Treatment of LUTS Secondary to BPH While Preserving Sexual Function: Randomized Controlled Study of Prostatic Urethral Lift

Kevin T. McVary, MD,* Steven N. Gange, MD,† Neal D. Shore, MD,‡ Damien M. Bolton, MD,§ Barrett E. Cowan, MD,¶ B. Thomas Brown, MD,** Alexis E. Te, MD,†† Peter T. Chin, MD,‡‡ Daniel B. Rukstalis, MD,§§ and Claus G. Roehrborn, MD¶¶ on behalf of the L.I.F.T. Study Investigators

*Southern Illinois University, Springfield, IL, USA; †Western Urological Clinic, Salt Lake City, UT, USA; ‡Carolina Urological Research Center, Myrtle Beach, SC, USA; §The Austin Hospital, Melbourne, Vic., Australia; ¶Urology Associates of Denver, Denver, CO, USA; **Atlantic Urological Associates, Daytona Beach, FL, USA; ††Weill Cornell Medical Center, New York, NY, USA; ‡‡Figtree Private Hospital, Figtree, NSW, Australia; §§Wake Forest University, Winston-Salem, NC, USA; ¶¶The University of Texas Southwestern Medical Center, Dallas, TX, USA

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ABSTRACT

Introduction. We analyzed data obtained from a randomized controlled blinded study of the prostatic urethral lift (PUL) to evaluate the sexual side effects of this novel treatment.

Aims. We sought to determine whether PUL, when conducted in a randomized study, significantly improved lower urinary tract symptoms (LUTS) and urinary flow rate while preserving sexual function.

Methods. Men ≥50 years with prostates 30–80 cc, International Prostate Symptom Score (IPSS) >12, and peak urinary flow rate (Qmax) ≤12 ml/s were randomized 2:1 between PUL and sham. Sexual activity was not an inclusion criterion. In PUL, permanent transprostatic implants are placed to retract encroaching lateral lobes and open the prostatic fossa. Sham entailed rigid cystoscopy with sounds to mimic PUL and a blinding screen.

Main Outcome Measures. Blinded groups were compared at 3 months and active arm then followed to 12 months for LUTS with IPSS and for sexual function with sexual health inventory for men (SHIM) and Male Sexual Health Questionnaire for Ejaculatory Dysfunction (MSHQ-EjD). Subjects were censored from primary sexual function analysis if they had baseline SHIM < 5 at enrollment. Secondary stratified analysis by erectile dysfunction (ED) severity was conducted.

Results. There was no evidence of degradation in erectile or ejaculatory function after PUL. SHIM and MSHQ-EjD scores were not different from control at 3 months but were modestly improved and statistically different from baseline at 1 year. Ejaculatory bother score was most improved with a 40% improvement over baseline. Twelve-month SHIM was significantly improved from baseline for men entering the study with severe ED, $P = 0.016$. IPSS and Qmax were significantly superior to both control at 3 months and baseline at 1 year. There was no instance of de novo sustained anejaculation or ED over the course of the study.

Conclusions. The PUL improves LUTS and urinary flow while preserving erectile and ejaculatory function. **McVary KT, Gange SN, Shore ND, Bolton DM, Cowan BE, Brown BT, Te AE, Chin PT, Rukstalis DB, and Roehrborn CG on behalf of the L.I.F.T. Study Investigators. Treatment of LUTS secondary to BPH while preserving sexual function: Randomized controlled study of Prostatic Urethral Lift. J Sex Med 2014;11:279–287.**

Key Words. Benign Prostatic Hyperplasia; Sexual Function; Erectile Dysfunction; Ejaculatory Dysfunction; Implant; Retrograde Ejaculation

Introduction

Nearly one of every three men over the age of 50 will consider treatment for bothersome lower urinary tract symptoms (LUTS) because of benign prostatic hyperplasia (BPH) [1,2]. A significant portion of these men are sexually active and view sexuality as being a vital component of their overall well-being and quality of life (QOL) [3,4]. Thus, when evaluating LUTS/BPH

treatment options, special attention should be given to the impact of treatment on sexual function [3,5,6].

All currently available BPH treatments offer a balance of risks and benefits both with regard to LUTS and sexual function. Medical therapy provides a modest 3.5–7.5 International Prostate Symptom Score (IPSS) improvement at 1 year. However, over 30% of patients discontinue treatment because of insufficient response and bothersome side effects, including sexual dysfunction [2]. Selective alpha blockers, such as tamsulosin and silodosin, have been shown to be associated with 1–5% erectile dysfunction (ED) and 10–28% ejaculatory dysfunction [7,8]. Recently, tadalafil has been shown to offer a 4.8–6.1 IPSS improvement while improving sexual function, but it offers no improvement in urinary flow [9,10]. Cavitating surgical procedures, such as transurethral resection, laser vaporization, or laser enucleation, offer much higher levels of LUTS relief (10–24 IPSS drop), yet they are associated with higher levels of sexual dysfunction. De novo postoperative ED rates have been reported from 3% to 14%, whereas complete loss of ejaculatory function ranges from 30% to 80% [8,11–15].

The prostatic urethral lift (PUL) has emerged as potentially offering rapid and meaningful mitigation of LUTS while maintaining sexual function. Permanent transprostatic UroLift implants (NeoTract, Inc., Pleasanton, CA, USA) are placed to hold prostate lobes open and relieve LUTS without the potential for thermal damage. Open-label studies have demonstrated IPSS reduction of 10.4–12.3 and Qmax increase of 2.6–4.0 ml/s at 1 year with no deleterious sexual side effects [16–19]. We report the analysis of sexual side effects from the first multicenter blinded randomized controlled trial of the PUL conducted at 19 centers in the USA, Canada, and Australia [20].

Aims

We sought to determine whether the PUL treatment, when conducted in a randomized controlled fashion, demonstrated significant improvement in LUTS and urinary flow rate while preserving sexual function.

Methods

The PUL

The PUL entails the delivery of permanent transprostatic UroLift implants into the lateral lobes to open the anterior aspect of the prostatic fossa. Because the implants are deployed into the anterolateral aspect of the prostate, interference with the neurovascular bundle is avoided (Figure 1). Under endoscopic guidance, the prostatic lobe is compressed with the delivery device, and a 19-gauge needle is delivered through the prostate. As the needle is retracted into the device, a nitinol tab is delivered to the prostatic capsule, and the attached monofilament suture is tensioned. Finally, a stainless steel end piece is affixed to the suture at the urethral surface and excess suture trimmed. By attaching the urethral end piece in situ, the length of each implant is tailored to the width of compressed prostate lobe at each site. Depending upon gland size, four to five implants are typically delivered.

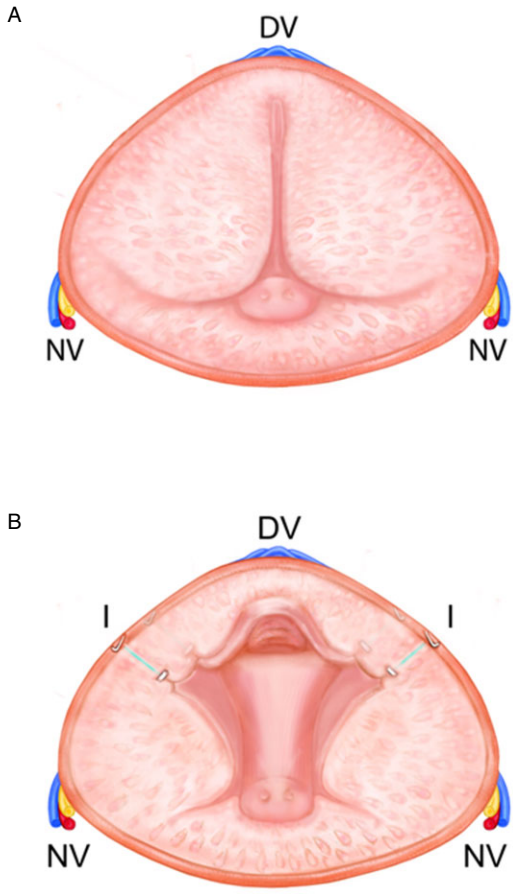

Figure 1 Cross-sectional view of prostate (A) before and (B) after treatment with prostatic urethral lift. Implants (I) are anterolaterally placed away from dorsal vein (DV) and neurovascular bundles (NV). Images courtesy of NeoTract, Inc.

Study Protocol and Objectives

A prospective, randomized, controlled, blinded study of the PUL was conducted in men at least

50 years old with no prior BPH procedure, a 30–80 cc prostate, IPSS > 12, Qmax ≤12 ml/s with a voided volume ≥125 ml. Subjects were required to wash out 2 weeks for alpha blockers and 3 months for 5 alpha reductase inhibitors. Phosphodiesterase type 5 inhibitors (PDE5i) were not washed out but were tracked, and sexual function data were censored upon initiation of PDE5i. Subjects were excluded for obstructive median lobe, postvoid residual volume >250 ml, bacterial prostatitis within 1 year, prostate specific antigen >10 (unless negative biopsy), cystolithiasis within 3 months, or active infection.

The protocol was approved by institutional review boards and ethics committees, the U.S. Food and Drug Administration, Health Canada, and the Therapeutic Goods Administration of Australia (Clinicaltrials.gov: NCT01294150). All adverse events, urinary flow rates, and cystoscopy videos were independently reviewed under the oversight of independent clinical events and data monitoring committees. Although surgeons were not blinded, a double blind was maintained through 3 months for both the patient and symptom assessor. PUL effectiveness was evaluated using IPSS, QOL, BPH Impact Index (BPHII), and Qmax, whereas sexual function was evaluated with International Index of Erectile Function (IIEF) and Male Sexual Health Questionnaire for Ejaculatory Dysfunction (MSHQ-EjD) questionnaires. IIEF allowed for evaluation of SHIM over 4-week intervals.

Randomized PUL and sham results were compared at 3 months, and PUL patients were then followed at 6 and 12 months. After the 3-month follow up, all patients were unblinded, and control patients were offered treatment, including PUL, as appropriate. The results of crossover patients and PUL arm results to 5 years will be reported in later publications as data become available.

A prospective secondary endpoint was to report the rates of de novo sustained ED and anejaculation. De novo sustained dysfunction was defined as first occurring within 3 months of treatment and occurring again within the 12-month follow-up period. For general estimating equation (GEE) analysis of SHIM and MSHQ-EjD outcomes, patient data were censored if SHIM < 5 or the subject reported no sexual activity.

Statistical Methods

Randomization was conducted through a central electronic data program just prior to treatment. For the intent to treat randomized comparison, two subjects that initiated BPH medication within the 3-month blinded period were assigned a zero IPSS improvement from baseline. No subject initiated PDE5i therapy during this blinded comparison period. Per protocol analysis, conducted for time points beyond unblinding, excluded data from patients at times after any other BPH treatment (procedure or drug). For sexual function analyses, data were censored for two patients at time of PDE5i initiation. Data from 22 patients on stable dose of PDE5i at baseline were included.

To evaluate per protocol change from baseline, a GEE model was fit to each output parameter using an exchangeable correlation structure and identity link. Change from baseline was the dependent variable; visit and baseline scores were used as independent variables. This model was used to calculate *P* values for each follow-up interval compared with baseline. Sexual function data were censored for any patient entering the study who (i) suffered from severe ED (SHIM < 5); (ii) was not sexually active; or (iii) was unwilling to complete sexual function questionnaires.

We completed additional analyses to understand the effect of baseline conditions on change in SHIM score. To more fully understand the extent to which baseline conditions affect results, men with baseline ED (SHIM < 5) were included in these analyses. One year change in SHIM was evaluated by baseline ED severity classifications as described by Rosen [21]: 22–25, no ED; 17–21, mild; 8–16, moderate; and 1–7, severe. SHIM score change was also analyzed with baseline severity split into two groups (Group A SHIM < 19; Group B SHIM ≥ 19). A linear correlation with 95% confidence interval was applied to compare 1-year SHIM change with baseline SHIM on a continuous basis.

Main Outcome Measures

PUL subject voiding symptoms (IPSS), urinary flow (QMax), erectile function (SHIM), and ejaculatory function (MHSQ-EjD) were compared with control at 3 months and compared with baseline to 12 months.

Results

A total of 206 men were 2:1 randomized receiving either the PUL (N = 140) or sham (N = 66). Baseline demographics were similar between groups with mean ages of 67 and 65, prostate volumes of 45 and 41 cc, IPSS of 22 and 24, Qmax of 8.9 and

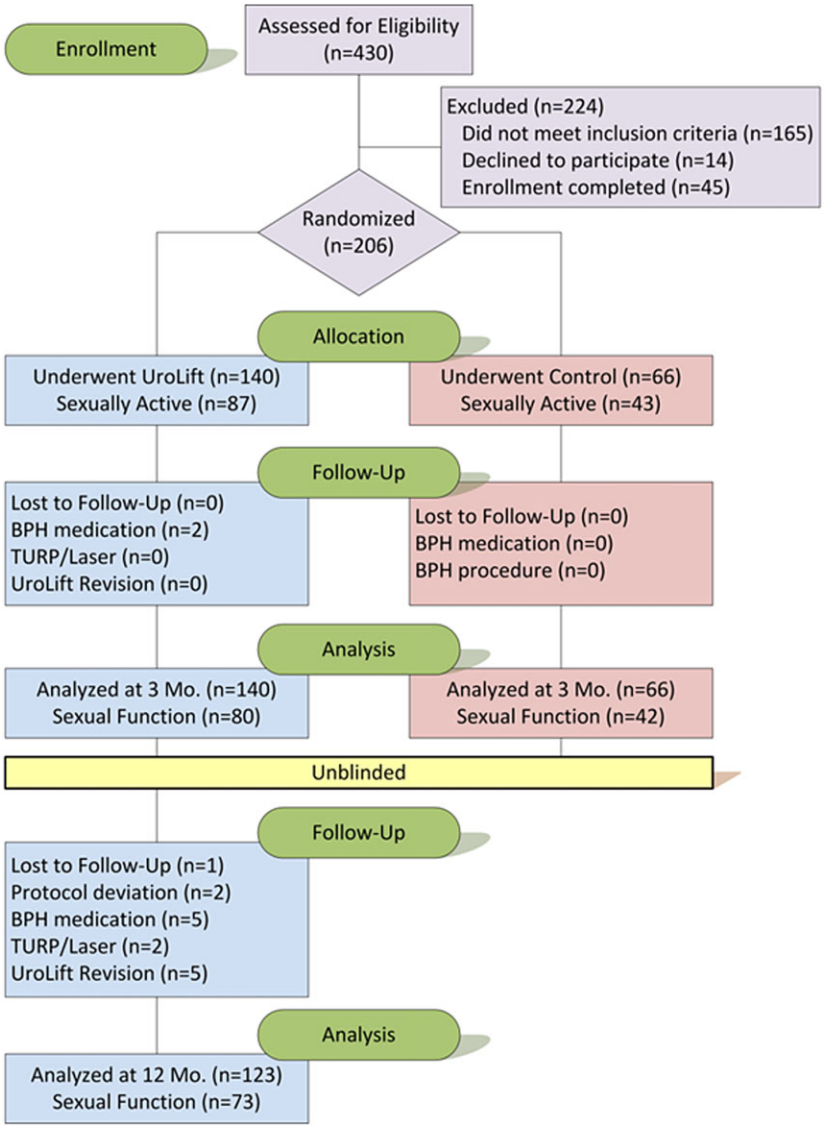

Figure 2 CONSORT (Consolidated Standards of Reporting Trials) diagram of randomized study.

8.8 ml/s, QOL of 4.6 and 4.7, and SHIM of 13.0 and 13.5 for PUL and sham, respectively. All subjects were available for randomized comparison at 3 months, and 123 of 140 PUL subjects were available for 12-month assessment (Figure 2). At baseline, 38% (53) PUL and 35% (23) sham subjects presented as sexually inactive or suffering from severe ED and were censored from the primary sexual function analysis.

An average of 4.9 implants was delivered across prostate volumes ranging 30–77 cc. In North America, 99% procedures were conducted with only local anesthesia (no intravenous access), and only 32% of subjects undergoing void trial required a postoperative catheter for a mean duration of 0.9 days. There was no run in period, and this data include the first procedures ever performed at each of these sites. All procedures were successfully completed. Adverse events were typically mild to moderate with the most common being the same for PUL and sham (transient dysuria, hematuria, and pelvic pain) [20].

There was no instance of de novo sustained anejaculation or ED over the course of the study. SHIM and MSHQ-EjD scores were not different from control at 3 months (Table 1). LUTS were greatly improved in the treatment group with 3-month IPSS improvement 88% greater than that of sham control, $P = 0.003$. Reduction was seen in both voiding and storage symptoms. Peak urinary flow rate improvement of 4.3 ml/s was significantly greater than control, $P = 0.005$. QOL as measured by both QOL and BPHII was significantly improved over control, $P < 0.001$.

Table 1 Comparison of mean change at 3 months for IPSS, Qmax, QOL, BPHII, MSHQ-EjD, and SHIM: PUL and control ITT groups

	PUL (ITT) (N = 140)			Control (ITT) (N = 66)			
	Baseline	3 Months	Change	Baseline	3 Months	Change	
Outcome measure	Mean, SD (n)						*P* value*
IPSS	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/s)	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
SHIM	18.0, 5.6 (80)	19.3, 6.3 (80)	1.3, 4.9 (80)	18.6, 5.3 (42)	19.2, 5.4 (42)	0.6, 3.6 (42)	0.356
MSHQ-EjD Function	9.1, 3.1 (80)	11.3, 3.2 (80)	2.2, 2.5 (80)	9.1, 3.0 (42)	10.6, 3.2 (42)	1.5, 2.6 (42)	0.217
MSHQ- EjD Bother	2.0, 1.6 (80)	1.0, 1.3 (80)	−1.0, 1.4 (80)	2.0, 1.6 (42)	1.4, 1.6 (42)	−0.6, 1.5 (42)	0.088

**P value* obtained using a two-sample *t*-test for IPSS, Qmax, QOL, BPHII; *P* value was obtained through generalized estimating equation (GEE) fit for SHIM, MSHQ-EjD.
ITT = intent to treat; IPSS = International Prostate Symptom Score; Qmax = peak urinary flow; QOL = IPSS quality of life; BPHII = benign prostatic hyperplasia Impact Index; SHIM = sexual health inventory for men; MSHQ-EjD = Male Sexual Health Questionnaire for Ejaculatory Dysfunction; PUL = prostatic urethral lift

Both LUTS and sexual function were improved by 1 month and sustained through 1 year (Table 2). Flow rate improvement was sustained at 4 ml/s at 1 year, and IPSS showed a 10.8 point (49%) improvement. Erectile and ejaculatory function showed modest but statistical improvements from baseline. The MSHQ-EjD function score, the sum of three questionnaire elements, improved 1.3 points (14%) at 12 months. The individual elements showed 12-month improvements of 0.2 (4%), 0.6 (23%), and 0.5 (22%) for ability to ejaculate, intensity of ejaculation, and amount of ejaculate, respectively (Table 3).

Stratification of men by baseline erectile function showed that SHIM was significantly improved from baseline for men entering the study with severe ED, $P = 0.016$ (Figure 3). Erectile function remained stable from baseline for healthy men. Stratifying patients into two groups (Group A SHIM < 19; Group B SHIM ≥ 19) showed similar results with no statistical change from baseline for Group B (–0.5, $P = 0.416$) but a

Table 2 SHIM, MSHQ-EjD, Peak Qmax and IPSS change from baseline after PUL

		1 Month	3 Months	6 Months	12 Months
SHIM	n (paired)	77	80	83	73
	Baseline	17.9 ± 5.9	17.9 ± 5.6	18.0 ± 5.7	18.2 ± 5.4
	Follow-Up	18.5 ± 6.8	19.2 ± 6.3	19.2 ± 6.4	18.6 ± 6.5
	Change [95% CI]	0.6 [–0.6–1.8]	1.3 [0.2–2.3]	1.2 [0.2–2.1]	0.4 [–0.7–1.6]
	P value	0.309	0.021	0.014	0.013
MSHQ-EjD Function	n (paired)	77	80	84	75
	Baseline	9.2 ± 3.1	9.0 ± 3.1	9.1 ± 3.2	9.2 ± 3.1
	Follow-up	11.3 ± 3.3	11.2 ± 3.2	10.9 ± 3.2	10.5 ± 3.2
	Change [95% CI]	2.1 [1.5–2.8]	2.2 [1.6–2.7]	1.8 [1.2–2.3]	1.3 [0.7–1.9]
	P value	<0.001	<0.001	<0.001	<0.001
MSHQ-EjD Bother	n (paired)	77	80	84	75
	Baseline	2.0 ± 1.6	2.0 ± 1.6	2.1 ± 1.6	2.0 ± 1.7
	Follow-up	1.3 ± 1.4	1.0 ± 1.3	1.1 ± 1.1	1.2 ± 1.3
	Change [95% CI]	–0.7 [–1.0—0.4]	–1.0 [–1.3—0.7]	–1.0 [–1.3—0.7]	–0.8 [–1.1—0.4]
	P value	<0.001	<0.001	<0.001	<0.001
Qmax (ml/second)	n (paired)		124		103
	Baseline		8.1 ± 2.4		8.1 ± 2.4
	Follow-up		12.4 ± 5.4		12.1 ± 5.4
	Change [95% CI]		4.4 [3.3–5.4]		4.0 [2.9–5.2]
	P value		<0.001		<0.001
IPSS	n (paired)	137	137	133	123
	Baseline	22.1 ± 5.4	22.1 ± 5.4	21.9 ± 5.4	21.8 ± 5.4
	Follow-up	12.3 ± 6.9	11.0 ± 7.6	11.0 ± 7.3	11.1 ± 7.0
	Change [95% CI]	–9.8 [–11.2—8.5]	–11.1 [–12.6—9.7]	–10.9 [–12.4—9.4]	–10.8 [–12.3—9.3]
	P value	<0.001	<0.001	<0.001	<0.001

Each parameter is listed as mean ± SD, and the change is represented as average and 95% confidence interval (CI). *P* values were obtained by fitting a generalized estimating equation to each parameter for all available subjects.
SHIM = sexual health inventory for men; MSHQ-EjD = Male Sexual Health Questionnaire for Ejaculatory Dysfunction; PUL = prostatic urethral lift; Qmax = peak urinary flow; IPSS = International Prostate Symptom Score; CI = confidence interval

Table 3 Male Sexual Health Questionnaire for Ejaculatory Dysfunction (MSHQ-EjD) change from baseline after prostatic urethral lift

	1 Month	3 Months	6 Months	12 Months
Question 1 [Frequency]: How often have you been able to ejaculate or "cum" when having sexual activity?				
n (paired)	77	80	84	75
Baseline	4.08 ± 1.06	4.04 ± 1.05	4.02 ± 1.11	4.05 ± 1.06
Follow-up	4.25 ± 1.07	4.38 ± 1.01	4.35 ± 0.95	4.23 ± 1.03
Change [95%CI]	0.17 [–0.06–0.39]	0.34 [0.15–0.52]	0.33 [0.11–0.54]	0.18 [–0.05–0.40]
P value	0.109	<0.001	<0.001	0.038
Question 2 [Intensity]: How would you rate the strength or force of your ejaculation?				
n (paired)	77	80	84	75
Baseline	2.57 ± 1.22	2.56 ± 1.22	2.58 ± 1.21	2.59 ± 1.21
Follow-up	3.56 ± 1.34	3.45 ± 1.29	3.30 ± 1.32	3.18 ± 1.31
Change [95% CI]	0.99 [0.70–1.29]	0.89 [0.62–1.15]	0.72 [0.48–0.95]	0.59 [0.33–0.84]
P value	<0.001	<0.001	<0.001	<0.001
Question 3 [Volume]: How would you rate the amount or volume of semen or fluid when you ejaculate?				
n (paired)	77	80	84	75
Baseline	2.49 ± 1.32	2.47 ± 1.35	2.54 ± 1.37	2.56 ± 1.37
Follow-up	3.48 ± 1.35	3.40 ± 1.38	3.30 ± 1.43	3.12 ± 1.27
Change [95% CI]	0.99 [0.67–1.30]	0.93 [0.67–1.18]	0.76 [0.50–1.02]	0.56 [0.30–0.82]
P value	<0.001	<0.001	<0.001	<0.001
Question 4 [Bother]: If you have had any ejaculation difficulties or have been unable to ejaculate, have you been bothered by this?				
n (paired)	77	80	84	75
Baseline	2.0 ± 1.6	2.0 ± 1.6	2.1 ± 1.6	2.0 ± 1.7
Follow-up	1.3 ± 1.4	1.0 ± 1.3	1.1 ± 1.1	1.2 ± 1.3
Change [95% CI]	–0.7 [–1.0—0.4]	–1.0 [–1.3—0.7]	–1.0 [–1.3—0.7]	–0.8 [–1.1—0.4]
P value	<0.001	<0.001	<0.001	<0.001

Each parameter is listed as mean ± standard deviation (SD), and the change is represented as average and 95% confidence interval (CI). *P* values were obtained by fitting a generalized estimating equation to each parameter for all available subjects.

statistical improvement for Group A (2.4, $P = 0.005$). A linear regression of 1-year SHIM change vs. baseline condition (Figure 4) showed improvement in SHIM as baseline conditions worsen and no significant deterioration in men with intact erectile function at baseline.

Discussion

The results of this randomized blinded study show that the PUL provided meaningful improvement in LUTS and urinary flow without compromising sexual function. Importantly, sexual function preservation is not limited to erectile function, the primary focus of most analyses, but also extends to ejaculatory function. Reliable preservation of ejaculatory function is uncommon among the leading BPH therapies, yet it has been shown to be of considerable importance to patients [6,21–25]. No PUL subject experienced de novo sustained anejaculation or ED. Bother associated with ejaculation (MSHQ-EjD Bother) improved 40% at 1 year, $P < 0.001$, and both intensity of ejaculation and amount of ejaculate improved 23% and 22% respectively, $P < 0.001$.

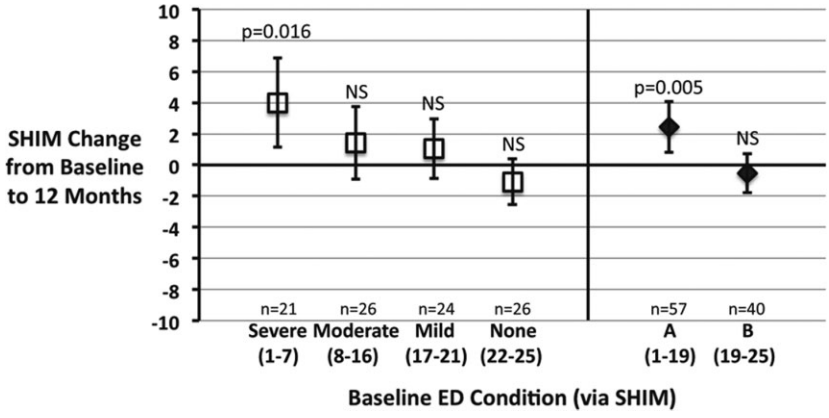

Figure 3 Change in sexual health inventory for men (SHIM, mean ± 95% confidence interval) score 12 months after treatment with prostatic urethral lift. Subjects stratified by baseline SHIM score in two ways: (left) stratification into four groups and (right) two groups. Men entering study with moderate to severe erectile dysfunction (ED) showed improvement. Sexually healthy men showed no changed from baseline.

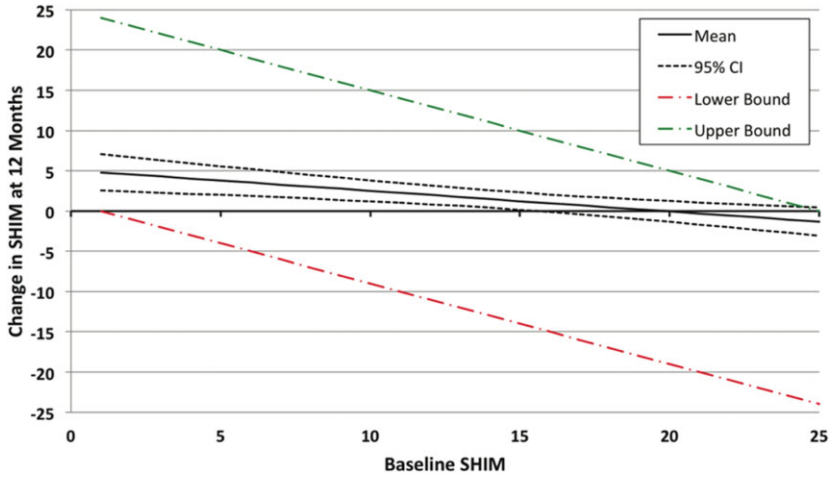

Figure 4 Average and 95% confidence interval of change in sexual health inventory for men (SHIM) score 12 months after treatment with prostatic urethral lift as a function of baseline SHIM. Upper and lower bounds show the range of possible change in SHIM for each baseline score (e.g., with baseline SHIM of 20, SHIM can increase 5 points or decrease 19 points, since SHIM as a measure ranges 1–25).

The role of LUTS as an independent predictor of sexual dysfunction has been established in the literature [25–27]. The link between LUTS and ED has received increased attention recently because both diseases are highly prevalent, frequently coassociated in the same aging male group, and contribute significantly to the overall QOL. The association between these two diseases has also garnered attention as investigators have hypothesized a common pathophysiology to explain the idea that they are causally linked. This common theme hypothesis has taken on a life of its own as pharmaceutical companies have worked to expand the indications of drugs for both diseases. As with the recent introduction of tadalafil for improvement in LUTS, we may see the emergence of PUL to offer considerably greater improvement in LUTS while preserving ejaculatory and erectile function.

Although the negative effect on ejaculatory function of prostate resection and vaporization has been well established, reports on erectile function changes have varied [7,8,11–15]. Technique, technology thermal penetration, and anatomical variances associated with thermal nerve damage have been proposed as explanations for the variability in outcomes [28–30]. We believe this variability may be due in part to the method by which ED data are analyzed, specifically (i) a dependence on adverse event reporting to determine sexual impact; (ii) a lack of baseline sexual function measurement; and (iii) reliance on simple mean changes for the entire cohort regardless of overall function or activity. A limitation of this study and others with primary endpoints focused on the treatment of LUTS is that no inclusion criteria are applied for sexual function. Men entering a study with SHIM < 5 may either have severe ED or be sexually inactive and can show large improvement with change in activity. For this reason, we censored their data from our primary analysis and believe adoption of this technique could lead to greater consistency and comparability in postprocedural ED reporting.

Evaluating SHIM for all subjects as a function of baseline score may be highly instructive to determine whether specific groups are helped or hurt by a therapy. In two separate studies each involving 150 subjects undergoing laser vaporization, overall erectile function was not significantly decreased, but both studies showed statistically significant worsening in SHIM (–5.8, $P = 0.003$; –5.0, $P = 0.02$, respectively) at 1 year for men with intact erectile function at baseline (SHIM ≥ 19) [31,32]. These results stand in contrast to PUL which showed no significant deterioration in SHIM for this stratified subgroup. Because men with severe ED at baseline can only stay the same or show improvement, SHIM change in this population could artificially buoy overall mean results. Figure 4 offers further insight into this phenomenon by presenting the upper and lower bounds of possible outcomes when plotted against baseline SHIM. If SHIM changes for PUL subjects simply rectified as a regression to the mean, one might expect the regression slope to parallel the boundaries. Instead, the subjects with no or mild ED remained stable, whereas those with poor erections at baseline tended to improve.

Conclusions

The PUL provides rapid and meaningful improvement in LUTS and urinary flow without

compromising sexual function. These results support the premise that PUL does not negatively affect the urogenital anatomy, thereby allowing for sexual function to improve naturally with improving LUTS.

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Corresponding Author: Kevin McVary, Surgery/Urology, Southern Illinois University School of Medicine, St. John's Pavilion, 301 North Eighth Street, PO Box 19665, Springfield, IL 62794-9665, USA. Tel: 217-545-8860; Fax: 217-545-7305; E-mail: kmcvary@siumed.edu

Conflict of Interest: The authors were each investigators in the L.I.F.T. Study that was funded by NeoTract, Inc. Drs. McVary, Gange, Chin, Rukstalis, and Roehrborn have consulted for NeoTract in clinical trial design.

Statement of Authorship

Category 1

(a) Conception and Design
Kevin T. McVary; Steven N. Gange; Neal D. Shore; Damien M. Bolton; Barrett E. Cowan; B. Thomas Brown; Alexis E. Te; Peter T. Chin; Daniel B. Rukstalis; Claus G. Roehrborn

(b) Acquisition of Data
Kevin T. McVary; Steven N. Gange; Neal D. Shore; Damien M. Bolton; Barrett E. Cowan; B. Thomas Brown; Alexis E. Te; Peter T. Chin; Daniel B. Rukstalis; Claus G. Roehrborn

(c) Analysis and Interpretation of Data
Kevin T. McVary; Steven N. Gange; Neal D. Shore; Damien M. Bolton; Barrett E. Cowan; B. Thomas Brown; Alexis E. Te; Peter T. Chin; Daniel B. Rukstalis; Claus G. Roehrborn

Category 2

(a) Drafting the Article
Kevin T. McVary; Steven N. Gange; Neal D. Shore; Damien M. Bolton; Barrett E. Cowan; B. Thomas Brown; Alexis E. Te; Peter T. Chin; Daniel B. Rukstalis; Claus G. Roehrborn

(b) Revising It for Intellectual Content
Kevin T. McVary; Steven N. Gange; Neal D. Shore; Damien M. Bolton; Barrett E. Cowan; B. Thomas Brown; Alexis E. Te; Peter T. Chin; Daniel B. Rukstalis; Claus G. Roehrborn

Category 3

(a) Final Approval of the Completed Article
Kevin T. McVary; Steven N. Gange; Neal D. Shore; Damien M. Bolton; Barrett E. Cowan; B. Thomas Brown; Alexis E. Te; Peter T. Chin; Daniel B. Rukstalis; Claus G. Roehrborn

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