modest International Prostate Symptom Score (IPSS) improvement; however, side effects or inadequate relief prompt >25% of men to discontinue treatment early [1,2]. A proportion of these patients choose surgical options. Transurethral resection of the prostate (TURP) is considered the gold standard for BPH, offering a two- to threefold mean IPSS improvement compared with drugs at 1 yr [3–5]. This improvement comes with a 20% perioperative morbidity rate and long-term complications including incontinence (3%), strictures (7%), erectile (10%) and especially ejaculatory dysfunction (65%) [3,5]. Although new laser-based modalities have been developed to decrease bleeding when compared with TURP, they still are associated with similar rates of perioperative morbidity [5,6].

A new less invasive technique to address LUTS is available, known as the prostatic urethral lift [7–10]. Using a novel set of intraprostatic UroLift implants, the encroaching prostate lobes are separated, relieving obstruction without tissue removal. IPSS reduction is greater than for medications, faster acting than thermal therapies, and without the complications of cavitating procedures such as TURP or laser. Prostatic urethral lift therapy appears to uniquely preserve sexual function, particularly antegrade ejaculation. The procedure has been refined as users have gained experience. This paper describes what has emerged as the preferred technique.

2. Methods

2.1. Theory of the prostatic urethral lift procedure

The premise of the prostatic urethral lift procedure is that differences in the mechanical properties of the prostate tissues permit a mechanical de-obstruction of the prostatic urethra. The urethra is compliant, the surrounding glandular tissue is compressible, and the fibromuscular prostatic capsule is tough. Thus applying a tissue-retracting implant between the urethra and the prostatic capsule lifts the urethra toward the capsule, thereby expanding the urethral lumen (Fig. 1).

Placement of the implants for optimal effect also ensures that important anatomic structures are not compromised. Implant placement at approximately 2 and 10 o'clock positions in the urethra provides an optimal effect to retract the obstructive lobes anterolaterally. The primary neurovascular bundles traverse the posterolateral surface of the prostate, away from the area of treatment. Similarly, the dorsal venous complex is found on the anterior surface, away from the implant placement site. Thus there is an ample target zone for UroLift implant delivery.

2.2. Equipment

The UroLift implant (NeoTract, Inc., Pleasanton, CA, USA) is a permanent implant consisting of a nitinol capsular tab (0.6 mm diameter × 8 mm long), a stainless-steel urethral end piece (8 mm × 1 mm × 0.5 mm), and an adjustable length of polyethylene terephthalate (PET) monofilament

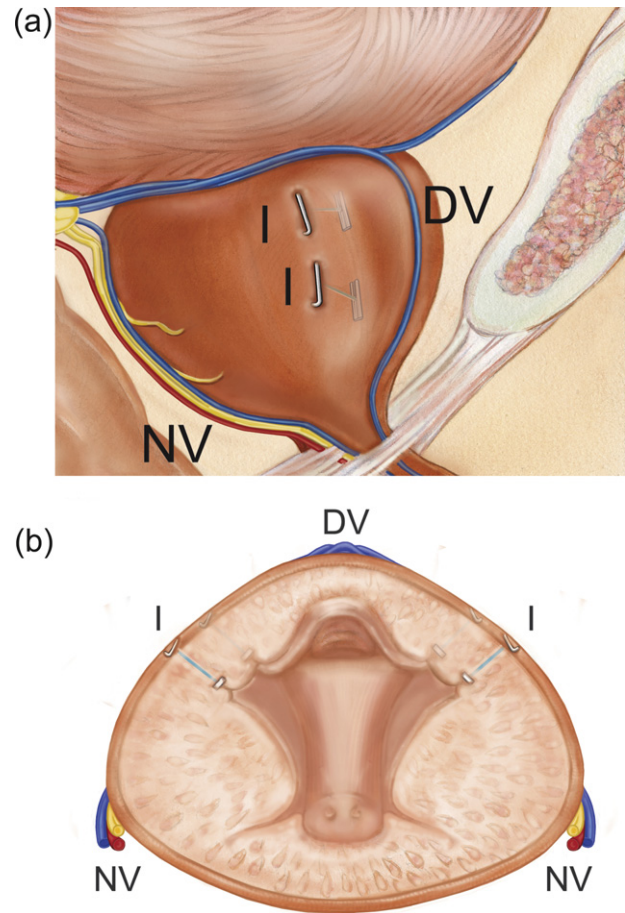


Fig. 1 – Human prostate in (a) full sagittal view and (b) transverse cross-sectional view after treatment with the prostatic urethral lift. UroLift implants (I) are deployed in the anterolateral aspect of the prostate, avoiding the neurovascular bundles (NV) or the dorsal venous complex (DV).

(0.4 mm diameter) between them (Fig. 2a). The UroLift system is a delivery device preloaded with the implant components and contains a spring-driven 19-gauge needle to traverse the prostatic lobe. The system is designed to: (1) deliver the implant to the desired anatomic location using cystoscopic guidance, (2) ensure delivery and attachment of the capsular tab onto the capsular surface, (3) customize the implant to the compressed lobe thickness at the point of delivery, and (4) allow the urethral end piece to invaginate into the urothelium, thereby minimizing foreign material exposure to the urine stream and promoting rapid epithelialization of the end piece. The polymeric monofilament component of the implant allows future interventions including TURP and laser treatments if necessary [7,8].

Direct visualization of implant placement is achieved using a smaller 2.9-mm 0° telescope (Storz Ref # 10324A) inserted into the UroLift system (Fig. 2b). Additionally the system is compatible with a 20F cystoscopy sheath (Storz Ref # 27027C). The telescope can be used for cystoscopy by means of a custom bridge (Storz Ref # PV27025F-2).

2.3. Study design and objectives

A retrospective analysis of prospectively accrued data on consecutive patients undergoing the prostatic urethral lift was conducted across seven centers in five countries. No procedures or results were omitted. The objectives of the study were to evaluate safety and effectiveness

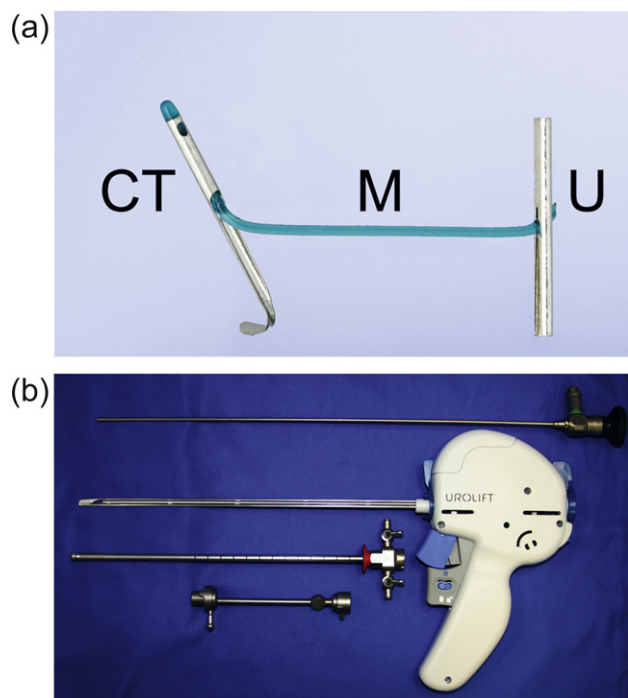


Fig. 2 – UroLift system and ancillary equipment. (a) UroLift implant composed of capsular tab (CT), monofilament (M), and urethral end piece (U); (b) UroLift delivery device with 2.9-mm telescope, 20F sheath, and telescope bridge.

with the most current device and surgical technique in day-to-day practice. At baseline, patients provided a complete medical history and physical examination, prostate transrectal ultrasound, urine analysis, postvoid residual (PVR), and maximum flow rate (Q_{max}) measurements. All patients completed a baseline IPSS questionnaire unless in retention. Effectiveness in alleviating LUTS was assessed by IPSS at baseline, 2 and 6 wk, 3, 6, and 12 mo postprocedure. Not all patients were followed at all time points because of practice variations at each center. To evaluate change from baseline, a general estimating equation model was fit to each output parameter (IPSS, Quality-of-Life [QOL] scale, Benign Prostatic Hyperplasia Impact Index [BPHII], Q_{max} , and PVR). Change from baseline was the dependent variable; visit and baseline score were used as independent variables. An exchangeable correlation structure and identity link were used. This model was used to calculate p values for each follow-up interval compared with baseline. Data from retreated patients were censored from the analysis at the time of retreatment. Statistical significance was defined as $p < 0.05$.

2.4. Patient selection

As with other surgical procedures, proper patient selection is critical to ensuring a good clinical outcome. Patients with a high bladder neck or a modest median lobe are more challenging to treat and are not recommended until proficiency in the technique has been obtained. The device is not designed to address an obstructive middle lobe or prostates >100 g, and treating these patients is not recommended. Typical inclusion criteria are a prostate volume <60 cm³, IPSS >12 , Q_{max} <15 ml/s, and PVR <350 ml.

2.5. Anesthesia

The procedure has been performed under general, spinal, and local anesthesia with oral or intravenous sedation. The most common

protocol for local anesthesia consisted of an oral sedative of 10 mg diazepam approximately 30 minutes prior to the procedure and instillation of topical lidocaine to the bladder and urethra. A catheter was used to drain the bladder and then instill 20 ml of cold (4°C) 2% lidocaine liquid [10]. Upon removal of the catheter, 10–20 ml of cold 2% lidocaine gel was instilled into the urethra followed by clamping the penis. The patient was then allowed to sit recumbent for 20 min prior to the procedure. For local anesthetic procedures, we found a bedside nurse helped to engage the patient, with the operator providing appropriate narration during the procedure.

2.6. Surgical technique

The overall technique goal is to create a continuous channel through the anterior prostatic fossa from bladder neck to verumontanum. Prior technique did not emphasize the anterior position of the channel, and retreatment rate was found to be higher [7,8]. Systematically, implants are delivered to both the right and left lateral lobes working distally from approximately 1.5 cm distal to the bladder neck. After each set of implants the prostate is assessed cystoscopically; if a continuous channel is observed, the procedure is deemed complete. Care is taken throughout the procedure to avoid trauma to the urethral mucosa; postoperative dysuria, hematuria, and catheterization can often be minimal with careful technique.

With the tip of the device still in the bladder, the UroLift system is turned 90° either right or left (depending on which lateral lobe is to be treated) and only then withdrawn into the prostatic urethra. The lateral lobes are not touched with the device until the site is chosen where the implant will be placed. Our experience has shown that it is critical to treat the proximal prostate adequately, just distal to the bladder neck. With the device tip at the bladder neck, it is retracted 1.5 cm and then pivoted laterally to approximately 20° from center (Fig. 3). The point of compression is approximately in the anterior third of the lateral lobe, leaving the bulk of the lobe posterior to the point of retraction, as evidenced by the B shape of the compressed prostate seen cystoscopically. Typical rotation of the device is either pointing toward 10 or 2 o'clock, in the anterolateral direction.

Once the proximal prostatic fossa is expanded with implants on each side, the prostatic urethra should be assessed from the viewpoint of the verumontanum. In small short prostates, the procedure is most likely complete with a widely open prostatic fossa. For larger prostates, the next implants should be placed at the distal-most location. With the verumontanum in view, angle the device tip to the anterior level of the initial implants (top third of the lobe; Fig. 4). In prostates ≤ 60 cm³, four implants typically open a continuous anterior channel. In larger prostates additional implants may be required between the proximal and distal deployments. It is particularly important in larger prostates to bias the opening of the urethra to the anterior aspect of the prostate, and it is not necessary to affect the large posterior mass of the lobes.

Delivery of the UroLift implant is achieved in a straightforward manner (Fig. 5) by (1) unlocking the safety lock, (2) depressing the needle trigger to release the needle, (3) fully retracting the needle while leaving the implant in situ (as the needle completes its retraction, the monofilament is then tensioned by the device to allow the capsular tab to secure itself to the prostatic capsule), and (4) depressing the release button that installs the urethral end piece onto the monofilament and trims the excess suture in a single step. The length of monofilament delivered at any one location is self-adjusted in situ by the tension and is essentially equal to the distance from the capsule to the urethral wall when compressed by the delivery device. The amount of opening achieved in the prostatic urethra is thus dictated by the amount of compression applied by the urologist with the delivery device tip. Because of this direct control of effect, it is possible for the urologist to

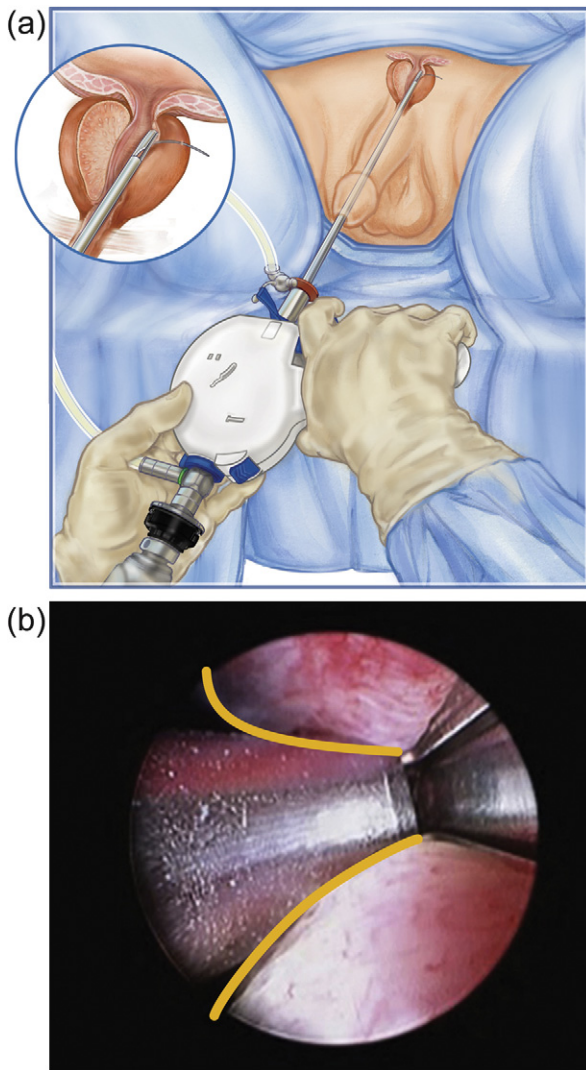


Fig. 3 – Deployment of proximal UroLift implant. (a) Surgical and internal view of implant deployment. The tip of the device is positioned 1.5 cm distal to the bladder neck and angled approximately 20° anterolaterally; (b) endoscopic compression of the anterior aspect of the lateral lobe produces a B shape with some lobe visible anterior (above) to the point of compression and more lobe typically visible below the point of compression.

first test the opening effect of the urethra cystoscopically to choose the best location for the implant before deployment.

Multiple imaging modalities have been used to confirm implant location. Figure 6 shows the effect of the UroLift implant both endoscopically and via computed tomography (CT). The urethral end piece is intentionally small so as to invaginate into a fold in the urethral mucosa. As seen in the cystoscopy at 6 mo, the implant is fully covered by mucosa, although a channel remains. Initial procedures used fluoroscopy to confirm that the capsular component reliably landed on the capsule or pubic fascia [7]. The CT scan shows the implant location with respect to these tissue planes and again highlights the anterior positioning, far from the neurovascular bundles.

3. Results

In this registry of 102 consecutive patients, all procedures were completed successfully. Patient demographics typically

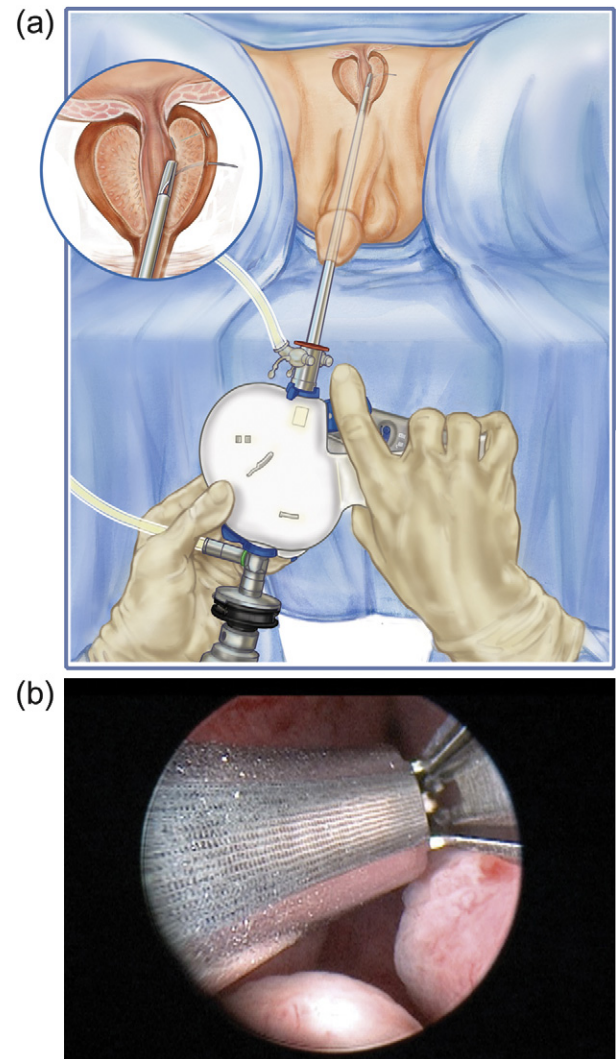


Fig. 4 – Deployment of distal UroLift implant. (a) Surgical and internal view of implant deployment distal to initial implant. The tip of the device is angled 20° anterolaterally; (b) deployment is just proximal (above) to the verumontanum.

reflected those of prior published studies [7–9] with a mean age of 68 ± 10 yr, prostate volume of 48 ± 21 cm³, IPSS of 23.2 ± 6.1 , QOL of 4.7 ± 1.0 , and Q_{\max} of 8.7 ± 4.0 ml/s. Because the cases studied represent the first cases performed at most sites, only 17% were conducted using local anesthesia. Although we found no trend in decreased complications or improved results, we did find that after approximately five cases, each investigator became comfortable with the technique. Average procedure time (patient time in procedure room) was 57.8 ± 15.8 min. Patients received an average of 4.5 implants (ranging from two to nine implants for prostate volumes of 16–149 cm³, respectively). Adverse events were typically mild to moderate with the most common short duration dysuria, hematuria, and urgency (25%, 16%, and 10%, respectively). There were three cases each of retention, urinary tract infection, and orchitis, all treated routinely. Four patients (6.5%) experienced insufficient improvement and were converted to TURP without complication at 2 wk, 3, 6, and 11 mo. The resectoscope

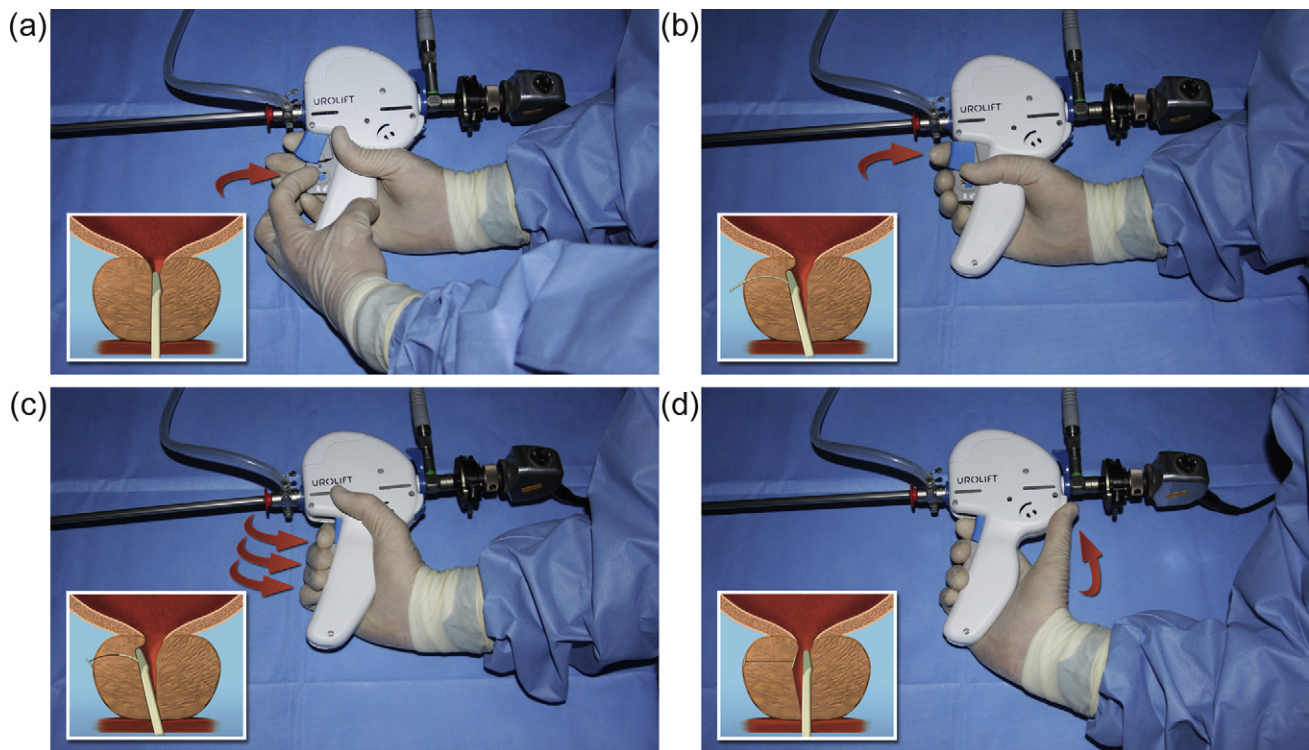


Fig. 5 – UroLift system delivery steps: (a) release safety lock, (b) deploy needle, (c) retract needle, delivering capsular tab and tensioning monofilament, (d) attach urethral end piece and trim monofilament.

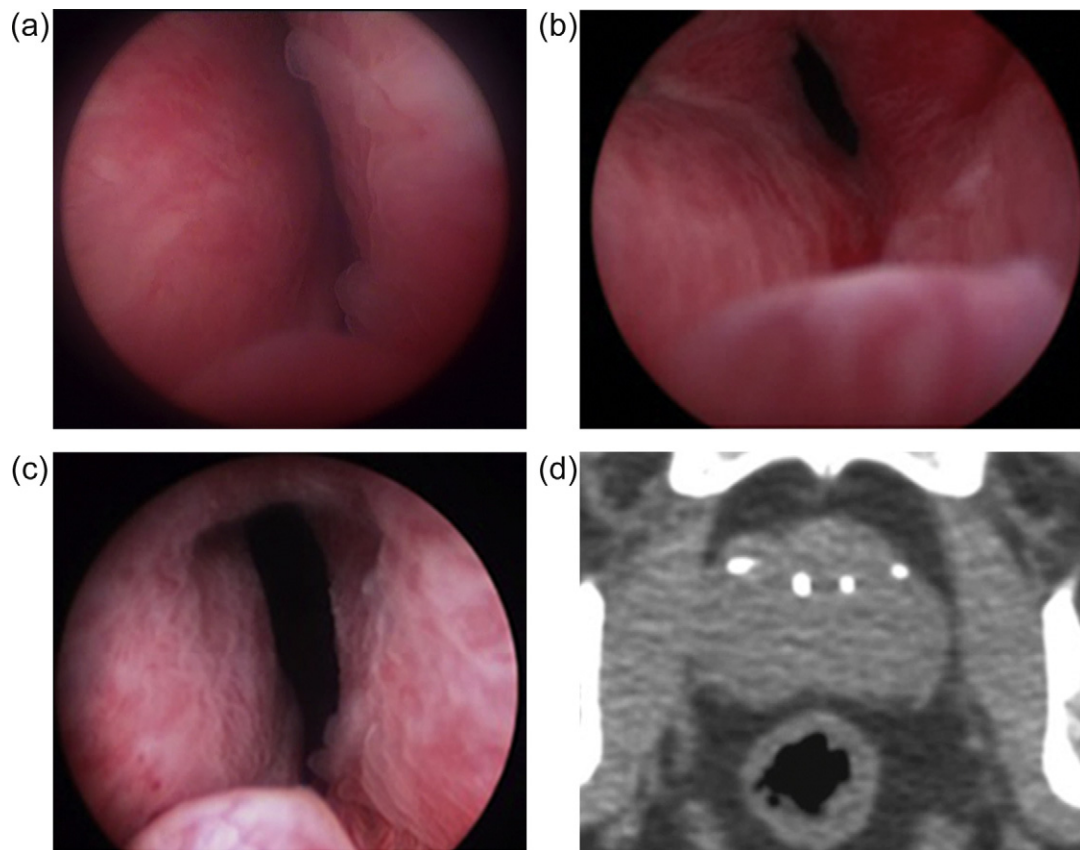


Fig. 6 – Surgical result of prostatic urethral lift. Cystoscopic view (a) prior to implantation, (b) directly after implantation, and (c) at 6 mo postimplantation. Computed tomography image (d) taken at 6 mo postimplantation shows metallic end pieces of UroLift implants situated on prostatic urethra and capsule.

Table 1 – International Prostate Symptom Score, Quality-of-Life scale, Benign Prostatic Hyperplasia Impact Index, maximum flow rate, and postvoid residual volume change from baseline through 1 year^a

	2 wk	6 wk	3 mo	6 mo	12 mo
IPSS					
n, paired values	56	95	82	75	51
Baseline	22.7 ± 5.6	22.9 ± 6.1	23.3 ± 6.0	23.2 ± 5.9	23.9 ± 6.3
Follow-up	14.5 ± 7.2	12.2 ± 6.6	10.7 ± 6.3	11.4 ± 6.0	11.6 ± 5.6
Change	–8.2	–10.7	–12.6	–11.8	–12.3
% change	–36	–47	–54	–51	–52
(95% CI)	(–26 to –46)	(–40 to –53)	(–48 to –61)	(–44 to –58)	(–45 to –58)
p value	<0.001	<0.001	<0.001	<0.001	<0.001
QOL					
n, paired values	55	73	65	59	43
Baseline	4.9 ± 0.9	4.7 ± 1.0	4.8 ± 0.9	4.7 ± 1.0	4.8 ± 1.0
Follow-up	3.0 ± 1.6	1.8 ± 1.3	2.0 ± 1.4	2.0 ± 1.3	2.3 ± 1.5
Change	–1.9	–2.9	–2.8	–2.7	–2.6
% change	–39	–62	–59	–58	–53
(95% CI)	(–32 to –47)	(–55 to –68)	(–48 to –66)	(–51 to –66)	(–44 to –62)
p value	<0.001	<0.001	<0.001	<0.001	<0.001
BPHII					
n, paired values	48	68	65	64	47
Baseline	7.3 ± 2.5	7.7 ± 2.5	7.6 ± 2.5	7.6 ± 2.5	7.7 ± 2.6
Follow-up	5.5 ± 3.6	3.4 ± 2.7	3.3 ± 2.8	3.4 ± 2.6	2.9 ± 2.8
Change	–1.8	–4.3	–4.3	–4.2	–4.7
% change	–24	–55	–57	–55	–62
(95% CI)	(–7 to –42)	(–46 to –64)	(–47 to –66)	(–46 to –65)	(–51 to –73)
p value	0.005	<0.001	<0.001	<0.001	<0.001
Q_{max}, ml/s					
n, paired values	32	67	80	53	41
Baseline	9.6 ± 3.2	8.9 ± 3.5	8.6 ± 3.8	8.5 ± 3.9	7.8 ± 4.0
Follow-up	13.3 ± 4.7	13.6 ± 5.3	12.9 ± 4.5	12.9 ± 5.0	11.9 ± 3.5
Change	3.7	4.7	4.3	4.4	4.0
% change	38	53	50	52	51
(95% CI)	(29 to –48)	(34 to –71)	(31 to –70)	(26 to –78)	(17 to –86)
p value	<0.001	<0.001	<0.001	<0.001	<0.001
PVR, ml					
n, paired values	28	48	41	37	29
Baseline	102 ± 91	112 ± 86	109 ± 91	105 ± 86	103 ± 89
Follow-up	91 ± 105	106 ± 112	95 ± 73	71 ± 86	106 ± 69
Change	–11	–7	–14	–35	3
% change	–10	–6	–13	–33	3
(95% CI)	(–61 to –41)	(–41 to –29)	(–44 to –18)	(–65 to –0.4)	(–41 to –46)
p value	0.099	0.775	0.082	0.002	0.299
BPHII = Benign Prostatic Hyperplasia Impact Index; CI = confidence interval; IPSS = International Prostate Symptom Score; PVR = postvoid residual; Q _{max} = maximum flow rate; QOL = quality-of-life (scale).					
^a Change in each parameter is listed in absolute terms, and in percentage change with a 95% CI.					

instantly melts the PET monofilament, and we found that virtually no consideration needed to be given to the presence of the implants. A total of 92% of patients either received no catheter (42%) or were catheterized overnight per hospital protocol (58%). Seven patients presented in urinary retention at baseline, and all remain catheter free with a mean follow-up of 8.3 mo (range: 1–12 mo).

The prostatic urethral lift improved LUTS rapidly and significantly throughout the 1-yr follow-up period (Table 1). IPSS was reduced 36% by 2 wk, reached maximal response by 3 mo, and remained improved by 52% at 1 yr. Quality of life, as measured by IPSS, QOL, and in some cases by BPHII, improved 53% and 62% at 1 yr, respectively. Q_{max} was statistically improved at all time points, remaining 51% improved at 1 yr. PVR volume displayed a large variance but remained stable from baseline to 1 yr. Although this study did not collect sexual function data via validated instruments, all were asked, and no patient reported a loss of ejaculatory emission.

4. Discussion

In the development of any new surgical procedure, it is important to have peer-reviewed communication on proper technique to enhance outcomes. In this paper we offer our current thinking on the optimal technique. As this promising therapy is more widely adopted, we confidently expect further developments of technique to address the variants of prostate anatomy. Surgical judgment and skill are required for optimal outcomes from the minimally invasive prostatic urethral lift.

For the vast majority of men experiencing obstructive LUTS, BPH is a quality-of-life issue. Treatment is only sought when the risk–benefit profile of the therapy appeals as likely to improve the patient's quality of life. As an example, for up to 30% of men taking BPH drugs, the annoyance of medical therapy outweighs the benefit and they discontinue therapy [1,2]. It is well known that most

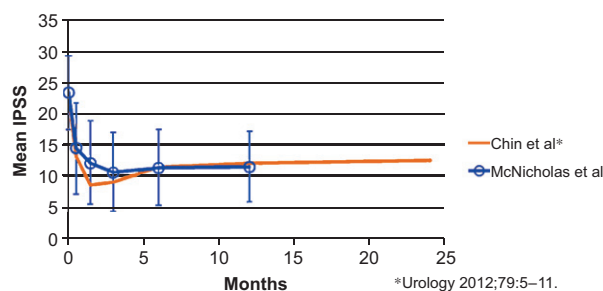


Fig. 7 – Comparison of results of this retrospective registry with prior published prospective data, showing a consistent therapeutic effect. IPSS = International Prostate Symptom Score.

TURP patients experience some form of sexual dysfunction, irritative symptoms (sometimes associated with temporary incontinence), and a prolonged recovery period. Because of this risk–benefit profile, many patients and their physicians do not accept TURP as an option. Several studies have shown that LUTS have a lesser impact on overall quality of life than sexual function or continence [11–15]. Risking compromise of these key functions with the goal of improving quality of life may not be appropriate. Finally, treatment with the less invasive microwave and radiofrequency heating therapies may also have fewer complications than TURP but is known to have unpredictable results and require 1–2 mo of worsened symptoms before improvement [3–5].

The prostatic urethral lift has emerged as a minimally invasive alternative treatment for LUTS secondary to BPH. Clinical experience has shown that this therapy offers a treatment paradigm very different from that of TURP or other interventional therapies. This retrospective registry of real-world results corroborates the findings of controlled prospective studies [7–10]: Patients have a meaningful improvement in LUTS by 2 wk while preserving normal prostate and ejaculatory function. Compared with TURP, the adverse effects of prostatic urethral lift appear to be minimal with patients reporting a complete return to normal activity by 9 d [7] and no report of sustained sexual dysfunction or incontinence [8,9]. As with any newly available therapy, long-term durability data in a large population are not yet available. The results of this study show a stable symptomatic relief over 1 yr that corroborates earlier results (Fig. 7) [8]. For the ideal lift patient, the risk of as yet unknown long-term results is outweighed by the benefit of achieving rapid relief while preserving sexual function, continence, and a normal quality of life.

The results of this study have the clear limitations of a nonblinded single-arm registry. Inclusion criteria, medication usage, and follow-up time intervals were not as controlled as in prospective studies. Randomized controlled studies of the prostatic urethral lift are currently underway across Europe, North America, and Australia (ClinicalTrials.gov identifiers NCT01294150 and NCT01533038). The current data, unlike those of randomized studies, do

represent the results of consecutive patients in normal urologic practices. With high-quality clinical data emerging and a clearly unique therapeutic offering evident, we believe this therapy may have a permanent place in our standard of care for BPH.

5. Conclusions

For most symptomatic men, LUTS secondary to BPH is a quality-of-life issue. Treatment with the prostatic urethral lift appears to offer rapid relief of symptoms while maintaining normal prostate and sexual function. Proper surgical technique can minimize postoperative adverse effects such as mild to moderate dysuria and hematuria and optimize the effectiveness of this minimally invasive therapy. The UroLift system appears to offer a unique option for the treatment of BPH. Randomized studies of this procedure are currently underway.

Author contributions: Thomas A. McNicholas had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Study concept and design: McNicholas, Woo, Fernández Arjona, Wetterauer, Vrijhof, Sievert.

Acquisition of data: McNicholas, Schoenthaler, Wetterauer, Vrijhof, Fernández Arjona, Chin, Woo, Bolton.

Analysis and interpretation of data: McNicholas.

Drafting of the manuscript: McNicholas, Woo, Chin.

Critical revision of the manuscript for important intellectual content: McNicholas, Schoenthaler, Wetterauer, Sievert, Vrijhof, Fernández Arjona, Chin, Woo, Bolton, Gange, Montorsi.

Statistical analysis: McNicholas, statistical consultant.

Obtaining funding: McNicholas, Schoenthaler, Wetterauer, Vrijhof, Fernández Arjona, Chin, Woo, Bolton.

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Supervision: McNicholas.

Other (specify): NeoTract, Inc. assisted in video editing and provided device-specific materials.

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Appendix A. Supplementary data

The Surgery in Motion video accompanying this article can be found in the online version at <http://dx.doi.org/10.1016/j.eururo.2013.01.008> and via www.europeanurology.com.

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