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Durability of the Prostatic Urethral Lift: 2-Year Results of the L.I.F.T. Study

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Abstract

Introduction: For a therapy to become an important part of a provider armamentarium it must be safer or better than existing therapies and be durable. The prostatic urethral lift offers rapid improvement in lower urinary tract symptoms associated with benign prostatic hyperplasia with minimal side effects. We report 2-year results of a multicenter, randomized, blinded trial of the prostatic urethral lift.

Methods: A total of 206 men 50 years old or older with an AUA-SI of 13 or greater, a peak flow rate of 12 ml per second or less and a 30 to 80 cc prostate were randomized 2:1 between the prostatic urethral lift and sham treatment. The prostatic urethral lift is performed by placing permanent transprostatic implants to lift apart the prostate lobes and reduce urethral obstruction. Sham treatment entailed rigid cystoscopy, a blinding screen and sounds that mimicked those of the prostatic urethral lift procedure. Patients were assessed for lower urinary tract symptoms, peak flow rate, quality of life and sexual function.

Results: The prostatic urethral lift reduced the AUA-SI 88% more than sham treatment (−11.1 vs −5.9, $p = 0.003$). Patients with the prostatic urethral lift experienced an AUA-SI reduction from 22.1 at baseline to 18.0 (−17%), 11.1 (−50%), 11.4 (−48%) and 12.5 (−42%) at 2 weeks, 3 months, and 1 and 2 years, respectively ($p < 0.0001$). The peak flow rate was increased 4.2 ml per second at 3 months and 2 years ($p < 0.0001$). By 2 years only 7.5% of patients required additional intervention for lower urinary tract symptoms. Adverse events were typically mild and transient. Encrustation did not develop on implants properly placed in the prostate. There was no occurrence of de novo sustained ejaculatory or erectile dysfunction.

Conclusions: The prostatic urethral lift preserves sexual function and provides rapid improvement in symptoms, flow and quality of life that are sustained to 2 years.

Key Words: urethra, prostate, benign prostatic hyperplasia, minimally invasive surgical procedures, prostheses and implants

Abbreviations and Acronyms

AUA-SI = American Urological Association Symptom Index

BPH = benign prostatic hyperplasia

BPHII = BPH Impact Index

FDA = Food and Drug Administration

GEE = general estimating equation

L.I.F.T. = Luminal Improvement Following Prostatic Tissue Approximation for the Treatment of LUTS secondary to BPH

LUTS = lower urinary tract symptoms

MSHQ-EjD = Male Sexual Health Questionnaire for Ejaculatory Dysfunction

PUL = prostatic urethral lift

Qmax = peak urinary flow rate

QOL = quality of life

SHIM = Sexual Health Inventory for Men

TURP = transurethral prostate resection

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Moderate to severe LUTS due to BPH affect almost 1 of 3 men older than 50 years. First line medical therapy provides a modest symptomatic improvement but compliance is poor with 25% to 30% of men abandoning medication, often due to insufficient relief and bothersome side effects.[1,2] Transurethral resection, vaporization and enucleation of the prostate offer greater durable improvement in symptoms and flow but are associated with significant morbidity, including permanent incontinence, stricture, erectile dysfunction and a high incidence of ejaculatory dysfunction.[3–5] Minimally invasive thermotherapies such as microwave and radiofrequency ablation offer improvement in symptoms without serious complication but are associated with high rates of postoperative irritation, catheterization and retreatment.[6,7]

PUL is performed by cystoscopically installing permanent UroLift® transprostatic implants that sculpt the prostate to reduce obstruction. PUL offers rapid, significant improvement in symptoms and flow while preserving ejaculatory and erectile function, and avoiding other complications associated with resection, vaporization and thermal heating.[8–14] AUA-SI is significantly decreased by 2 weeks and durable to 1 year. An open label study showed favorable outcomes in a small PUL cohort to 2 and 3 years.[13]

We report the 2-year results of a multicenter, randomized study of PUL entitled L.I.F.T.: Luminal Improvement Following Prostatic Tissue Approximation for the Treatment of LUTS secondary to BPH. We then set these results in context by reviewing the BPH procedure literature to assess durability and retreatment.

Materials and Methods

Protocol

A prospective, randomized, controlled, blinded study of the safety and effectiveness of the PUL procedure was performed in men older than 50 years with an AUA-SI of 13 or greater, a peak flow rate of 12 ml per second or less with a 125 ml voided volume and a 30 to 80 cc volume prostate as measured by transrectal ultrasound. At 19 centers in the United States, Canada and Australia a total of 206 subjects were randomized 2:1 to active treatment with the PUL device or a sham procedure with rigid cystoscopy. The study was performed with approval from institutional review boards and the United States FDA (Clinicaltrials.gov NCT01294150).

A double blind was maintained and tested through the 3-month end point with the patient and questionnaire administrator blinded to randomization. Subjects were required to undergo a washout of 2 weeks for α-blocker, 3 months for 5α-reductase inhibitor and 3 days for anticoagulants before treatment. Subjects were excluded from study due to prior surgical treatment of LUTS, median lobe obstruction, current urinary retention, post-void residual urine volume greater than 250 ml, active infection, prostate specific antigen greater than 10 ng/ml (unless biopsy was negative), cystolithiasis within 3 months and bacterial prostatitis within 1 year. Those with prostate specific antigen increased above age specific ranges underwent evaluation until prostate cancer was excluded to the satisfaction of the investigator. After the 3-month blinded comparison sham treated patients were allowed to enter a crossover PUL study for persistent symptoms.[9] Men treated with PUL were followed to 2 years and will continue to be followed to 5 years.

Procedures

During PUL adjustable UroLift implants are permanently implanted in the prostate to lift apart the lateral lobes and reduce obstruction of the urethral lumen (fig. 1). Rigid [F1] cystoscopy is first performed to plan the procedure and rule out an obstructive median lobe. The implant delivery device is then inserted in a 20Fr sheath and angled lateral and slightly upward to compress the obstructive lobe. The implant, consisting of a monofilament with a metallic tab, is inserted through the prostatic lobe with a 19 gauge needle and deployed on the prostatic capsule. The monofilament is tensioned, secured by the urethral end piece and cut to a specific width of the compressed lobe at that location.

Because the fibromuscular capsule is less compliant than periurethral tissue, the capsular tab is held in place while the urethral end piece lifts the lateral lobe and expands the urethral lumen. The narrow footprint of the urethral end piece ensures that it embeds in the softer adenoma, promoting epithelialization.

All procedures were performed with a surgical screen such that the patient could not see below his waist. Sham treatment

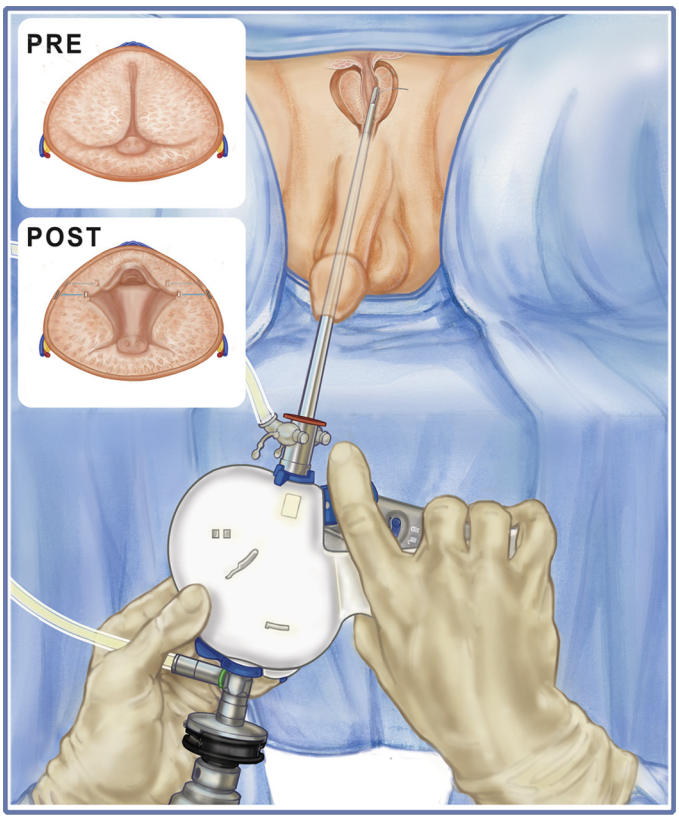

Figure 1. PUL procedure showing transurethral delivery of transprostatic implant. Insets, transverse images of prostate before (*PRE*) and after (*POST*) PUL.

consisted of rigid cystoscopy with sounds that mimicked those of PUL, including firing a biopsy gun to imitate the PUL device.

Assessments

AUA-SI, QOL, BPHII and safety were assessed at each followup visit. AUA-SI questions and groups (storage vs voiding symptoms) were also analyzed individually during followup. Qmax and post-void residual urine volume were recorded at 3, 12 and 24 months. Sexual health was assessed by the SHIM for erectile function and by the MSHQ-EjD. An independent clinical events committee adjudicated all adverse events. Independent central reviewers evaluated all recorded cystoscopic videos and over read all flow waveforms using the 2-second rule.[15] Men were censored from per protocol analysis if they underwent another procedure for LUTS or were actively receiving LUTS medication.

Statistical Methods

To evaluate per protocol change from baseline a GEE model was fit to each output parameter. The change from baseline was the dependent variable, and visit and baseline scores served 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

Early Outcomes

Of 206 men enrolled in study 140 were randomized to and treated with PUL from February to December 2011. In the United States all except 1 procedure (99.4%) were performed using local anesthesia. Four patients also underwent a periprostatic block. The remaining patients typically received oral sedative with 2% lidocaine liquid in the bladder and 2% lidocaine gel in the urethra with 20-minute penile clamping. Patients tolerated the procedure well and no procedure was abandoned due to discomfort.

An average of 4.9 implants was used in prostates ranging in size from 30 to 77 cc. Of patients treated with PUL 32% required catheterization after a voiding trial failed. Mean catheterization duration was 0.9 days in the total cohort and voiding returned to the preoperative activity level by a mean $\pm$ SD of 8.6 $\pm$ 7.5 days. Adverse events were typically mild and transient. The most frequent adverse events were hematuria, dysuria, pelvic pain, urgency and urge incontinence. Sexual function was preserved with no reported incidence of de novo sustained erectile or ejaculatory dysfunction.

The primary end point of the randomized study was met when patients treated with PUL demonstrated an 88% greater decrease in the AUA-SI than those treated with the sham procedure at 3 months (-11.1 vs -5.9, $p = 0.003$).[11] Further, the effects of PUL on Qmax, QOL and BPHII were significantly better than those of controls. AUA-SI subgroup analysis showed that voiding function improved significantly by 2 weeks after PUL while storage function improvement became significant by 4 weeks (each $p < 0.0001$, fig. 2). Storage and voiding symptoms in patients with PUL continued to improve to 3 months. [F2]

Two-Year Results

Subjects experienced symptom relief by 2 weeks, which improved to 3 months and was sustained to 2 years (see table). The average change from baseline at each time point was statistically significant for AUA-SI, Qmax and QOL assessments ($p < 0.0001$). At 2 years symptoms, QOL and Qmax remained improved by 42% (-9.2 AUA-SI), 48% (-2.2 QOL) and 58% (4.2 ml per second), respectively. The therapeutic effect of PUL at 2 years closely mimicked that of previously published results (fig. 3). [T1] [F3]

At 2 years 106 patients treated with PUL were included in the per protocol analysis. Of the men 13 with a mean AUA-SI improvement of -12.6 points at 1 year had missing data or withdrew early from study for a 91% rate of study retention and analysis. Two men were withdrawn from study due to unrelated cancer, 3 died of an unrelated cause as adjudicated by the clinical events committee and the FDA, 4 discontinued the study, 1 was lost to followup and 3 missed the 2-year visit. Data on 11 patients were censored at 2 years due to the use of LUTS medication at followup. When comparing subjects censored due to medication with the rest of the cohort, p values ranged from 0.15 to 0.66, indicating a lack of statistical bias in censoring these subjects. For subjects missing data at 2 years or who refused further participation the change in the AUA-SI at each time point was compared with that of the remaining cohort to determine whether men with missing data were systematically different from subjects evaluated at 2 years. There was no evidence to suggest that men with missing data were doing worse than those who were not missing since p values ranged from 0.15 to 0.38. Overall statistical GEE analysis of missing or censored data showed no significant difference

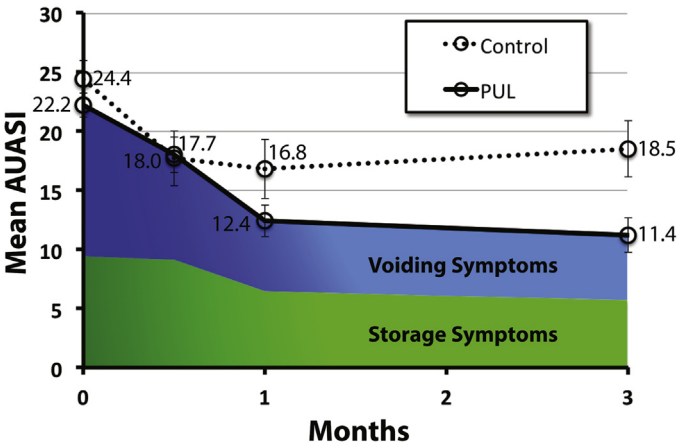

Figure 2. Mean AUA-SI in randomized, blinded PUL and sham treated control groups. AUA-SI PUL reduction was 88% greater than in controls ($p = 0.003$). Subgroup analysis of PUL AUA-SI showed significant voiding symptom decrease by 2 weeks and significant storage symptom decrease by 1 month (each $p < 0.0001$). Subgroups continued to improve to 3 months ($p < 0.0001$). Whiskers indicate 95% CI.

Table.
AUA-SI, QOL, BPHII and Qmax from baseline to 2 years in men treated with PUL

	Mean ± SD 2 Wks		Mean ± SD 1 Mo		Mean ± SD 3 Mos		Mean ± SD 6 Mos		Mean ± SD 12 Mos		Mean ± SD 24 Mos	
AUA-SI:*												
No. pts (paired)	138		138		139		136		126		106	
Baseline	22.22 ± 5.51	(21.30, 23.15)	22.17 ± 5.50	(21.24, 23.09)	22.21 ± 5.50	(21.29, 23.13)	22.11 ± 5.51	(21.18, 23.05)	22.02 ± 5.56	(21.04, 23.00)	21.74 ± 5.62	(20.65, 22.82)
Followup	17.98 ± 7.83	(16.66, 19.30)	12.26 ± 6.90	(11.10, 13.42)	11.08 ± 7.63	(9.80, 12.36)	11.19 ± 7.28	(9.96, 12.43)	11.40 ± 7.25	(10.12, 12.67)	12.52 ± 7.80	(11.02, 14.02)
Change (95% CI)	−4.25 ± 7.63	(−5.53, −2.96)	−9.91 ± 7.08	(−11.10, −8.71)	−11.13 ± 7.68	(−12.42, −9.84)	−10.92 ± 7.62	(−12.21, −9.63)	−10.63 ± 7.44	(−11.94, −9.31)	−9.22 ± 7.57	(−10.67, −7.76)
% Change (95% CI)	−17.3 ± 7.6	(−23.1, −11.6)	−43.9 ± 7.1	(−48.6, −39.2)	−49.9 ± 7.7	(−55.1, −44.6)	−48.8 ± 7.6	(−54.2, −43.4)	−47.8 ± 7.4	(−53.2, −42.3)	−42.0 ± 7.6	(−48.5, −35.4)
QOL:*												
No. pts (paired)	139		138		139		136		126		106	
Baseline	4.60 ± 1.06	(4.42, 4.78)	4.59 ± 1.06	(4.41, 4.77)	4.60 ± 1.06	(4.42, 4.78)	4.58 ± 1.06	(4.40, 4.76)	4.54 ± 1.01	(4.36, 4.72)	4.51 ± 1.00	(4.32, 4.70)
Followup	3.63 ± 1.64	(3.36, 3.91)	2.58 ± 1.67	(2.30, 2.86)	2.38 ± 1.71	(2.09, 2.67)	2.15 ± 1.65	(1.88, 2.43)	2.24 ± 1.60	(1.96, 2.52)	2.29 ± 1.63	(1.98, 2.61)
Change (95% CI)	−0.96 ± 1.73	(−1.25, −0.67)	−2.01 ± 1.74	(−2.30, −1.71)	−2.22 ± 1.78	(−2.51, −1.92)	−2.43 ± 1.68	(−2.71, −2.14)	−2.30 ± 1.59	(−2.58, −2.02)	−2.22 ± 1.71	(−2.55, −1.89)
% Change (95% CI)	−17.3 ± 1.7	(−24.7, −9.8)	−42.0 ± 1.7	(−48.4, −35.7)	−46.8 ± 1.8	(−53.2, −40.3)	−52.2 ± 1.7	(−58.1, −46.2)	−50.7 ± 1.6	(−56.8, −44.7)	−48.2 ± 1.7	(−55.3, −41.1)
BPHII:												
No. pts (paired)	139		138		139		136		126		106	
Baseline	6.84 ± 2.82	(6.37, 7.31)	6.83 ± 2.83	(6.35, 7.30)	6.85 ± 2.83	(6.37, 7.32)	6.87 ± 2.82	(6.39, 7.35)	6.75 ± 2.79	(6.25, 7.24)	6.47 ± 2.87	(5.92, 7.02)
Followup	7.02 ± 3.46	(6.44, 7.60)	4.01 ± 3.04	(3.50, 4.53)	2.89 ± 2.97	(2.39, 3.39)	2.65 ± 2.81	(2.17, 3.12)	2.78 ± 2.90	(2.27, 3.29)	2.71 ± 2.94	(2.14, 3.27)
Change (95% CI)	0.18 ± 3.89	(−0.47, 0.83)	−2.81 ± 3.46	(−3.39, −2.23)	−3.96 ± 3.21	(−4.50, −3.42)	−4.22 ± 3.20	(−4.76, −3.68)	−3.97 ± 3.26	(−4.54, −3.39)	−3.76 ± 3.45	(−4.43, −3.10)
% Change (95% CI)	30.3 ± 3.9	(9.9, 50.7)	−32.6 ± 3.5	(−45.5, −19.7)	−55.8 ± 3.2	(−63.5, −48.0)	−59.8 ± 3.2	(−66.5, −53.1)	−58.1 ± 3.3	(−66.1, −50.1)	−55.6 ± 3.4	(−65.3, −45.9)
p Value (GEE)	0.6135		<0.0001		<0.0001		<0.0001		<0.0001		<0.0001	
Qmax:	–		–				–					
No. pts (paired)					124				105		89	
Baseline					8.02 ± 2.38	(7.60, 8.45)			8.00 ± 2.35	(7.54, 8.46)	8.29 ± 2.38	(7.79, 8.79)
Followup					12.27 ± 5.25	(11.33, 13.20)			11.98 ± 5.24	(10.97, 12.99)	12.44 ± 5.38	(11.30, 13.57)
Change (95% CI)					4.24 ± 5.13	(3.33, 5.15)			3.98 ± 4.92	(3.03, 4.93)	4.15 ± 5.05	(3.08, 5.21)
% Change (95% CI)					63.7 ± 5.1	(49.3, 78.1)			58.4 ± 4.9	(43.0, 73.7)	57.9 ± 5.0	(40.4, 75.5)
p Value (GEE)					<0.0001				<0.0001		<0.0001	

*At 2 weeks, and 1, 3, 6, 12 and 24 months GEE p <0.0001.

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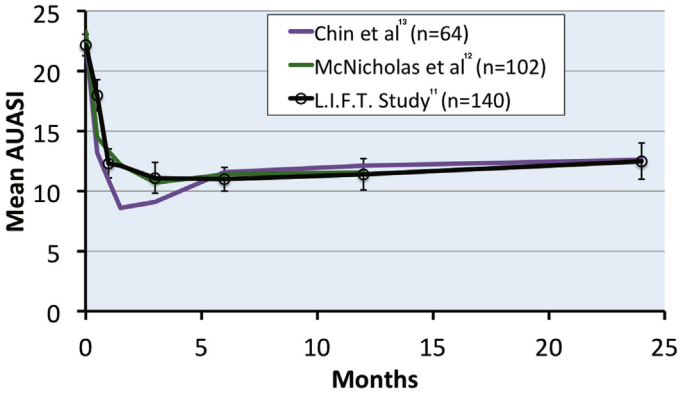

Figure 3. Comparison of mean 2-year results of L.I.F.T. randomized study with previously published data shows consistent therapeutic effect. Whiskers indicate 95% CI.

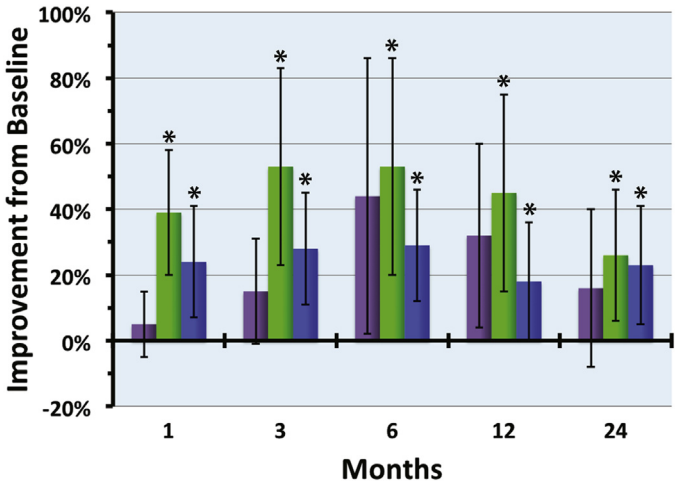

Figure 4. Matched mean percent improvement from baseline for SHIM (blue bars), and MSHQ-EjD function (green bars) and bother (green bars) scores. MSHQ-EjD improvement was defined as decreased bother score and functional improvement was defined as positive change from baseline. Whiskers indicate 95% CI. Asterisk indicates significantly different vs baseline (GEE $p < 0.0001$).

between missing and reported groups, thus, indicating a lack of statistical bias in reported results.

With regard to the need to follow on treatment the data were available on 134 of 140 men. By 2 years 7.5% of the patients underwent an additional LUTS procedure, including 5 who received additional PUL implants and 5 treated with TURP or laser vaporization. All procedures were performed routinely without a complication associated with prior PUL.

Between 1 and 2 years of followup there was 1 related serious adverse event (0.7%) in which a subject experienced chills attributable to analgesia medication after a PUL revision procedure. Eight men underwent a secondary intervention for reasons other than failure to cure, including bladder neck contracture in 1 (0.7%) and urethral stricture in 1 (0.7%), while a calcified PUL implant was removed in 6 (4.4%) using endoscopic graspers, of whom 1 received replacement implants. As reported previously, cystoscopy at 1 year revealed encrustation on 14 of 642 implants (2.1%), which were inadvertently deployed such that part of the implant was exposed to static urine in the bladder. By the 2-year followup 6 subjects with encrusted implants had the implants removed. No encrustation was observed on implants deployed in the prostate. To date 2 patients have undergone radical prostatectomy for prostate cancer. The procedures were performed routinely with no disruption to normal dissection planes caused by the implants.

Sexual function was preserved with no reported incidence of de novo sustained erectile or ejaculatory dysfunction. The SHIM erectile function score remained stable through 2 years (baseline 13.4, 1-month change −0.6, 1-year change 0.3 and [F4] 2-year change 0.0, p not significant, fig. 4). MSHQ-EjD ejaculatory function and bother scores improved by 1 month (function baseline 7.8 and 1-month change 2.0, and bother baseline 2.4 and 1-month change −0.8, each $p < 0.0001$). It remained improved at 2 years (function and bother change 0.9 and −0.7, respectively, $p < 0.0001$).

Discussion

The results of the 2-year analysis of this randomized study confirm that PUL can offer rapid, durable LUTS relief with minimal morbidity and with preservation of sexual function. Symptom relief and urinary flow rate improvements were statistically significant at all time points. AUA-SI subgroup analysis suggests that the PUL mechanism of action is to first reduce urinary obstruction and voiding symptoms, allowing for bladder function and storage symptoms to improve shortly thereafter. Proper training is required for PUL. This study reveals that implants that are not fully in the prostate should be removed perioperatively to prevent possible encrustation. No implant deployed in the prostate showed signs of encrustation. There was no incidence of de novo sustained erectile or ejaculatory dysfunction. As measured by SHIM, erectile function was preserved and ejaculatory function showed statistical improvement that was sustained to 2 years. Preservation of ejaculatory and erectile function is a unique aspect of PUL among LUTS procedures.[3–7] Peak urinary flow rate improvement was clinically and statistically improved by 3 months and maintained to 2 years, further supporting the sustained reduction in urinary obstruction.

PUL was well tolerated with the patient under local anesthesia and most patients who were not catheterized as standard of care did not require catheterization postoperatively. Average time to return to preoperative activity was 9 days.

At 7 L.I.F.T. study centers a subsequent FDA investigational study was performed in an additional 51 patients to better quantify local anesthesia tolerance and postoperative recovery.[8] Tolerance of flexible cystoscopy was a useful indicator of the comfort level for PUL using local anesthesia. Postoperative catheterization was decreased to 20% for a mean dwell time of less than a day. Return to preoperative activity was shortened to 5.1 days. Patients missed an average of only 2.8 days of work for treatment and recovery. Symptom and urinary flow results correlated with the results of this trial and other published studies. These results imply that there is a learning curve to achieve optimal results, and proper patient selection and

careful transurethral access can enable PUL to be performed using local anesthesia with rapid recovery and improvement.

When considering adoption of a new procedure for BPH LUTS, practicing urologists weigh the potential side effects and invasiveness of a therapy with the durability and level of the therapeutic effect. The therapeutic effect of PUL at 2 years in the L.I.F.T. study closely mimicked that of previously published results of AUA-SI reduction, indicating that outcomes after PUL are durable and consistent.[8,9,11−13] Further, the cumulative rate of invasive reintervention for failure to cure by 2 years was only 7.5%, increasing only slightly from 4.8% by 1 year. These rates are within the range of those seen with TURP (2.3% to 4.3% at 1 year and 5.8% to 9.7% at 5 years)[16−18] and laser vaporization (1.7% to 5.3% at 1 year, 6.7% at 2 years and 6.8% to 34% at 5 years).[19−24] The overall rate of any secondary urological procedures by 2 years was 13.4% for PUL. This compares well to the secondary procedure rate for TURP, estimated to be 5.8% to 12.5% at 1 year and 12.3% to 17% at 3 to 5 years,[17,18] and laser vaporization, estimated to be 4.6% to 18.4% at 1 year[20,25,26] and 8.9% to 50.0% at 3 to 5 years.[22−24,27−29] Transurethral microwave therapy and transurethral needle ablation have significantly higher retreatment rates than TURP. The results of this study suggest that the overall secondary procedure rate after PUL would be considerably less than after transurethral microwave therapy (31% to 40% at 3 years) and transurethral needle ablation (20% to 36% at 2-3 years), although direct comparison is difficult due to the paucity of data.[6,7]

A potential limitation of this analysis is the number of subjects who were censored or missing. Statistical testing showed that the AUA-SI change in missing or censored data groups did not significantly differ from the AUA-SI change score of those analyzed. Comparing the durability of PUL with that of other BPH procedures is performed with variations in study inclusion criteria and, therefore, patient selection bias may be a factor. Subjects under this study protocol will continue to be studied to 5 years and will be reported on in the future.

Conclusions

PUL offers LUTS improvement that is rapid, clinically meaningful and sustained through 2 years. It can reliably be performed using local anesthesia and it causes low postoperative morbidity. Sexual function is preserved, including anterograde ejaculation. The need for retreatment or secondary intervention by 2 years is in line with that of other available BPH procedures. Subjects in this study cohort will be assessed through 5 years for continued safety and durability of treatment.

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