

Multicentre prospective crossover study of the 'prostatic urethral lift' for the treatment of lower urinary tract symptoms secondary to benign prostatic hyperplasia

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Objective

- To assess the clinical effect of the 'prostatic urethral lift' (PUL) on lower urinary tract symptoms (LUTS) associated with benign prostatic hyperplasia (BPH) through a crossover design study.

Patients and Methods

- Men aged ≥ 50 years with an International Prostate Symptom Score of ≥ 13 , a maximum urinary flow rate (Q_{max}) of ≤ 12 mL/s, and a prostate of 30–80 mL were enrolled into a crossover study after completing a prospective, randomised, controlled, 'blinded' pivotal study in which they were control subjects receiving a sham procedure.
- Patients were followed for 1 year after crossover PUL at 19 centres in the USA, Canada and Australia. The sham procedure involved rigid cystoscopy with simulated active treatment sounds.
- PUL involved placing permanent UroLift® (NeoTract, Inc., Pleasanton, CA, USA) implants into the lateral lobes of the prostate to enlarge the urethral lumen.
- Urinary symptom relief, health-related quality of life (HRQL) impact, urinary flow parameters, sexual function, and adverse events were assessed and compared between the sham and PUL using paired statistical analysis.

Results

- Symptom, flow, HRQL and sexual function assessments showed response improvements from baseline results, similar to results from other published studies, and most parameters were markedly improved after PUL vs the sham procedure in the same patients.
- Symptom, flow, and HRQL improvements were durable over the 12 months of the study.
- Adverse events associated with the procedure were typically transient and mild to moderate; one patient (2%) required re-intervention with transurethral resection of the prostate in the first year.
- There were no occurrences of de novo, sustained ejaculatory or erectile dysfunction.

Conclusion

- The PUL can be performed under local anaesthesia, causes minimal associated perioperative complications, allows patients to quickly return to normal activity, provides rapid and durable improvement in symptoms, and preserves sexual function.

Keywords

prostate, benign prostatic hyperplasia, minimally invasive surgical procedure, crossover, sham, sexual function

Introduction

BPH is common in men beyond middle age and often causes bothersome LUTS that can detrimentally affect a man's health-related quality of life (HRQL). The 'prostatic urethral lift' (PUL) is a mechanical approach to addressing LUTS that has the potential to offer rapid and significant mitigation of symptoms, preservation of sexual function and minimal

perioperative risk [1–4]. Small UroLift® implants (NeoTract, Inc., Pleasanton, CA, USA) are delivered transurethrally to separate the lateral lobes of the prostate and relieve obstruction. Previously published studies have reported symptom reduction considerably greater than drugs, faster acting and more durable than thermal therapies, and without the more serious complications associated with TURP or laser [1–4]. We report on a group of patients who underwent a

sham procedure followed by PUL 3–6 months later. These patients allow for analysis of the individual effect of active vs sham procedure, a rare opportunity in medical device clinical research.

Crossover studies have been shown to effectively compare relative therapeutic effects of pharmaceutical treatments with placebo or other treatments, but this design has rarely been used to study medical devices [5–8]. The primary challenges with conducting a medical device crossover study design are: (i) while sham control groups can crossover to active treatment, it is not possible to cross active arm subjects back to control; and (ii) while ‘blinding’ can be maintained for sham, it is typically not feasible to maintain a ‘blind’ when these subjects crossover to active treatment. Device trials consequently use the ‘one-way’ instead of the ‘two-way’ crossover design. We sought to compare the effects of PUL when delivered 3–6 months after a sham procedure using this self-controlled paired data set.

Patients and Methods

A crossover study of the PUL procedure after sham control was conducted at 19 centres in the USA, Canada, and Australia in men with moderate to severe LUTS secondary to BPH. While enrolled in a randomised double-blind study published by Roehrborn *et al.* [3], patients underwent a sham procedure that involved rigid cystoscopy and mimicking surgical sounds. After the primary endpoint comparison at 3 months, these sham controls were unblinded and, if eligible, offered enrolment into the crossover study, where they were treated with PUL and followed to 12 months.

Eligible patients for the crossover study were aged ≥ 50 years, provided informed consent, had no prior surgical BPH treatment, and were either washed out or naïve to α -blockers and 5 α -reductase inhibitors. Each patient had an IPSS score of ≥ 13 , a maximum urinary flow rate (Q_{\max}) of ≤ 12 mL/s with a voided volume of 125 mL, and a prostate of volume of 30–80 mL without an obstructing median lobe. Patients were excluded for retention, post-void residual urine volume (PVR) of >250 mL, active infection, PSA level of >10 ng/mL unless negative biopsy, cystolithiasis within 3 months, and bacterial prostatitis within 1 year. The study protocol was approved by the USA Food and Drug Administration, Health Canada, and the Therapeutic Goods Administration of Australia, as well as the Institutional Review Boards at each of the 19 enrolling sites (Clinicaltrials.gov: NCT01294150).

Control (Sham) Procedure

The sham control procedure was conducted in a manner that simulated PUL. A visual obstruction was erected in the room so that the recumbent patient could not see the operator or endoscopy image. During rigid cystoscopy, the operator called

for devices and support personnel opened packaging materials. Then, at appropriate times during the procedure, the operator simulated the UroLift delivery device sounds by activating a standard disposable biopsy device that was not inserted into the patient.

Study Procedure the PUL

The PUL involves the delivery of permanent *in situ* tailored transprostatic UroLift® implant (NeoTract, Inc., Pleasanton, CA, USA) to reshape the prostatic fossa, allowing for a continuous channel through the anterior aspect of the prostate (Fig. 1) [1–4]. Under cystoscopic visualisation through a 20 F sheath, the system compresses the obstructing tissue and delivers through a hollow 19-G needle a monofilament that traverses the prostate lobe with a metallic tab seated on the capsular surface. The monofilament is tensioned and sized *in situ* to fit the compressed prostate lobe. A urethral end piece is then affixed to the monofilament, which is trimmed to the newly fixed length. Typically four implants are delivered to create a continuous anterior channel.

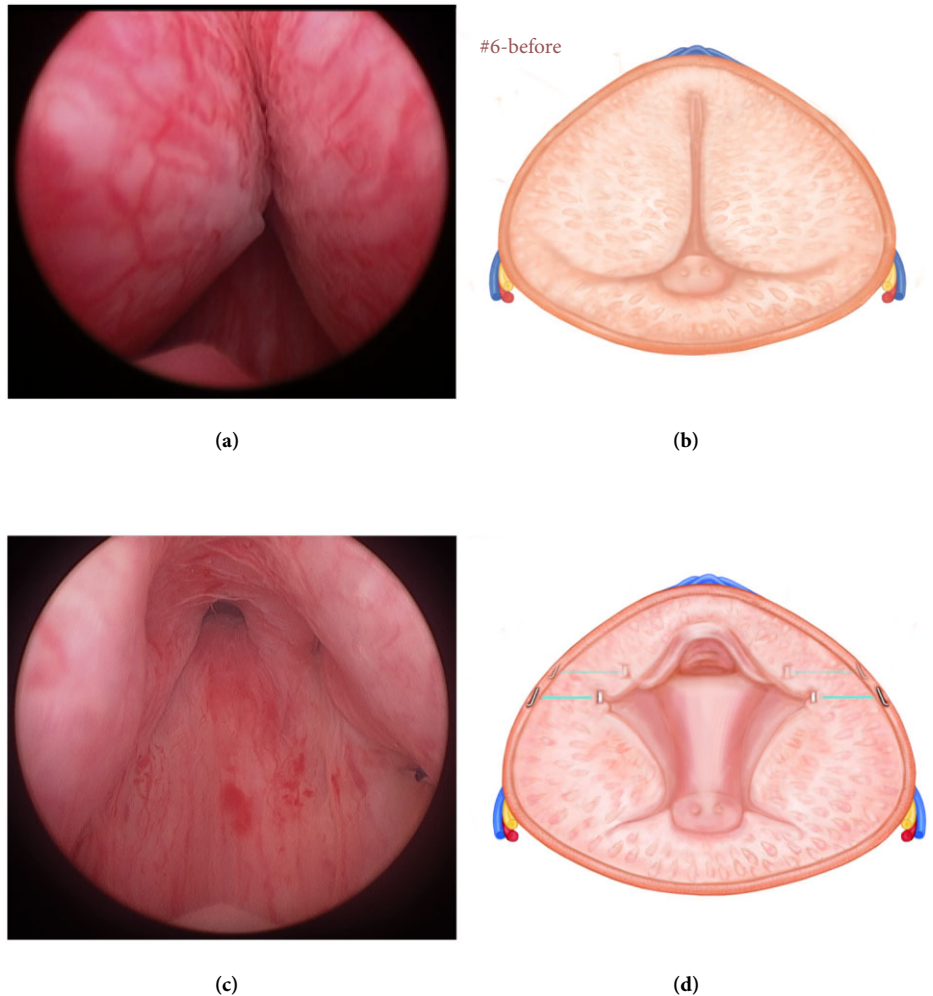
Study Endpoints

The IPSS, HRQL (as assessed by the eighth question of the IPSS), and BPH Impact Index (BPHII) were assessed at baseline and 2 weeks, 1 and 3 months after both the sham and PUL procedures and additionally at 6 and 12 months after the PUL. The five-item version of the International Index of Erectile Function (IIEF-5, equivalent to the Sexual Health Inventory for Men [SHIM]) and the Male Sexual Health Questionnaire for Ejaculatory Function (MSHQ-EjD) and Bother (MSHQ-Bother) were assessed at baseline and 1 and 3 months after both the sham and PUL procedures and additionally at 6 and 12 months after the PUL in patients who were sexually active. Q_{\max} and PVR were assessed at 3 and 12 months. Safety was assessed at each follow-up visit through adverse event reporting. An independent Clinical Events Committee (CEC) adjudicated all reported events, and an independent reviewer over-read each flow waveform using the two-second rule.

Statistical Methods

Descriptive statistics were used to describe the baseline and follow-up values of all study parameters (IPSS, HRQL, BPHII, Q_{\max} , PVR, SHIM, and MSHQ-EjD). Where stated, values are reported as the mean (standard deviation). The change between baseline and 3 months for the sham procedure vs the PUL was compared using a paired Student’s *t*-test, in which each patient served as their own control. Additionally, a general estimating equation model (GEE) was fitted to each study output parameter. The change from baseline was the dependent variable; baseline score and visit were the independent variables. In this model, an exchangeable

Fig. 1 The Prostatic Urethral Lift procedure. (a & b) Before treatment, the enlarged lateral lobes obstruct the urethra. (c & d) After transurethral delivery through a 19 gauge needle, the UroLift® implants reshape the prostate to allow for a patent channel through the anterior aspect of the prostatic fossa.



correlation structure and identity link were used and *P* values for each follow-up interval compared with baseline were calculated using SAS (SAS Institute, Inc. Cary, NC) and R (The R Foundation, Vienna, Austria); a *P* < 0.05 was considered to indicate statistical significance.

Results

Procedure

Between February and December 2011, 66 men underwent a sham procedure as part of a 'blinded' randomised study [3]. After unblinding at 3 months, 53 subjects (80%) elected to enrol in this crossover study and undergo PUL (Table 1). Over the 12-month follow-up, no PUL patient required α -blocker therapy and one (2%) progressed to a standard TURP intervention, which was completed without complication.

The mean (SD) crossover PUL procedure time was 53 (15) min for delivering a mean (range) of 4.4 (2–8) implants in prostates ranging in volume from 30 to 70 mL. While Australian standard of care required general anaesthesia, no

Table 1 Baseline characteristics for patients who elected crossover PUL procedure 3–6 months subsequent to receiving a rigid cystoscopy sham procedure.

Characteristic	Cross-over PUL (n = 53) Mean (SD, range)	N
Age, years	64 (8.0, 50–79)	53
Prostate volume, mL*	40.3 (9.9, 30–68)	53
IPSS	23.3 (5.5, 13–34)	53
HRQL (IPSS question 8)	4.5 (1.2, 2–6)	53
BPHII	6.3 (3.0, 1–12)	52
Q _{max} , mL/s	8.8 (4.2, 2.0–30.0)	53
PVR, mL	67.8 (66.44, 0–262)	53
PSA level, ng/mL	2.26 (1.85, 0–8)	53
IIEF-5	12.8 (8.3, 1–25)	53
MSHQ-EjD	9.5 (10.0, 3–14)	42

*Baseline data was used for those patients who did not have data collected immediately before crossover.

patient enrolled in North America underwent general anaesthesia; 44/46 (96%) of procedures were conducted under local anaesthesia using cold lidocaine with sedative and the remaining two (4%) used prostatic block. Of the 53 patients

Table 2 Baseline, follow-up, and change in each outcome measure (IPSS, HRQL, BPHII, MSHQ-EjD, MSHQ-Bother, and IIEF-5) after control sham therapy followed by crossover PUL in the same patient cohort. Each parameter is presented as the mean (SD). The 3-month change in each parameter in the control vs crossover period was compared using a paired Student's *t*-test.

Outcome measure (paired sample size, <i>n</i>)	Control sham therapy period			Crossover PUL period			<i>P</i>
	Baseline*	3 months	Change	Baseline*	3 months	Change	
IPSS (53)	25.2 (5.7)	20.2 (8.3)	-5.0 (7.5)	23.4 (5.5)	12.3 (7.9)	-11.1 (7.2)	<0.001
HRQL, IPSS question 8 (52)	4.8 (1.1)	3.9 (1.6)	-0.8 (1.4)	4.5 (1.2)	2.2 (1.5)	-2.3 (1.7)	<0.001
BPHII (52)	7.2 (3.2)	5.3 (3.2)	-1.9 (3.4)	6.2 (2.9)	3 (2.9)	-3.3 (2.9)	0.024
Q _{max} (39)	7.9 (2.4)	10.3 (4.6)	2.4 (5.1)	9.6 (4.3)	12.0 (6.1)	2.4 (5.3)	1
MSHQ-EjD (36)	11.3 (4.2)	9.1 (3.8)	-2.1 (4.2)	8.9 (3.6)	9.9 (3.7)	1.0 (2.9)	0.003
MSHQ-Bother (36)	3.3 (1.7)	2.4 (1.7)	-0.8 (1.6)	2.5 (1.7)	2.1 (1.6)	-0.4 (1.3)	0.312
IIEF-5 (SHIM) (36)	16.2 (7.2)	17 (7.2)	0.8 (4.3)	16 (6.7)	16.3 (8.2)	0.3 (4.7)	0.636

*Baseline value was defined as the value before the initial sham procedure for the Control group and the value before PUL for the Cross-over group. Note that the baseline value for the Crossover group was 3–6 months after the sham procedure.

undergoing crossover PUL, 41 underwent void trial after the procedure. No postoperative catheterisation was required for 27 (66%) of these tested patients, and the mean catheter duration for all patients was 33 h. The PUL patients reported a mean (SD) complete return to preoperative activity by 6.5 (6.8) days.

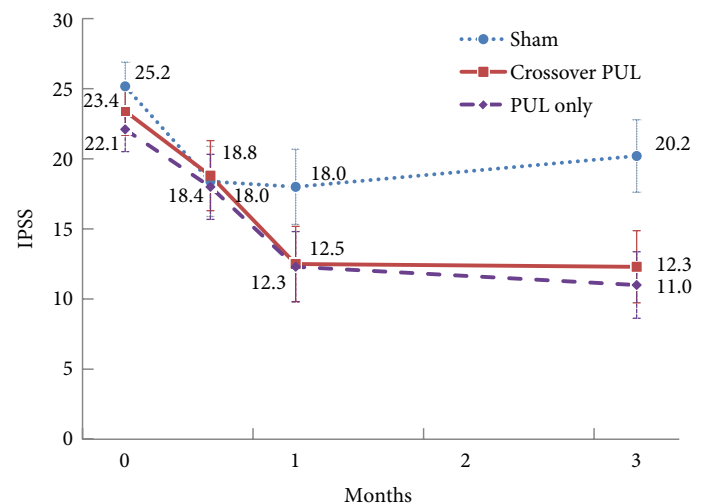
Effectiveness

The therapeutic effect of the PUL was significantly greater than that seen for the sham procedure in this crossover study. The mean IPSS improvement after crossover PUL (11.1 points) was 122% greater than after sham (5.0 points) at 3 months ($P < 0.001$; Table 2). The IPSS reduction seen in crossover PUL patients closely mimics that of previously published randomised results (Fig. 2) [3]. Improvements in HRQL (IPSS question 8) and BPHII, were also significantly greater for crossover PUL patients vs sham ($P < 0.001$ and $P = 0.024$, respectively). Q_{max} showed stepwise improvement, increasing from 7.9 (2.4) mL/s at baseline to 10.3 (4.6) mL/s 3 months after sham and further increasing to 12.0 (6.1) mL/s and 12.5 (5.3) mL/s at 3 and 12 months after crossover PUL, respectively (Fig. 3). The PUL showed clinically and statistically significant improvement in IPSS, HRQL, BPHII and Q_{max} throughout the course of the 12-month study (Tables 3,4). Sexual function was maintained with no significant degradation in SHIM or MSHQ-EjD at any time point after the PUL, and the general trend was improvement in all measures after the PUL (Table 3). Ejaculatory function showed a statistically significant difference between the sham procedure, which decreased ejaculatory function, and the PUL treatment, which increased ejaculatory function, at 3 months (Table 2).

Safety

The adverse events reported for PUL were typically mild to moderate and resolved within 2 weeks; the most commonly occurring events were dysuria (36%), haematuria (26%), and

Fig. 2 Comparison of the IPSS from baseline to 3-month follow-up for patients who underwent sham procedure and later crossover PUL procedure. Also plotted are the 'blinded' and randomised results from Roehrborn et al. [3] on PUL only patients. Crossover PUL IPSS improvement is significantly greater than that of sham and closely mimics prior published results. Values shown are the mean absolute IPSS, error bars represent the 95% CI.



pelvic pain/discomfort (21%) (Table 5). No patient required a blood transfusion and haematuria typically resolved within 3 days. The patients who reported pelvic pain or discomfort at the 1 month visit rated their pain on a visual analogue scale. The mean pain scores after the PUL showed no significant difference those after the sham procedure (2.71 and 2.67 out of 10, respectively; $P = 0.9$). There was no incidence of *de novo*, sustained erectile dysfunction or retrograde ejaculation. One patient progressed to TURP 12 months after treatment due to persistent nocturia.

Related adverse events were also examined using the Clavien-Dindo classification. Most were mild, typically Class I or II, while none were Class IV or V. There were two Class III

Table 3 IPSS, HRQL, BPHII, SHIM, MSHQ-EjD, and change from baseline (after sham procedure and before PUL) after PUL. *P* values were obtained from a general estimating equation.

	2 Weeks	1 Months	3 Months	6 Months	12 Months
IPSS					
<i>n</i> (paired)	53	53	52	53	48
Mean (SD) score:					
baseline	23.3 (5.5)	23.3 (5.5)	23.4 (5.5)	23.3 (5.5)	23.3 (5.6)
follow-up	18.8 (8.2)	12.5 (7.0)	12.3 (7.9)	13.0 (7.6)	14.6 (7.7)
change	-4.5 (7.4)	-10.9 (6.9)	-11.1 (7.2)	-10.3 (8.2)	-8.7 (7.5)
Mean % change (95% CI)	-18 (-27, -10)	-46 (-53, -39)	-48 (-56, -40)	-43 (-52, -34)	-37 (-46, -27)
<i>P</i>	<0.001	<0.001	<0.001	<0.001	<0.001
HRQL (IPSS question 8)					
<i>n</i> (paired)	53	53	52	53	48
Mean (SD) score:					
baseline	4.5 (1.2)	4.5 (1.2)	4.5 (1.2)	4.5 (1.2)	4.6 (1.2)
follow-up	3.4 (1.6)	2.4 (1.5)	2.2 (1.5)	2.5 (1.4)	2.6 (1.6)
change	-1.1 (1.7)	-2.2 (1.8)	-2.3 (1.7)	-2.1 (1.6)	-2.0 (1.7)
Mean % change (95% CI)	-20 (-32, -9)	-43 (-53, -33)	-49 (-59, -39)	-44 (-53, -35)	-41 (-53, -29)
<i>P</i>	<0.001	<0.001	<0.001	<0.001	<0.001
BPHII					
<i>n</i> (paired)	53	53	52	53	48
Mean (SD) score:					
baseline	6.3 (3.0)	6.3 (3.0)	6.2 (2.9)	6.3 (3.0)	6.4 (2.9)
follow-up	6.5 (3.2)	3.3 (3.0)	3.0 (2.9)	2.9 (2.5)	3.4 (2.7)
change	0.2 (3.5)	-3.1 (3.3)	-3.3 (2.9)	-3.5 (2.7)	-3.1 (3.1)
Mean % change (95% CI)	38 (-2, 79)	-41 (-59, -23)	-52 (-64, -41)	-53 (-64, -42)	-44 (-58, -30)
<i>P</i>	0.67	<0.001	<0.001	<0.001	<0.001
IIIEF-5 (SHIM)					
<i>n</i> (paired)		34	40	38	33
Mean (SD) score:					
baseline		15.1 (7.4)	15.5 (7.0)	15.4 (7.2)	15.9 (6.6)
follow-up		15.7 (8.1)	16.2 (8.1)	16.6 (7.6)	16.8 (6.8)
change		0.5 (4.6)	0.7 (9.2)	1.1 (4.6)	0.9 (5.7)
<i>P</i>		0.51	0.66	0.16	0.30
MSHQ-EjD					
<i>n</i> (paired)		34	39	38	33
Mean (SD) score:					
baseline		9.1 (3.1)	9.4 (3.0)	9.2 (3.0)	9.3 (2.8)
follow-up		10.5 (3.0)	9.7 (3.6)	9.9 (2.9)	10.1 (2.6)
change		1.4 (2.3)	0.3 (4.6)	0.7 (2.3)	0.8 (2.8)
<i>P</i>		<0.001	0.98	0.69	0.62
MSHQ-Bother					
<i>n</i> (paired)		34	37	38	33
Mean (SD) score:					
baseline		2.7 (1.7)	2.6 (1.7)	2.6 (1.7)	2.5 (1.7)
follow-up		2.2 (1.6)	2.2 (1.5)	2.2 (1.3)	2.1 (1.3)
change		-0.5 (1.1)	-0.4 (2.3)	-0.4 (1.3)	-0.4 (1.4)
<i>P</i>		0.008	0.44	0.33	0.23

events, each of those was a patient who presented in hospital for urinary retention; one was discharged the same day with a catheter and the other was readmitted for 2 days.

In all, 48 patients, with a total of 215 implants, underwent cystoscopy at 12 months. An independent reviewer found no evidence of encrustation on the implants delivered within the prostate, no increase over baseline in oedema or inflammation, no *de novo* strictures, and no evidence of abnormal pathology in the prostatic urethra. Surface encrustation was observed on 10 implants (4.7%) that were inadvertently delivered such that part of the implant was exposed to urine within the bladder. Two of these 10 implants were removed using cystoscopic grasping forceps and two were removed from a single patient

when he underwent TURP; the remaining implants were left *in situ* as they were asymptomatic; the patients will be monitored.

Discussion

The results of this crossover study show that, with each patient serving as his own control, the PUL procedure is associated with a clinically and statistically significant treatment effect beyond sham therapy. The crossover PUL LUTS improvement is consistent with that observed when comparing separate randomised groups. The mean (SD) 3-month IPSS improvement after crossover PUL was virtually identical to that seen with a separate group of patients in a 'blinded'

Fig. 3 Q_{max} shows stepwise improvement starting at baseline, improving 3 months after sham, and further improving 3 months after crossover PUL. The improvement after crossover is stable through to the 12-month assessment.

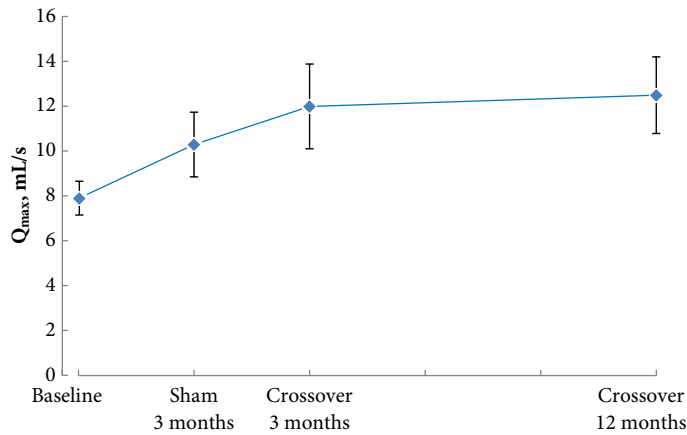


Table 4 Q_{max} and PVR change from baseline (after sham procedure and before PUL) after PUL. *P* values were obtained from a general estimating equation.

	3 Months	12 Months
Q_{max} , mL/s		
<i>n</i> (paired)	40	37
Mean (SD):		
baseline	9.6 (4.2)	9.9 (4.3)
follow-up	12.1 (6.0)	12.5 (5.3)
change	2.5 (5.3)	2.5 (5.0)
Mean % change (95% CI)	34 (15, 53)	35 (12, 57)
<i>P</i>	0.002	0.005
PVR, mL		
<i>n</i> (paired)	51	46
Mean:		
baseline	66.12	68.02
follow-up	52.89	56.80
change	-13.23	-11.23
Mean % change (95% CI)	9.26 (67.35, -48.84)	4.67 (55.70, -46.36)
<i>P</i>	0.241	0.262

randomised study, at 11.1 (7.2) vs 11.1 (7.7), respectively [3]. In both comparisons, the improvement after the PUL was significantly greater than the effect of sham rigid cystoscopy. This high level of repeatability serves as a validation of the consistent therapeutic effect of the PUL. Both 'blinded' and crossover (open-label) PUL patients had rapid, durable relief with minimal morbidity and virtually no sexual compromise.

There was a change in IPSS score at 2 weeks for both sham and crossover PUL. For the sham procedure, this could be due to the psychological effect of undergoing a treatment and the temporary urethral dilatation associated with rigid cystoscopy. From 2 weeks to 3 months, the sham effect begins to diminish, while the PUL effect continues to improve. In the longer term, the 12-month IPSS improvement from the time of crossover was 8.7 points, but the cumulative improvement from true

baseline of enrolment was 10.6 points, again consistent with the 10.8 and 12.3 point improvements at 12 months reported in prior studies [3,4]. A possible explanation for this cumulative effect is that dilatation during the sham procedure does not fully dissipate by 3 months but appears to no longer contribute to overall effect by 12 months.

By contrast, urinary flow rate change was more durable after sham rigid cystoscopy. At 3 months after sham cystoscopy, there was a 2.4 mL/s increase in Q_{max} from baseline. After crossover PUL, Q_{max} further improved 2.5 mL/s at 3 months and was maintained to 12 months. The cumulative 12 months Q_{max} improvement of 4.6 mL/s is similar to the 4.0 mL/s improvement reported in both randomised and open label studies [3,4]. The continued improvement in flow after the sham procedure may be a result of a lingering dilatatory effect from rigid cystoscopy.

For a minimally invasive approach, patient satisfaction is often determined by return to normal activity and perioperative complications [9]. Morbidity associated with the PUL procedure was low as was the need for postoperative catheterisation. Adverse events were as expected after a rigid cystoscopic intervention, with most events transient and either mild or moderate. Pelvic pain was tracked carefully, and visual analogue scores were not different between the PUL and sham procedures. On average, PUL patients returned to normal preoperative activity in less than a week, which is considerably more rapid than the 4–6 weeks typical of other BPH therapies [10]. In PUL procedures conducted in the USA and Canada, all were conducted with local anaesthesia (96%) or prostate block (4%).

After the crossover PUL procedure, no patient had new onset, sustained ejaculatory or erectile dysfunction. Further, sexual function measures in the 'erectile function', 'ejaculatory function', and 'ejaculatory bother' domains improved after PUL at every time point, although most changes were not statistically significant. This preservation in overall sexual function after a BPH procedure stands in contrast to the 41–65% rates of ejaculatory dysfunction and 7–10% rates of erectile dysfunction reported for TURP or laser procedures [11–13]. Iatrogenic sexual dysfunction can significantly affect HRQL [14]. One study has shown that 19% of men would even forego treatment for cancer if it compromised their sexual function [15]. While erectile function is more commonly analysed, ejaculatory function has also been found to be of high importance to many patients [16]. The increase in ejaculatory function after PUL compared with the functional compromise after the sham procedure, suggests that PUL may be uniquely suited to treat LUTS while preserving sexual function and is consistent with the prior randomised study [17].

The primary strength of the present study lies in the statistical power associated with the paired measures analysis that was

Table 5 Overview of adjudicated adverse events of interest.

	0–3 months						3–12 months		
	Control (n = 53)			Cross-over (n = 53)			Cross-over (n = 53)		
	Events		Patients	Events		Patients	Events		Patients
	n	n	%	n	n	%	n	n	%
Related SAE	0	0	0	0	0	0	1	1	1.9
Unrelated SAE	1	1	1.9	2	2	3.8	6	6	11.3
Related AE	19	15	28.3	73	41	77.4	14	12	22.6
dysuria	7	7	13.2	19	19	35.8	1	1	1.9
haematuria	2	2	3.8	14	14	26.4	0	0	0
pelvic pain/discomfort	3	3	5.7	11	11	20.8	0	0	0
urgency	0	0	0	5	4	7.5	2	2	3.8
retention	0	0	0	4	4	7.5	0	0	0
bladder spasm	0	0	0	1	1	1.9	0	0	0
urgency incontinence	3	3	5.7	1	1	1.9	2	2	3.8
urinary tract infection	0	0	0	1	1	1.9	1	1	1.9
erectile dysfunction*	0	0	0	0	0	0	0	0	0
retrograde ejaculation*	0	0	0	0	0	0	0	0	0

*Sexual dysfunction adjudicated as new onset and sustained. Related, device or procedure related; SAE, serious adverse event; AE, adverse event.

permitted because each patient served as his own control. The results from this self-controlled data set, which included open-label PUL therapy, corroborates previously published results from a randomised study. In contrast to the randomised study, the analysis of the self-controlled data set may provide more insight into what the patient response might be outside of a clinical study. In everyday use, the patient generally has free will to choose the treatment, perhaps in view of previous other treatment failures. It could be argued that the crossover phase comes closer to assessing the results expected for a commercialised product under a free will choice. The fact that the results from the randomised and crossover phases are similar is reassuring.

Conversely, some weaknesses of the study must be recognised; notably, the duration of follow-up is only to 1 year at this point. An earlier study showed a similar reduction in IPSS at 1 year (10.4 vs 10.6 points observed in the present study) and 2-year durability of LUTS improvement, thereby providing some evidence of the longevity of this minimally invasive therapy [2]. Additionally, as the present study included open-label PUL therapy, the possibility of a placebo effect cannot be excluded. However, the consistency between the 3-month results in the present study and in a prior randomised study indicate a true therapeutic effect.

In conclusion, the PUL is associated with early symptom relief, low morbidity and preservation of sexual function. Not surprisingly, PUL reduces symptoms more than rigid cystoscopy at 3 months and the results of this open label self-controlled study corroborate earlier findings in a randomised study.

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Conflict of Interest

A.L.C.I., W.K.B., S.F.R., R.F.T., J.B., J.E.F. I., and P.T.C. have been investigators for the Neotract sponsored study from which this data has been extracted.

H.H.W. and P.T.C. have been consultants to Neotract and hold stock in Neotract.

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Abbreviations: BPHII, BPH Impact Index; HRQL, health-related quality of life; IIEF, International Index of Erectile Function; MSHQ-EjD, Male Sexual Health Questionnaire for Ejaculatory Function; Q_{max} , maximum urinary flow rate; PUL, prostatic urethral lift; PVR, post-void residual urine volume; SHIM, Sexual Health Inventory for Men.