The Prostatic Urethral Lift for the Treatment of Lower Urinary Tract Symptoms Associated with Prostate Enlargement Due to Benign Prostatic Hyperplasia: The L.I.F.T. Study

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Purpose: We report the first multicenter randomized blinded trial of the prostatic urethral lift for the treatment of lower urinary tract symptoms secondary to benign prostatic hyperplasia.

Materials and Methods: Men at least 50 years old with AUASI (American Urological Association Symptom Index) 13 or greater, a maximum flow rate 12 ml per second or less and a prostate 30 to 80 cc were randomized 2:1 between prostatic urethral lift and sham. In the prostatic urethral lift group small permanent implants are placed within the prostate to retract encroaching lobes and open the prostatic urethra. Sham entailed rigid cystoscopy with sounds mimicking the prostatic urethral lift. The primary end point was comparison of AUASI reduction at 3 months. The prostatic urethral lift arm subjects were followed to 1 year and assessed for lower urinary tract symptoms, peak urinary flow rate, quality of life and sexual function.

Results: A total of 206 men were randomized (prostatic urethral lift 140 vs sham 66). The prostatic urethral lift and sham AUASI was reduced by 11.1 ± 7.67 and 5.9 ± 7.66, respectively ($p = 0.003$), thus meeting the primary end point. Prostatic urethral lift subjects experienced AUASI reduction from 22.1 baseline to 18.0, 11.0 and 11.1 at 2 weeks, 3 months and 12 months, respectively, $p < 0.001$. Peak urinary flow rate increased 4.4 ml per second at 3 months and was sustained at 4.0 ml per second at 12 months, $p < 0.001$.

Abbreviations and Acronyms

AE = adverse event
BPH = benign prostatic hyperplasia
BPHII = BPH Impact Index
IIEF = International Index of Erectile Function
ITT = intent to treat
LUTS = lower urinary tract symptoms
MSHQ-EjD = Male Sexual Health Questionnaire for Ejaculatory Dysfunction
PUL = prostatic urethral lift
PVR = post-void residual volume
Qmax = peak urinary flow
QOL = quality of life
TURP = transurethral resection of the prostate

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See Editorial on page 1976.

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Adverse events were typically mild and transient. There was no occurrence of de novo ejaculatory or erectile dysfunction.

Conclusions: The prostatic urethral lift, reliably performed with the patient under local anesthesia, provides rapid and sustained improvement in symptoms and flow, while preserving sexual function.

Key Words: prostate; prostatic hyperplasia; urethra; surgical procedures, minimally invasive; therapeutics

Bothersome LUTS due to BPH affect 30% of men older than 50 years including 8 million men in the United States.[1,2] All currently available treatments have a balance of risks and benefits, leaving a large chasm between medical and surgical options. Medical therapy provides a modest 3.5 to 7.5 AUASI improvement at 1 year. However, bothersome side effects or inadequate relief prompt 30% of men to discontinue treatment.[1,2] Transurethral resection of the prostate, considered the surgical gold standard for BPH, offers a 14.9 AUASI improvement, but this improvement comes with a 20% perioperative morbidity rate and long-term complications that include incontinence (3%), strictures (7%), erectile dysfunction (10%) and loss of ejaculatory function (65%).[3,4] While new laser based modalities have demonstrated decreased bleeding, they are associated with morbidity rates similar to TURP.[4,5]

The prostatic urethral lift has emerged in the literature as potentially offering rapid and significant mitigation of LUTS while maintaining a morbidity profile considerably better than that of surgical resection or ablation, including a unique preservation of sexual function.[6–10] Permanent intraprostatic UroLift® implants (NeoTract, Inc., Pleasanton, California) are delivered to separate encroaching lateral prostate lobes and relieve obstruction without thermal injury or resection of prostatic tissue. Single arm studies show an AUASI reduction considerably larger than drugs, faster acting than thermal therapies and without serious complications associated with TURP or laser.[6–9] We report the first multicenter randomized controlled and blinded study of PUL. This study encompasses 19 centers in 3 countries and is entitled L.I.F.T. (Luminal Improvement Following Prostatic Tissue Approximation for the Treatment of LUTS secondary to BPH).

MATERIALS AND METHODS

The prostatic urethral lift Procedure

During the prostatic urethral lift procedure, transprostatic adjustable UroLift implants are permanently implanted to retract obstructing lateral lobes and expand the urethral lumen (fig. 1).[6–10] After rigid cystoscopy is performed, the implant delivery device is inserted into the 20Fr sheath. Under cystoscopic visualization using a 2.9 mm 0 degree lens, the delivery device is angled anterolaterally to compress the obstructive lobe. A 19 gauge needle, housing a monofilament with metallic tab, is then deployed through the prostate lobe. As the needle is retracted, the tab engages the prostate capsule and the monofilament is tensioned. Finally, the urethral end-piece is attached to the monofilament, which is then cut, delivering the in situ sized implant. Because the fibromuscular capsule is less compliant than the periurethral tissue, the capsular tab holds firmly in place while the urethral end-piece holds the lobe in its displaced position thus expanding the urethral lumen. When implanted, the urethral end-piece invaginates into the urethral wall where focal injury promotes epithelialization (fig. 2). The objective of the PUL is to create a channel through the anterior aspect of the prostatic fossa.

The sham control procedure was conducted with as similar an experience as possible. For all active and control procedures, a surgical drape was used so that the subject could not see the surgeon or endoscopic image. As a rigid cystoscopy was performed, the surgeon called for devices that were opened but not deployed. A disposable biopsy device was not inserted, but was deployed 4 times to simulate the device sounds.

Study Protocol and Objectives

A prospective, randomized, controlled, blinded study of the prostatic urethral lift procedure was conducted in men with symptomatic BPH. The U.S. Food and Drug Administration, Health Canada and the Therapeutic Goods Administration of Australia approved the study, as did institutional review boards at each of the 19 enrolling sites (Clinicaltrials.gov: NCT01294150). The primary objective was to determine the safety and efficacy of the PUL to support U.S. market approval for the implant

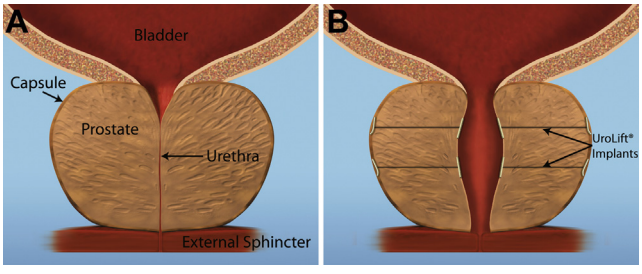

Figure 1. PUL procedure effect showing prostate obstructed by BPH (*A*) and after procedure with permanent implants retracting prostatic tissue and increasing prostatic urethral lumen (*B*).

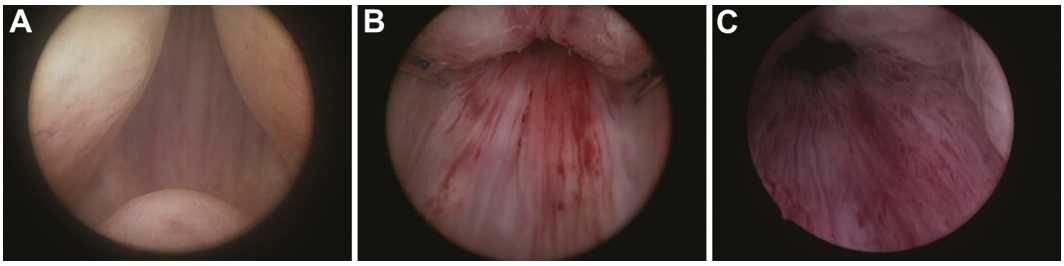

Figure 2. Cystoscopic view of PUL before treatment (*A*), at end of procedure (*B*) and 1 year after treatment (*C*). Implant invaginates into prostatic urethral wall (arrow) leaving epithelialized permanent channel in prostatic fossa.

technology. An independent data monitoring committee assessed safety, and all AEs were adjudicated and assessed by an independent clinical events committee. An independent central reviewer over-read all uroflow waveforms, calculating Qmax using the 2-second rule,[11] and evaluated all cystoscopy videos from baseline and 1 year. A double-blind was maintained through the 3-month end point with the patient and questionnaire administrator blinded to randomization. Blinding of participants was tested upon discharge and at each followup to 3 months.

Eligible subjects were at least 50 years old, provided informed consent, had no prior surgical treatment for BPH, and were required to undergo washouts of 2 weeks for α-blocker, 3 months for 5α-reductase inhibitor and 3 days for anticoagulants. Admission to the study required AUASI 13 or greater, Qmax 12 ml per second or less with a 125 ml voided volume and a 30 to 80 cc prostate. Subjects were excluded for median lobe obstruction, retention, PVR greater than 250 ml, active infection, prostate specific antigen greater than 10 ng/ml (unless negative biopsy), cystolithiasis within 3 months and bacterial prostatitis within 1 year.

The primary efficacy end point was to demonstrate, on an ITT basis, that the reduction in AUASI at 3 months after the PUL procedure was at least 25% greater than that of sham. All subjects in the PUL group were followed through 1 year to evaluate durability of effect. QOL, BPHII, IIEF and the MSHQ-EjD were assessed at 2 weeks and at 1, 3, 6 and 12 months. Qmax and PVR were assessed at 3 and 12 months. The protocol calls for followup visits on an annual basis to 5 years. All subjects were unblinded after the 3-month end point and control patients were offered the PUL or other intervention if symptoms persisted. The long-term results from these patients will be presented in a separate report.

Statistical Methods

Randomization was conducted just before treatment using permuted blocks of various sizes chosen at random through a central electronic data program. The study was powered for the primary end point assuming a Student's t test comparison of mean values on an ITT basis, 0.05 2-sided type 1 error and 80% statistical power. AUASI reductions for the PUL and sham were estimated from available literature. For ITT analysis, any subject that underwent additional BPH therapy (procedure or medications) was treated as a treatment failure and was assigned a zero reduction from baseline.

To evaluate per protocol change from baseline a general estimating equation model was fit to each output parameter. 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 followup interval compared to baseline.

RESULTS

Procedure

Between February and December 2011, 206 men were 2:1 randomized and treated with the PUL (140) or sham control (66) across 19 centers (United States 14, Canada 2, Australia 3). Baseline demographics were similar among randomized groups (table 1). All subjects were evaluated for the ITT primary end point at 3 months with 2 subjects counted as zero change due to initiating BPH medication (fig. 3). After the randomized comparison followup, all subjects were unblinded. Of 66 control subjects 53 later elected to undergo the PUL procedure and followup will be detailed in another report. There were 123 PUL subjects included in the per protocol analysis at 12 months. Five subjects elected to undergo PUL revision due to insufficient response. Two subjects elected subsequent prostate resection. Seven subjects were censored due to use of BPH medication. One subject discontinued participation and 2 were excluded from study due to significant protocol deviations.

Table 1. *Subject demographics*

	PUL Group Mean (SD)	Control Group Mean (SD)
Age	67 (8.6)	65 (8.0)
Ht (in)	70.1 (2.5)	69.4 (3.6)
Wt (lbs)	197.3 (30.7)	187.8 (30.2)
Body mass index (kg/m^2)	28.3 (4.2)	27.4 (3.6)
Prostate vol (cc)	44.5 (12.4)	40.9 (10.8)
AUASI	22.2 (5.4)	24.4 (5.8)
Qmax (ml/sec)	8.9 (2.2)	8.8 (2.2)
PVR (ml)	85.5 (69.2)	87.7 (72.4)
QOL	4.6 (1.1)	4.7 (1.1)
Prostate specific antigen (ng/ml)	2.4 (2.0)	2.1 (1.6)
IIEF-5	13.0 (8.4)	13.5 (8.5)
MSHQ-EjD	8.7 (3.2)	8.8 (3.2)

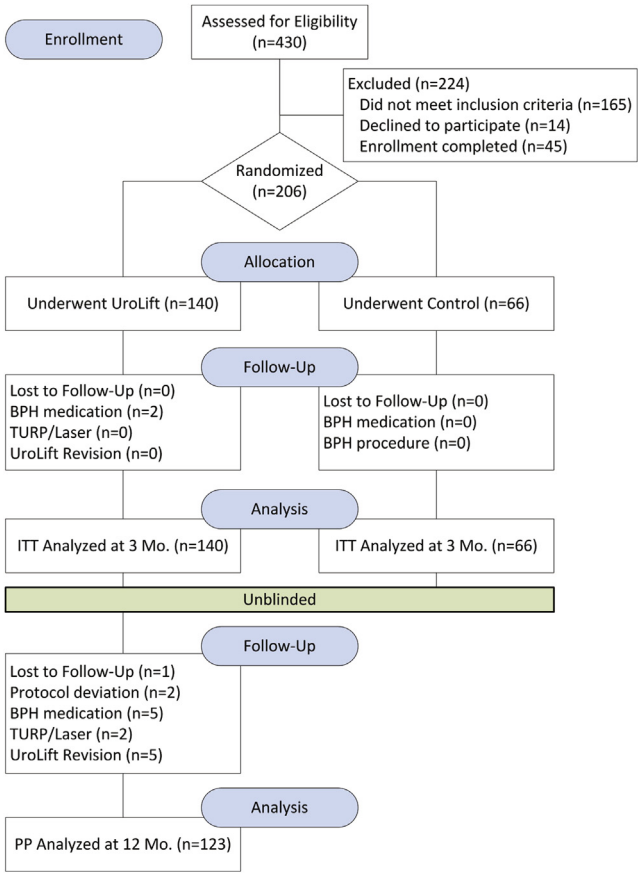

Figure 3. CONSORT (CONsolidated Standards of Reporting Trials) flow diagram of L.I.F.T. study.

All procedures were successfully completed with no perioperative serious AEs. Overall PUL procedure time was 66.2 ± 23.8 minutes, while that for control was 46.8 ± 17.2. An average of 4.9 implants (range 2 to 11) was delivered in prostates ranging from 30 to 77 cc. While Australian standard of care dictated general anesthesia, in North America 168 of 169 procedures were conducted with the patient under local anesthesia. Only 4 procedures used a periprostatic block and the remainder used 10 mg oral diazepam 30 minutes before the procedure and instillation of (4C) 2% lidocaine liquid to the bladder via catheter and cold 2% lidocaine gel to the urethra. The penis was then clamped for 20 minutes. A nurse engaged the conscious patient behind the surgical drape. Postoperative catheterization was administered in 40 PUL subjects as a standard of care. Of the remaining 100 subjects 68 (68%) required no catheter after void trial and the mean duration of catheterization was 0.9 days. PUL subjects reported a return to preoperative activity level as 8.6 ± 7.5 days, compared to 3.1 ± 4.4 days for control. Blinding and the sham procedure were successful with more than 80% of control subjects guessing they underwent PUL or were not sure at point of discharge. This rate remained at 57% at 3 months followup. Only 4 subjects were unblinded within 3 months.

Efficacy

The primary end point was met at 3 months AUASI reduction being at least 25% greater for the PUL than that of control ($p = 0.003$, fig. 4). The mean AUASI reduction for the PUL was 88% greater than sham control. In addition to AUASI, PUL therapeutic effects were significantly better than control with regard to Qmax, QOL and BPHII (table 2). There was no statistical difference between groups with regard sexual function. PUL AUASI reduction was clinically and statistically significant by 2 weeks, further improved to 3 months and was sustained at 1 year (table 3). Durability of effect was further tested by comparing cumulative frequency of AUASI change at 6 and 12 months (fig. 5).

Safety

Two serious AEs were adjudicated as related to the procedure (table 4). The first entailed an overnight stay for clot retention coincident with reinitiating warfarin therapy, and the second was a subject who required removal of a bladder stone at 12 months that had formed from confirmed bladder gravel at baseline and was not associated with an implant. One subject died of unrelated causes as adjudicated by clinical events committee and data monitoring committee. Less serious AEs (postoperative dysuria, hematuria, pain/discomfort and urgency) were typically mild to moderate and resolved within 2 weeks. There was no incidence of de novo sustained ejaculatory or erectile dysfunction.

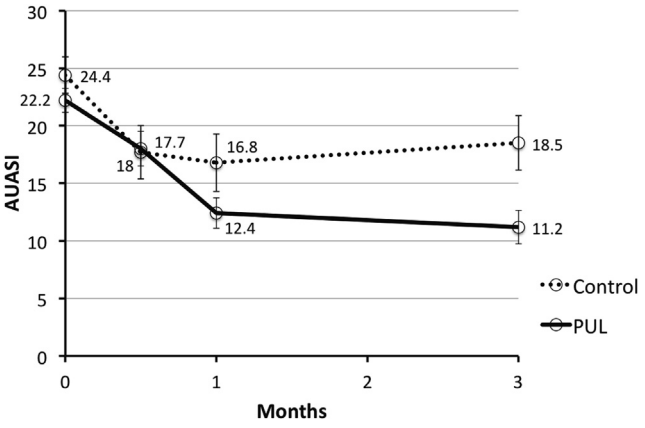

Figure 4. Comparison of AUASI score throughout blinded period for subjects randomized to PUL arm and sham control arm. Values shown are mean and error bars represent 95% CI. All points reflect ITT population of 140 PUL and 66 control subjects.

Table 2. *Comparison of mean change in outcomes at 3 months*

Outcome Measure	PUL-ITT Group Mean, SD (No. responses)			Control ITT Group Mean, SD (No. responses)			p Value (2-sample t - test)
	Baseline	*3 Mos*	*Change*	*Baseline*	*3 Mos*	*Change*	
AUASI	22.2, 5.48 (140)	11.2, 7.65 (140)	−11.1, 7.67 (140)	24.4, 5.75 (66)	18.5, 8.59 (66)	−5.9, 7.66 (66)	0.003
Qmax (ml/sec)	8.02, 2.43 (126)	12.29, 5.40 (126)	4.28, 5.16 (126)	7.93, 2.41 (56)	9.91, 4.29 (56)	1.98, 4.88 (56)	0.005
QOL	4.6, 1.1 (140)	2.4, 1.7 (140)	−2.2, 1.8 (140)	4.7, 1.1 (66)	3.6, 1.6 (66)	−1.0, 1.5 (66)	<0.001
BPHII	6.9, 2.8 (140)	3.0, 3.1 (140)	−3.9, 3.2 (140)	7.0, 3.0 (66)	4.9, 3.2 (66)	−2.1, 3.3 (66)	<0.001
MSHQ-EjD	8.7, 3.1 (94)	10.9, 3.2 (94)	2.2, 2.5 (94)	8.8, 3.1 (50)	10.5, 3.5 (50)	1.7, 2.6 (50)	0.283
MSHQ-Bother	2.4, 1.7 (117)	1.6, 1.7 (117)	−0.8, 1.5 (117)	2.2, 1.7 (60)	1.5, 1.7 (60)	−0.7, 1.6 (60)	0.595
IIEF-5	13.3, 8.4 (132)	13.4, 9.2 (132)	0.1, 5.8 (132)	13.7, 8.5 (65)	15.2, 8.5 (65)	1.5, 6.4 (65)	0.139
PVR (ml)	85.5, 69.2 (140)	75.8, 83.9 (140)	−9.7, 85.5 (140)	85.6, 70.8 (65)	63.4, 64.0 (65)	−22.2, 70.7 (65)	0.306

Of the 140 PUL subjects 131 (94%), with a total of 642 implants, agreed to undergo cystoscopy at 12 months. Independent video review, conducted on 127 available videos, found no strictures, a mild increase in inflammation and edema in only 1 and 5 patients, respectively, and no evidence of abnormal pathology. There was no evidence of encrustation on implants delivered within the prostate. Encrustation was observed on 14 (2.1%) implants in 10 subjects that were inadvertently delivered such that part of the implant was exposed inside the bladder. An additional 13 implants showed some exposure to the bladder with no encrustation. One encrusted implant was later removed with endoscopic forceps.

DISCUSSION

The results of this randomized study confirm that the PUL can offer rapid and durable LUTS relief with minimal morbidity and no compromise of sexual function. AUASI was reduced from baseline by 4 points at 2 weeks, reached 11 points by 3 months and remained stable to 1 year. Qmax improvement (4 ml per second) was both clinically and statistically significant. The formidable sham effect

Table 3. *Change in outcomes from baseline through 1 year*

	2 Wks	1 Mo	3 Mos	6 Mos	12 Mos
AUASI:					
No. (paired)	137	137	137	133	123
Mean ± SD baseline	22.1 ± 5.4	22.1 ± 5.4	22.1 ± 5.4	21.9 ± 5.4	21.8 ± 5.4
Mean ± SD followup	18.0 ± 7.9	12.3 ± 6.9	11.0 ± 7.6	11.0 ± 7.3	11.1 ± 7.0
Change	−4.1	−9.8	−11.1	−10.9	−10.8
% Change (95% CI)	−17 (−10 − −24)	−44 (−38 − −49)	−50 (−44 − −56)	−49 (−43 − −55)	−49 (−42 − −55)
p Value	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001
QOL:					
No. (paired)	137	137	137	133	123
Mean ± SD baseline	4.6 ± 1.1	4.6 ± 1.1	4.6 ± 1.1	4.6 ± 1.1	4.5 ± 1.0
Mean ± SD followup	3.6 ± 1.6	2.6 ± 1.7	2.4 ± 1.7	2.1 ± 1.7	2.2 ± 1.6
Change	−1.0	−2.0	−2.2	−2.4	−2.4
% Change (95% CI)	−17 (−9 − −26)	−42 (−35 − −49)	−47 (−39 − −54)	−52 (−45 − −59)	−51 (−45 − −58)
p Value	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001
BPHII:					
No. (paired)	137	137	137	133	123
Mean ± SD baseline	6.8 ± 2.8	6.8 ± 2.8	6.8 ± 2.8	6.8 ± 2.8	6.6 ± 2.8
Mean ± SD followup	7.0 ± 3.4	4.0 ± 3.1	2.9 ± 3.0	2.6 ± 2.8	2.7 ± 2.9
Change	0.2	−2.8	−3.9	−4.2	−4.0
% Change (95% CI)	+3.1 (0.7 − 5.4)	−33 (−18 −−47)	−56 (−47 − −65)	−60 (−52 − −68)	−59 (−49 − −68)
p Value	0.613	<0.0001	<0.0001	<0.0001	<0.0001
Qmax (ml/sec):					
No. (paired)			124		103
Mean ± SD baseline			8.1 ± 2.4		8.1 ± 2.4
Mean ± SD followup			12.4 ± 5.4		12.1 ± 5.4
Change			4.4		4.0
% Change (95% CI)			64 (48 − 80)		59 (41−77)
p Value			<0.0001		<0.0001
PVR (ml):					
No. (paired)			137		120
Mean ± SD baseline			83 ± 67		82 ± 66
Mean ± SD followup			72 ± 81		70 ± 98
Change			−11		−12
% Change (95% CI)			−40 (11 − −91)		−18 (18−54)
p Value			0.1460		0.1111

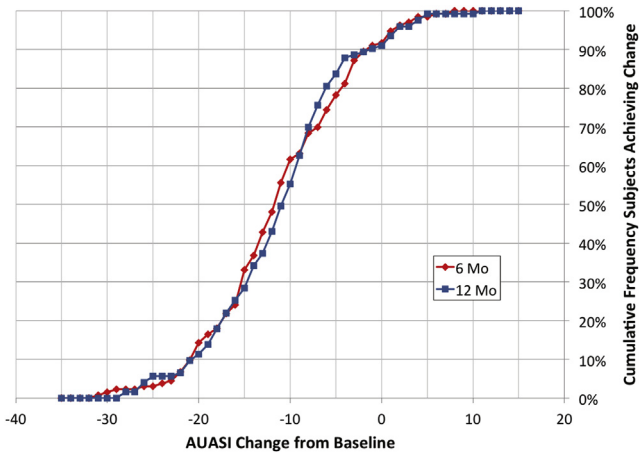

Figure 5. Cumulative frequency distribution of subjects achieving AUASI reduction at 6 and 12 months. Cumulative frequency shows percent of subjects (y axis) achieving each AUASI change (x axis). Decreasing durability would show rightward shift in data from 6 to 12 months but instead data are superimposable.

observed in this study and in the literature is likely due to a combination of placebo, dilation and regression.[12–16] Nevertheless, PUL treatment effect was considerably and statistically greater in all measures. Covariate analysis using an ANCOVA model showed no effect of prostate volume on this result. Stable erectile function and the absence of ejaculatory dysfunction suggest that this tissue sparing approach does not cause the adverse sexual function effects that accompany other BPH therapies.[3,17] The low morbidity and ability to conduct the procedure with the patient under local anesthesia suggest that the PUL may offer benefits in the treatment of LUTS secondary to BPH.

This study demonstrates the durability of the PUL to 1 year and AUASI improvement corroborates prior 2-year results.[6,8] The 5% re-treatment rate at 1 year is similar to prior reports showing 6% at 1 year and 8% at 2 years.[6,8] Two subjects (1.4%) were treated with TURP and laser vaporization without difficulty or complication, as with prior reports.[6–8] Five PUL revisions were conducted routinely with good acute results. Figure 5 offers a method by which to predict long-term durability. Decreasing durability would show a rightward shift in the data from 6 to 12 months but instead the data are superimposable. This protocol will continue to follow subjects an additional 4 years to confirm the predicted stability of effect.

Intensive inspection was given to long-term cystoscopic examination of the implants, demonstrating biocompatibility and no occurrence of encrustation within the prostatic urethra. It is important to note that this procedure does require surgical skill and decision making gained from experience. Misplacement of the implant such that it is exposed to bladder urine may result in encrustation. Closely adhering to the technique of implant delivery no closer than 1 cm to the bladder neck and insuring appropriate angulation can avoid this issue. We recommend that at the end of each PUL procedure, the operator inspect the bladder interior to confirm that no implants are exposed. If detected, the misplaced implant can be easily removed with endoscopic forceps.

Preservation of ejaculatory function has been shown to be of importance to men and has recently become a focus in evaluating BPH therapies, both interventional and medical.[18–21] No PUL subjects experienced de novo sustained erectile dysfunction or anejaculation. We believe this result to be an important advantage of the PUL. If a man achieves LUTS relief yet the treatment impacts the ability to perform sexually, the overall quality of life may not be improved.

Table 4. *Overview of adjudicated adverse events*

	PUL Group 0-3 Mos		Control Group 0-3 Mos		PUL Group 3-12 Mos	
	No. Events	No. Subjects (%)	No. Events	No. Subjects (%)	No. Events	No. Subjects (%)
Serious AEs	9	7 (5.0)	1	1 (1.5)	16	16 (11.4)
Related seriasAE	1	1 (0.7)	0	0 (0)	1	1 (0.7)
All AEs	268	122 (87.1)	53	34 (51.5)	144	73 (52.1)
Related AEc	203	113 (80.7)	26	20 (30.3)	44	35 (25.0)
Dysuria		48 (34.3)		11 (16.7)		1 (0.7)
Hematuria		36 (25.7)		3 (4.5)		1 (0.7)
Pelvic pain/discomfort		25 (17.9)		3 (4.5)		2 (1.4)
Urgency		10 (7.1)		0 (0)		3 (2.1)
Bladder spasm		5 (3.6)		0 (0)		1 (0.7)
Urge incontinence		5 (3.6)		1 (1.5)		1 (0.7)
Urinary tract infection		4 (2.9)		1 (1.5)		0 (0)
Retention		1 (0.7)		1 (1.5)		1 (0.7)
Erectile dysfunction		0 (0)		0 (0)		0 (0)
Retrograde ejaculation		0 (0)		0 (0)		0 (0)

CONCLUSIONS

The prostatic urethral lift provides a clinically meaningful improvement in LUTS secondary to BPH and urinary flow. The procedure can reliably be performed with the patient under local anesthesia with low morbidity and preserves of all aspects of sexual function. This rapidly acting and minimally invasive treatment offers attractive benefits for the treatment of symptomatic BPH.

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